Genetically modified plants and foods

Challenges and future issues in Europe

Final report
April 2009

EPTA
European Parliamentary Technology Assessment

The conclusions in this report are the responsibility of the following eight members of the European Parliamentary Technology Assessment network (EPTA):

The Danish Board of Technology, Denmark

Contact: Lars Klüver
www.tekno.dk

Institute Society and Technology, Flanders

Contact: Robby Berloznik
www.samenlevingentechnologie.be

Institute of Technology Assessment, Austria

Contact: Michael Nentwich
www.oeaw.ac.at/ita

The Norwegian Board of Technology, Norway

Contact: Tore Tennøe
www.teknologiradet.no

Office of Technology Assessment at the German Parliament, Germany

Contact: Armin Grunwald
www.tab.fzk.de

Parliamentary Office of Science and Technology, UK

Contact: David Cope
www.parliament.uk/post/home.htm

Scientific Technology Options Assessment,
European Parliament

Contact: Theodoros Karapiperis
www.europarl.europa.eu/stoa/default_en.htm

TA-SWISS – Center for Technology Assessment,
Switzerland

Contact: Sergio Bellucci
www.ta-swiss.ch

Zentrum für Technologiefolgen-Abschätzung
Centre d'évaluation des choix technologiques
Centro per la valutazione delle scelte tecnologiche
Centre for Technology Assessment

Authors of the report:

Danielle Bütschi

Søren Gram

Jon Magnar Haugen

Rolf Meyer

Arnold Sauter

Stef Steyaert

Helge Torgersen

Additional contributors to the project:

Peter Border

Jarka Chloupkova

Jofey Craig

Els van den Cruyce

Jamie Rubbi-Clarke

Casper Linnestad

Willy Weyns

Acknowledgement:

The authors wish to express their gratitude

- To all the European experts who participated in the survey by filling in the questionnaire,
- To the peer reviewers who made it possible to substantially improve the resulting report in reaction to their critical and constructive comments on the first version,
- To Ulrike Goelsdorf from TAB who produced the figures and was responsible for the final layout of the report,
- And to Alison Hepper, Heidelberg, for a thorough native speaker's review of the text.

Berlin, April 2009

EPTA

European Parliamentary Technology Assessment

CONTENTS

CONTENTS

FOREWORD

Biotechnology in general and genetic engineering in particular have been among the most controversially discussed modern technologies for decades. They are regarded as an important key to increasing economic competition on the one hand, but provoke concerns about health, safety and environmental issues on the other. The public perceptions of biomedical applications and of applications in agriculture and food production have clearly diverged. While there has been growing acceptance of medical applications, the public's rejection of genetically modified (GM) foods persists in many countries. Particularly in Europe, agricultural GM technology is still being contested. For over two decades, the proponents and opponents of GM have not succeeded in finding a common ground despite major efforts invested in conducting numerous projects, in organising dialogues and in developing and implementing elaborated regulatory tools.

Problems arose at different levels: in European Union (EU) Member States as well as within and among EU institutions. GM crops and food policy ran into troubles. For example, the coexistence of GM crops with conventional and organic crops, as well as the labelling and tracing of GM food products are topics of ongoing discussion. Repeatedly, there have been regulatory impasses over the approval of particular crop varieties. At a global level, there have been trade conflicts over GM products in recent years. Today, the future of GM crops in Europe is as unclear as ever. In contrast to the development and use of GM plants and foods in the United States and other countries, the cultivation of GM crops in Europe is very limited.

However, in spite of the apparent lack of change regarding this situation, it is possible to identify some movement and various changes which will lead to new challenges to European policies as well as to intensified public debate. Apart from past and present regulatory conflicts, important technological developments and far-reaching shifts in framework conditions have recently taken place which will considerably influence future debates:

- Novel varieties of crops with new traits are about to enter the regulatory approval procedures. A new generation of GM crops, capable of producing medicine and industrial chemicals, for example, is emerging.
- The demand for agricultural products has changed to include more energy crops. Market conditions for agricultural products have turned out to be highly volatile and are increasingly linked to the energy markets.
- Environmental challenges and the requirements of sustainable development have altered the conditions for agriculture in many places.

The question today is whether and how all this will translate into new challenges to the governance of GM technology in Europe. Can we expect old impasses to vanish or new ones to arise? Can we identify indications for change, and if so, in which direction? What could be tomorrow's issues in the GM debate in Europe? What could be done in order to prepare policy makers and the European public for these newly

emerging questions? These questions formed the main motivation to initiate and conduct the joint EPTA (European Parliamentary Technology Assessment) project "Genetically Modified Plants and Foods".

GM crops and foods have been a major topic for the EPTA (www.eptanetwork.org) members and associates. Building on their wealth of experience in the field of Technology Assessment (TA) on GM issues, the following eight members of EPTA have come together to identify the developments and challenges ahead:

- Centre for Technology Assessment (TA-SWISS – Switzerland)
- Danish Board of Technology (DBT – Denmark)
- Institute Society and Technology (I.S.T. – Flanders) (the former Flemish Institute for Science and Technology Assessment – viWTA)
- Institute for Technology Assessment (ITA – Austria)
- Norwegian Board of Technology (NBT – Norway), together with the Norwegian Biotechnology Advisory Board
- Office of Technology Assessment at the German Parliament (TAB – Germany) (project co-ordinator)
- Parliamentary Office of Science and Technology (POST – United Kingdom)
- Scientific Technology Options Assessment (STOA – European Parliament)

The final report of the project "Genetically Modified Plants and Foods" departs from the results of a considerable number of TA and TA-inspired projects in the past. Specific perspectives and positions from different countries, extracted from parliamentarian and other TA exercises, were brought together and evaluated with respect to a pan-European perspective. On the basis of this review, the joint EPTA project concentrated on *new* questions and possible *new* answers by identifying future challenges rather than by attempting to simply establish a mainstream view on contested issues of the past. Thus, the project applied a *forward approach* to the GM plants and foods field creating *added value* to existing work. The main conclusions of the joined effort are on

- The regulatory challenges for the European system in the upcoming years,
- Issues of a possible public debate in the future,
- Approaches for TA to handle the future issues.

As its main results, the final report includes a picture of the current state of affairs in the GM field, identifications of challenges ahead as well as some hints at possible paths to take in the future. These results are focused on *conclusions* rather than on policy recommendations. The conclusions address the European level and take into account new developments in the fields of technology and regulation. We hope that this report will be helpful in clarifying relevant issues of the next phase of the European GM debate, and that it will find its way to the European audience and beyond.

Armin Grunwald, Head of TAB

EXECUTIVE SUMMARY 1.

GM plants and their role in European agriculture as well as in the regulatory system and in society at large have long been controversial issues. In addition, recent developments with respect to new technologies, expanding international trade and the increasing demand for food and fuel have changed the general framework. The question is whether these developments challenge the established way in which GM plants and food have been dealt with in Europe so far.

Reviews of reports from EPTA member organisations on various aspects of GM plant application, their regulation and associated problems rendered a list of developments and consequently possible challenges to European policy on GM plants. Proceeding from this list of challenges, a questionnaire was developed, and 183 experts involved in the development, assessment and policy making on GM plants in Europe were invited to respond. These experts, 71 of whom completed the questionnaire, come from Austria, Belgium, Denmark, Finland, Germany, Norway, Switzerland and the United Kingdom. The questionnaire results and the experts' comments were analysed in the light of the results of the EPTA members' reports.

All in all, the regulatory system for GM plants and food in Europe does not seem to be fully prepared to meet all existing and foreseeable future challenges. Five key areas of challenges for the European system of GMO regulation in the years to come were identified, as were a number of possible approaches for future technology assessment activities.

CHALLENGE 1: NEW DRIVING FORCES FOR GM PLANT INTRODUCTION

Altogether, more factors were identified that encourage rather than discourage the introduction of GM crops, in particular the increasing use of and demand for bioenergy and biomass. This is a major difference to debates in the past. GM plants for non-food uses can be attractive to farmers. Further, such products may also find more demand from consumers, or at least be less prone to be avoided by sceptics as their GM origin is more obscure.

A decisive issue for the future cultivation of GM crops in Europe is the question of which aims agriculture is expected to fulfil. Sustainability is expected to be given strong weight, more particularly input and impact reduction while ensuring high product quality.

Area of action: The future of GM plants and food in Europe is not only determined by negotiations over regulatory details, it is also a question as to which kind of sustainable agriculture will be developed in Europe in the light of different, and sometimes conflicting, sustainability goals. A broad societal dialogue on future sustainable

European agriculture in a global context is, therefore, needed in order to determine the future role of GM plants and food.

CHALLENGE 2: NOVEL GM PLANTS, TECHNOLOGIES AND APPLICATIONS

Several classes of novel GM crops are currently under development. These include both crops for food uses, for instance crops with improved nutritional value, and crops for non-food uses such as energy, plastics or pharmaceuticals. A majority of the experts consulted think that a variety of such crops will be available and authorised for cultivation in Europe within the next 10 years. Such novel GM plants, especially those for the non-food sector, could pose regulatory challenges. In the case of plant-made pharmaceuticals, different approval procedures might have to be reconciled.

In general, discussions over criteria and procedures for risk assessment/management, may be ongoing in the future. At the same time, the potential risks from outgrowing or gene flow from non-food crops might pose additional problems for coexistence. On the other hand, crops developed to provide benefits in terms of health and food quality factors (e.g. nutritional enhancement) are also expected to appear, which may encourage public acceptance and consumer demand. This ambivalence is also mirrored in the discussion of whether benefits should be included in assessment procedures. While the proponents of GM technology may hope that such a measure could overcome public rejection, opponents claim that uncertainties are not tolerable in the absence of clear public benefit.

While understanding risks is expected to remain an important priority for European public research in the future, experts also expect resources for the development of new crops. Novel technologies such as smart breeding and cisgenics are regarded as important for plant breeding in general, but not as an alternative that could replace GM. However, they may blur the distinction between GM and non-GM plants.

Area of action: As is true for every field of technology, research policy is an important area of action. Crop development may again come to the forefront of public research. To make good use of any money that becomes available in this context, it would be necessary to assess not only the technical performance of newly developed plants but also the chances of these plants to meet societal goals. Concerning GM regulation, non-food GM plants might render an ongoing revision of the regulatory framework necessary. This pertains to parameters for risk assessment and management, confinement, coexistence and liability, as well as to the question of including benefit evaluation.

CHALLENGE 3: PUBLIC OPINION: STILL A DECISIVE FACTOR

Public attitudes are considered an important factor influencing both the use of GM technology and its development. Concerning future GM non-food products, a majority of experts expect public attitudes to become more positive over the next 10–15 years, while the level of acceptance of GM food products will remain unchanged. Factors considered highly important for consumer acceptance are free consumer choice and a high quality of information, as well as consumer benefits and the absence of risk issues related to health and the environment. Non-food GM plants may, however, also give rise to specific environmental and health concerns. In addition, expectations regarding the popularity of biofuels may be overoptimistic considering that they will be competing with food. It, therefore, remains unclear whether and how the overall public acceptance of GM plants will change.

Area of action: For the time being, there is little indication of an increase in overall acceptance. While it is possible that public perception will change as new consumer-oriented GM products become available, this cannot be taken for granted. Since public attitudes are subject to the influence of many factors, including ethical concerns, consumer protection policy is not the only one of relevance. A variety of other fields from agricultural policy to GM regulation are also relevant. An early discussion and open dialogue concerning the potential opportunities and possible problems can help to prevent disappointment on either side. Meeting the expectations regarding the high quality of information remains a major challenge.

CHALLENGE 4: COEXISTENCE AND LABELLING UNDER A GROWING USE OF GM PLANTS IN EUROPE AND THE WORLD

The concept of coexistence can be considered a political answer to the normative demand for freedom of choice. However, it also has implications for the (presumably descriptive) scientific risk assessment, as the behaviour, and thus risks, of a crop are more predictable if volunteering and intermixing can be ruled out. Due to small areas and the relatively short time of agricultural cropping, robust experience with the EU regulation on coexistence is still some way ahead. For the first generation of GM plants, many EPTA member reports and the majority of expert opinions conclude that coexistence can work in principle over the next 15 years. But experts are divided on many details, for instance whether coexistence will work for certain specific crops or for a broad range of them, for small- or large-scale cultivation, and whether all risks can be contained through such measures. While a majority expect first-generation GM plants to be grown within the next 10 years in Europe, fewer than half of the respondents believe this will be the case in their home countries. With regard to marketing, half of the respondents think that coexistence and labelling will generally work. The rest expect different scenarios such as failure of the labelling regime or the blockade of GM food. Taken together, this suggests that the concept of coexistence remains a challenge, despite existing regulation and an extensive debate in the past.

Area of action: Doubts as to whether coexistence will work may pertain to particular items of regulation on the assessment and management of GM plants; however, they could also be taken as an indication that the expertise involved or elements of the authorisation process are at stake. In particular, independence from the vested interests of authorities involved could be better demonstrated by incorporating a broader spectrum of scientific opinions and/or representation of interests. Regarding authorisation, a recurrent problem seems to be the proper disentanglement of science and policy. The requirements for scientific evidence, on the one hand, and room for manoeuvre in politics, on the other, do not seem to be sufficiently defined. Likewise, a defined remit for political decision-making at the national level would be desirable, for example in order to restrict, or promote, the use of GM plants.

CHALLENGE 5: INTERNATIONAL TRADE RULES AND DOMESTIC DECISION-MAKING

The global increase in acreage covered by GM crops, pending international trade conflicts, the development of international regulations, and different approaches to risk assessment in various countries have challenged EU policy on GM plants. Regardless of the outcome of the recent World Trade Organization (WTO) conflict, most experts are convinced that the general principles of the EU regulatory system can be maintained. Concurrently, many respondents think that restrictive practices of individual EU Member States will have to change, and more harmonisation among them will be necessary.

Area of action: The recent WTO conflict highlights the need to reconcile different international agreements in order not to thwart the aims of these agreements. Therefore, not only areas specific for GM organisms (GMOs) might be considered to be at stake, but also the possible integration of environmental and social standards into WTO regulations. Many of the problems encountered at the WTO level are said to have derived from different interpretations by member states of the EU regulatory framework. Possible solutions would be to give more leeway to national sovereignty (subsidiarity) or to increase harmonisation among Member States. A considerable number of experts seem to consider further harmonisation and a reform of competent authorities/institutions an option for further improving the robustness of the EU regulatory system.

UPCOMING ISSUES FOR TECHNOLOGY ASSESSMENT

Agricultural biotechnology has been one of the most prominent technological fields TA has dealt with, and this will probably continue to be the case in the future. Four developments call for further interest and novel approaches.

- Technological developments extending the use of GM plants include energy plants, plants for nutritionally enhanced products, or plants for producing pharmaceutically active substances. In addition, crops with enhanced agricultural traits such as drought resistance could have enhanced survival capabilities and improved yield. Under environmental conditions of climatic change they might pose novel challenges for risk assessment.
- Changed general conditions for agriculture challenge established practices and aims, as shown by the example of fuel production from staple crops, and the increasing demand in food.
- Institutions and levels of decision-making are under continuous debate, for instance regarding the room left for national manoeuvre. A rising issue is the repercussion of international agreements, and of globalised trade in food and feed.
- Public attitudes towards GM plants and food may change in the future, which could have an impact on future political decisions. In the past, many factors not immediately related to GM technology as such but to broader social and cultural issues have been shown, or suspected, to influence public perception. In addition, with a larger number of Member States the diversity of the European landscape of public perceptions might even increase.

TA is required to help clarify available or requested technological solutions and their societal implications. TA should provide an improved understanding of social and cultural factors influencing these technological developments, their embedding into society, and the ways implications such as risks and benefits are perceived. Efforts should be taken to involve experts, stakeholders and citizens in dialogues about new developments. The development of novel forms of negotiation aimed at opening up new communication channels for actors who find it hard to speak to each other remains a task for TA.

Despite past extensive investigations, there is no doubt that the issue of GM plants will remain on the TA agenda. As different TA organisations dispose of different expertise and experience regarding approaches, transnational cooperation remains an attractive option.

BACKGROUND, CONTEXT AND AIMS OF THE PROJECT 2.

Biotechnology, and especially genetic engineering, has long been one of the most controversial modern technologies. On the one hand, it is seen as an important key to increasing economic competition and a source of innovation with a high potential for solving agricultural and environmental problems. On the other hand, it raises concerns about health and safety issues as well as ecological impacts and provokes certain ethical and moral objections.

The first GMO was produced in 1973. Over the past three and a half decades, great progress has been made in modern biotechnology. Today, it plays an important role in medicine and in agriculture. However, favourable public perception of biomedical applications has significantly and lastingly diverged from the perception of agrifood biotechnology. Extensive surveys such as the Eurobarometer have repeatedly shown that on average in the EU, public perception of GM plants is hardly positive at all, while that of GM food has long been, and still remains, decidedly negative, although there are significant differences between EU Member States.

This goes well with the observation that over the past 15 years, heated debates have taken place in many European countries among decision makers, experts and stakeholders about GM plants and foods.

While the proponents of GM plants argue in favour of the environmental benefits of GM crops (fewer fertilisers, fewer pesticides, less tillage) and on higher productivity perspectives, the opponents put more emphasis on health and environmental risks, as well as factors such as naturalness and the integrity of nature. An additional point of criticism is the ownership of seeds and the power of multi-national companies. Confronted with these opposing claims, consumers may have difficulties in seeing clear benefits for themselves and/or society at large (at least with regard to so-called first-generation GM food products, see below), which may have contributed to the general scepticism towards GM crops observed in surveys on public perception. This scepticism is claimed to have influenced EU regulation on GM plants – often regarded as restrictive compared to its US counterpart.

Whether a sceptical public is the “cause” and a restrictive policy the “effect” remains hypothetical. There are, however, various dimensions of public perception that often become condensed in the debate: Citizens may be concerned about the long-term impact on the environment or yield, for example, especially for farmers in developing countries. Citizens as political subjects may entertain general concerns about power relations, values and the way our lives should be organised. Citizens as consumers may follow different rationales, guided mainly by individual benefit and risk calculations. These are all politically relevant but rely on, and are susceptible to, different lines of argumentation. It is not always clear which of these takes the lead in a public debate.

Therefore, when considering the future of GM plants and food in Europe and reflecting on the way this debate could evolve, it is necessary to take all dimensions into account. More specifically, it is necessary to consider whether GM technology will find a more positive response from the European public or not, and whether or not consumers will remain sceptical about GM crops and products.

The multitude of factors involved and arguments raised have made it difficult to devise a policy on GM plants and food that would be acceptable to the majority of the European public and suit the interests of industry and various sectors of agriculture as well. In response to public concerns on the one hand, and to regulatory difficulties and delayed decision-making at the European level on the other, the European Directive on deliberate releases (2001/18/EC) and other relevant EU regulations have put a new framework for GM crops and food in the EU into force. This framework puts more emphasis on the precautionary principle, specifies the criteria for risk assessment, stipulates a general and a case-specific post-market monitoring, and introduces a time limit for authorisations as well as a mandatory follow-up evaluation. In addition, the labelling regime has been changed.

In the first instance, the regulations focus on GM crops commercialised for fodder and for human consumption. In order to secure the coexistence of GM crops with conventional and organic crops and food products, proper labelling and traceability of GM food products have become major topics of concern and ongoing discussion.

Taken together, the regulatory framework for GM crops, feed and food has developed comprehensively. It was not until recently, however, that a number of new applications for GM product approvals were issued, so that it is still unclear how functional the regulatory framework really is. First experience revealed that some regulatory problems that were supposed to have been solved in fact still exist. It remains to be seen whether the EU regulation will prove capable of fulfilling expectations in daily practice.

While the regulatory framework is currently being put to the test with the first generation of GM crops, technical development has not come to a halt. New varieties with new properties are about to be launched and may enter the authorisation pipeline. In this context, it has been claimed that public perception could change due to new properties of GM products that carry consumer benefits. Further, an increase in demand and prices seems to call for more productivity in agriculture, which could also favour GM approaches.

Finally, the WTO ruling in 2006 has been interpreted as putting pressure on the regulatory approach in Europe. It highlighted different interpretations on both sides of the Atlantic with respect to the necessary level of evidence for possible risks that had caused tensions for considerable time without having been finally resolved.

These developments, amongst others, may lead to new debates, entail challenges for the European regulatory system and give rise to new tasks for TA. In order to discover more about future challenges, we devised a project that builds on the combined

experience of eight major European TA institutions. In recent years, these institutions have contributed to the debates on the impacts and the prospects of GM plants. They have carried out a considerable number of projects on issues related to GM plants and food, including consensus conferences, expert surveys, or scientific assessments. The ensuing reports have flagged up many agricultural, technological, economical and political developments that could turn out to be challenging for the EU regulation on GM crops, feed and food. The present work under the umbrella of EPTA aims to make use of the many insights gained during these projects and of the different expertises of the colleagues involved. Although they give some consideration to developments at the European level, national TA institutions generally direct their efforts at national issues and the needs of national parliaments in the first place. However, we think that collectively we will be able to acquire a more comprehensive view and thus arrive at more substantiated general conclusions.

APPROACH 3.

Eight EPTA members and associates met to conduct the joint EPTA project "Genetically modified plants and foods". These were:

- Centre for Technology Assessment (TA-SWISS – Switzerland)
- Danish Board of Technology (DBT – Denmark)
- Institute Society and Technology (I.S.T. – Flanders) (the former Flemish Institute for Science and Technology Assessment – viWTA)
- Institute for Technology Assessment (ITA – Austria)
- Norwegian Board of Technology (NBT – Norway), together with the Norwegian Biotechnology Advisory Board
- Office of Technology Assessment at the German Parliament (TAB – Germany) (project co-ordinator)
- Parliamentary Office of Science and Technology (POST – United Kingdom)
- Scientific Technology Options Assessment (STOA – European Parliament)

The EPTA Council approved the joint EPTA project and its approach on 17th October 2006. A Project Manager Group with researchers from all participating EPTA members and associates organised and carried out the project work. The project's objectives were to provide information on the following:

- Regulatory challenges for the European system in the years to come,
- Points of public debate in the future,
- Approaches for TA to handle the issues identified.

In addition to using the collected knowledge and expertise of the participating TA institutions in order to identify relevant future topics, the project combined a look back into the past – by means of reviewing recent TA projects – with a view to the future through an experts' survey.

IDENTIFICATION OF ISSUES

All researchers participating in the project had been involved previously in at least one or, as a rule, several TA projects on issues related to GM plants. Therefore, we could assume that the combined expertise of all participants would cover a wide variety of topics previously addressed in national TA reports. The overall perspective, however, was set by the central question as to whether or not EU regulation is fully adequate to meet new challenges.

In a series of brainstorming sessions among the group of researchers (Project Manager Group), several issues were identified that merit further investigation. These sessions took place during the initial project meetings, and the results were further discussed via electronic communication.

REVIEW AND DISCUSSION OF RESULTS FROM PAST TA PROJECTS

The aim of the review exercise was to make use of previous TA project reports on questions pertaining to GM plants (including food and feed issues as well as non-food plants) in order to put together different pieces of knowledge from various perspectives. This served to learn more about the developments that gave rise to the present situation, and to identify questions that might still be relevant for the future. Apart from constituting an independent source of information, the reports also flagged up topics that could be investigated further through the following experts' survey.

Before starting the review process, the Project Manager Group developed common criteria for the selection of projects and a checklist for the reviews. Selection criteria were:

- The project was executed by an EPTA member, an associate member or a national or domestic TA institution.
- The project used an interdisciplinary or multi-dimensional approach.
- The project included recommendations, options and/or needs for action.

Additionally, one of the following criteria had to be fulfilled in order to restrict the sample to relevant and important reports:

- The project results served to back up a political decision.
- The project was an important participatory event or exercise at a national or regional level.
- The project and its results were highly visible and played a role in public debate.

In addition, we aimed at a broad variety of approaches, such as expert opinions and reviews of scientific findings, reports from expert committees or from hearings, stakeholder discourses and projects involving lay people such as consensus conferences and citizens' juries. All participating institutions reviewed a number of project reports from their own country (and one each from France and Finland) and drafted short summaries. In general, the reviews follow a common scheme:

- Background;
- Basic data about the project;
- Major outcomes;
- Impacts and follow-up;
- Identify major challenges.

A list of project titles can be found in Annex 2; the full texts of all project reviews are available on the project website as Annex 3 (www.eptanetwork.org/EPTA/projects.php?pid=150). In total, 29 reviews were produced. Six reports each came from Austria and Germany, four each from Denmark and Switzerland, three each from Belgium (Flanders) and Norway, and one each from Finland, France and the United Kingdom. The unequal number of reports from various countries may be regarded as having been influenced by the differing measure of

attention attracted by the issue in public debate, regulatory action, and work in TA institutions.

The range of projects covered very different topics related to issues of GM plants, as well as different TA approaches, in order to gain an overview of the status of the debate and of different opinions and standpoints in society. We are, of course, aware that from a methodological point of view, it might be difficult to compare results from such a variety of different exercises in any systematic way. However, in this step we primarily aimed at collecting pertinent issues and relevant views rather than performing a systematic comparison. Again, we strived to exploit the combined knowledge of the participating institutions generated over recent years on technical and regulatory issues and societal debates regarding GM plants and food.

PRELIMINARY CONCLUSIONS IDENTIFYING POINTS TO CONSIDER

In a next step, the major results of the reviewed projects as they appeared in the summaries or recommendations were screened for statements with regard to prospects for the future, predicted problems, possible impacts of decisions, and demand for future action. These statements were grouped in clusters according to their main point of reference. This resulted in three clusters:

- Technological challenges,
- Societal challenges, and
- Regulatory challenges.

Each group had a number of sub-clusters. These clusters were then condensed in several rounds of discussions among project members during the following project meetings and served as a basis for preliminary conclusions and points to consider, to be further corroborated or challenged by the following experts' survey.

EXPERTS' SURVEY

The aim of the survey was to collect information and opinions from experts (from a wide variety of backgrounds and fields of expertise) on major challenges in the area of GM plants and foods as identified in the previous step.

CHOICE OF EXPERTS

National experts of the following affiliations were identified by the members of the Project Manager Group, respectively, and invited to fill in a questionnaire:

- Science: Plant breeding, genetics/genome research
- Science: TA, ecology, society, innovation and policy research
- Administration: Ministries, competent authorities
- Industry: Biotech industry (incl. consulting)
- Industry: Plant breeding

- Stakeholder: agriculture, food, retailer, trade unions
- Stakeholder: environment and consumers

In total, 183 experts in the field of GM crops and food were invited to participate in the questionnaire. The number of experts invited again differed according to country, a factor largely depending on the national context. We do not claim that the survey is strictly representative –the restricted number of countries represented in the project alone would prohibit such a claim. Rather, we tried to cover variety as much as possible, with a broad range of expertises and affiliations.

The experts had different areas of expertise, with a considerable number sharing a technical background. The questionnaire we developed (see below) was not tailored to tap into a particular area of expertise, but covered a very broad set of issues, including societal ones. In other words, all experts would be confronted with issues where they had no professional expertise. For example, experts for breeding transgenic crops were asked for their views on public perception, an area in which they would not be expected to possess any professional expertise.

The reason we did this was that we considered these experts to have been exposed, time and again, to relevant issues outside their professional area, so that they could be expected to entertain a well-based opinion. Further, we believe it is interesting in its own right to give a picture of current thinking by prominent experts and stakeholders. These individuals' perceptions of the future influence their internal strategies and decisions, thereby forming an independent driving force for the future of GM plants and food. Moreover, they are often asked to give their opinion on regulatory and societal issues regarding GM plants, thereby playing an important though informal role in determining future policies. Thus, their views may be important in relation to legislation and decision-making, even if their knowledge does not derive from any immediate professional occupation but from contingent exposure.

DEVELOPMENT OF THE QUESTIONNAIRE

The questionnaire was developed on the basis of the points identified for consideration in the reviews, with the intention of covering the relevant topics. As this would have resulted in a questionnaire that was far too long, the project members chose the most relevant topics from their own TA experience. Inevitably, this implied a certain amount of deliberate shortening; however, this was necessary in terms of practicality. Topics to be taken on board were discussed intensely in several rounds, and a final choice made.

The resulting broad scope of questions, combined with the number of experts we wanted to involve, led us to rely on a questionnaire with closed questions. Such a methodology is usually adopted for quantitative surveys. However, in this case, it was obvious that a strictly quantitative analysis would be hardly feasible, due to the relatively low number of respondents. We therefore left ample space for comments and thus allowed experts to display more thorough reflections, and thus included elements

of a qualitative approach. A first version of the questionnaire was pre-tested with one to three experts per participating country.

The final questionnaire consisted of 15 closed questions (with the option of providing explanations or comments) and one open question on areas for further investigation. The sections of the questionnaire were:

I. Factors influencing the future of GM plants in Europe

   I.1 General assessment

   I.2 New GM plants, new applications

   I.3 Public attitude and acceptance

II. Challenges for European/EU policy

   II.1 Challenges linked to freedom of choice, labelling and coexistence

   II.2 Challenges linked to new generation of GM crops

   II.3 Global aspects of GM regulation

III. Challenges for research policy

IV. Areas of action

The whole questionnaire and the tables of results are documented in Annex 4 and 5, available on the project website (www.eptanetwork.org/EPTA/ projects.php?pid=150).

SURVEY

The survey was conducted online from mid-November to the end of December 2007. Overall, 101 of the 183 invited experts opened the file; 30 of these then decided not to fill in the questionnaire; most of them discontinued after reading the introductory page. We received a full set of answers from 71 respondents. This gives a response rate of 39%.

The survey was carried out in the home countries of participating institutions' plus Finland. Table 1 shows the distribution of respondents by country.

TABLE 1: COMPLETED QUESTIONNAIRES BY COUNTRY

Country	Number of participating experts
Austria	17
Belgium	6
Denmark	7
Finland	3

Germany	21
Norway	8
Switzerland	5
United Kingdom	1
Not assignable	3

In a self-categorisation as part of the questionnaire, the 71 respondents assigned themselves to different affiliations (Table 2). Nearly half of the experts ticked the category "university/research institute".

TABLE 2: COMPLETED QUESTIONNAIRES BY AFFILIATION

Affiliation	Number of participating experts
University/research institute	34
Industry	11
Governmental agency	13
Agricultural organisation	5
Environmental or consumer organisation	2
Other, please specify	6[a]

a These 6 respondents described themselves as: 'communication, journalist', 'environment and development organisation', 'NGO on critical technology assessment', 'used to work at NGO, now consultant', 'Trade Association Biotechnology', 'retail.

When interpreting this figure, one must realise that "science" was not specified and therefore included very different sciences. Consequently, plant scientists, sociologists, ecologists, bioengineers, philosophers, etc. all ticked this category. Regrettably, the participation from representatives of NGOs such as consumer and environmental groups was low. Sample controls revealed that some experts assigned themselves to universities/research institutes even if they had frequently performed work for NGOs or were prominent members. A similar situation might have occurred with scientists affiliated to industry. Regardless of the underlying reasons, this bias tends to reduce the accuracy of such self-assignment.

ANALYSIS AND DISCUSSION

In a final step, the results from different parts of the Project Manager Group discussions, project reviews, and experts' survey were brought together. In the group discussions, the material was sorted and divided into chapters, and project members joined in "tandems" to perform a first analysis of each chapter. The main points to consider were discrepancies between the results of the Project Manager Group

discussions and the project reviews, on the one hand, and the experts' survey on the other. The draft analyses were further refined in several rounds of discussions with all project members, whereby the original partition was in part revised. On the basis of the Project Manager Group discussions, a draft report was written, with one group member each responsible for a particular chapter and another one for its review. In a final round, conclusions were drafted and discussed among all members.

The draft report was peer-reviewed by six experts from different European countries. Comments from the peer review were discussed in a project meeting. Three project members were assigned the task of organising the writing of a new version which took the reviewers' comments into account. The second draft version was again reviewed by the same six experts. Taking into account the resulting comments, the report was discussed in a final round of all project members, and a final revision authorised.

Chapter 4 presents the main findings. For each section, background information is provided, which is mostly derived from the Project Manager Group discussions. This is followed by the results of the project reviews, leading to preliminary conclusions and resulting questions. Results from the experts' survey are then presented in the form of bar charts. This does not mean that we understood this survey to be predominantly quantitative. As mentioned above, we were more concerned about bringing in people with a broad set of backgrounds rather than obtaining the most representative sample. This also prevents any statistical analysis of the data. Nevertheless, on a few occasions we mention explicitly how responses are distributed according to the respondents' affiliations. In the final part of each sub-chapter, we discuss the results from the experts' survey and the results of the review analysis with a view to formulating conclusions. These conclusions provided a basis for identifying future challenges for different areas of political action and possible future TA exercises (in Chap. 5).

REVIEW AND SURVEY RESULTS 4.

THE FUTURE DEMAND FOR GM PLANTS AND FOOD: FACTORS AND PROSPECTS 4.1

BACKGROUND

For centuries, ways of enhancing productivity in the agricultural sector have been and continue to be in high demand. In this context, many agronomists argue that since GM crops are assumed to have a better performance than conventional ones, the demand for GM varieties and their cultivation will noticeably increase over the coming years.

In 2007, the estimated global area of GM crops was around 114 million hectares (representing approx. 5% of arable land worldwide). GM crops were grown in 23 countries (James 2007). Twelve years after the commercial introduction of transgenic plants, there are still only two genetic traits (herbicide tolerance and/or insect resistance) and four crops that represent more than 99% of the acreage: soybean (51%), maize (31%), cotton (13%) and rapeseed/canola (5%). The global area of GM crops has grown continually, including in some important emerging countries. The leading country is the USA with 57.7 million hectares, representing half of the total global area, followed by Argentina (19.1 million hectares), Brazil (15.0 million hectares), Canada (7.0 million hectares), India (6.2 million hectares) and China (3.8 million hectares). In contrast, the cultivation of GM crops in Europe is very limited. In 1999, the approval process for GM plants came to a temporary halt in the EU (until 2004). The GM crop area in Europe is still very restricted, with around 110,000 ha in 2007 (combined in the Czech Republic, France, Germany, Portugal, Slovakia and Spain), and only GM insect-resistant maize is approved for planting.

However, new technological, political, economical and societal developments may affect the way GM crops and related issues will be considered in European politics and among the public. This chapter explores the relevance of different driving forces that affect the demand for GM plants and food in Europe.

RESULTS FROM THE TA PROJECT REVIEWS AND FUTURE ISSUES

Several of the projects reviewed discussed factors that could influence the future of GM plants and food (while others primarily focused on a retrospective analysis). The following summary is based on information from eleven reports:

- *Austria, "GMO-free" claims and the avoidance of GMOs in food*
- *Germany, Green Biotechnology Discourse*
- *Germany, Gene technology Report*
- *Germany, Genetic engineering, breeding and biodiversity*
- *Germany, Transgenic plants of the 2nd and 3rd generation*

- *Denmark, New GM crops – new debate*
- *Denmark, Coexistence*
- *Norway, Coexistence*
- *Norway, GM food*
- *Switzerland, Genetic Technology and Nutrition*
- *UK, GM dialogue*

First, it is considered that technological developments will be a crucial driving force. Innovations include the development of plant varieties with better resistance to drought, cold, flooding, pests and diseases. Moreover, research is directed at developing the second and third generation of GM plants capable of producing pharmaceutical ingredients or industrial materials. Research developments also concern "energy plants" that produce biomass, which may be used for biofuels. Promoters of these developments expect them to bring benefits for both human health and the environment, even though many uncertainties remain. There are also hopes for business opportunities and for more efficient production methods *(Germany, Transgenic plants of the 2nd and 3rd generation; Denmark, New GM crops – new debate; see Sect. 4.2).*

Second, economic factors must also be considered when discussing the future of GM plants and food. Europe is part of a globalised world, where more and more GM crops are being planted and exported. Will it be possible for Europe to stay apart from this global trend, considering that substantial quantities of GM soy and maize are imported into European countries? Can European countries and their agricultural sectors remain competitive without breeding GM plants? *(Austria, "GMO-free" claims and the avoidance of GMOs in food; Denmark, Coexistence; Norway, Coexistence;).*

Other structural factors may affect the future of GM plants and food as well. These relate to the increasing world food demand, which requires more efficient agriculture at global and local levels. Parallel to this, the increasing use of biomass and bioenergy as an alternative to fossil energy could also affect the demand for GM plants *(Germany, Gene Technology Report).* Furthermore, concentration trends in the food chain may have an impact. The seed industry is undergoing a fundamental change as big agrochemical companies heavily invest in agrobiotechnology and absorb small seed companies *(Germany, Genetic engineering, breeding and biodiversity).* The retail sector is also experiencing a trend towards concentration, with a few retailers dominating the market and thus being able to dictate the kind of products to be sold (e.g. GM-free products). At the same time, consumers demand an ever wider and more diverse supply of food products, from fresh products to a broad range of processed food. There is a trend towards specific "categories" of food: "light" products, organic food, food produced according to sustainability principles, fair trade food, etc. Such a multitude of consumer demands may also support a market for innovative technologies.

Moreover, there are regulatory factors that affect the future of GM plants and food. EU regulation of GMOs is based on the precautionary principle and the freedom of choice

(which entails segregation and labelling), and adopts a process-oriented approach. It is different from the US system, which is predominantly product-based and does not include any mandatory labelling of GM products *(UK, GM dialogue)*. The question of how these two systems could coexist and whether the EU system is robust in particular with respect to WTO rules, is discussed in more detail in Sect. 4.6.

The impact of the trends mentioned will be influenced by public reactions. Most surveys - as confirmed by various TA projects reviewed - show that one of the most important concerns relating to GM plants and food is their possible detrimental impact on health (antibiotic resistance, allergic reactions, etc.). The impact of GM plants on the environment is another important public concern in Europe. How will perceptions of risk evolve in the future? How will people react to and perceive new applications, new production systems and new policies? *(Germany, Gene technology Report; Germany, Green Biotechnology Discourse; Norway, GM food).*

PRELIMINARY CONCLUSIONS AND RESULTING QUESTIONS

A wide range of factors potentially influence the future demand for and use of GM crops, and it is hardly possible to foresee which of these will be the most important in the future. The TA projects reviewed did not reveal one single factor or driving force or even a few of them that will be particularly influential; rather, there will be a mix of factors depending on the context.

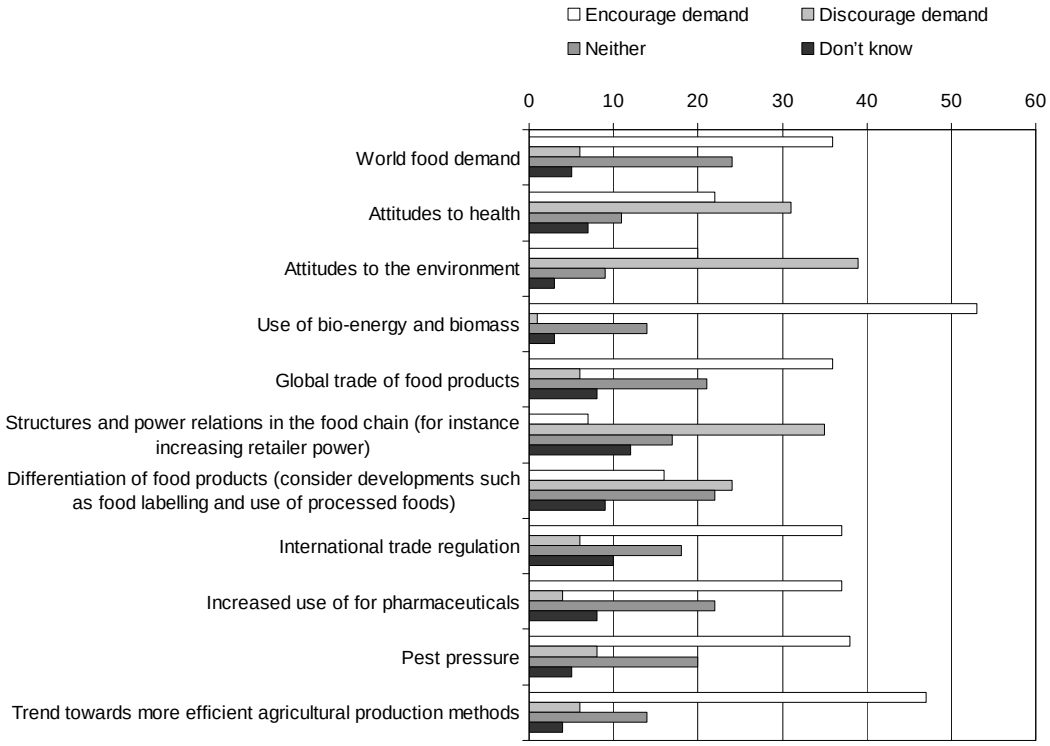
We therefore decided to begin the survey by asking the experts to give their overall view on the importance of different factors that could positively or negatively influence the future situation of GM plants and food in Europe. The two following questions pertained to their expectations on the future demand in general and whether the already existing "first generation" of GM crops would be grown to a noticeable extent over the coming years in Europe.

RESULTS OF THE EXPERT SURVEY

INFLUENCING FACTORS

All the factors listed (Fig. 1) were perceived as relevant for the future demand for GM plants and food, judging from the low rate of respondents ticking ‘Neither’ or ‘Don’t know’. Accordingly, the future of GM plants and food would be affected by a mix of factors.

FIGURE 1: INFLUENCING FACTORS FOR THE FUTURE OF GM PLANTS AND FOOD IN EUROPE (*Question 1A; n = 71)*



Question: Many factors will influence the future of GM plants and food in Europe. Below is a list of frequently cited major factors. Please indicate for each factor whether you think it will encourage or discourage the demand for GM plants and foods. Please feel free to add other important factors not listed.

Looking at the results in more detail, it appears that three in four experts considered the use of bioenergy and biomass to be a factor encouraging the demand for GM plants and food. This result must be seen in the light of the increasing demand for alternative energy sources. Respondents seemingly expected that GM plants might be required to satisfy this fast-growing market.

The trend towards more efficient agricultural methods was also considered an important factor, with two-thirds of respondents expecting it to encourage GM demand. This certainly reflected a recent trend in increasing prices for some agricultural products.

Around half of the respondents (44% and 55%, respectively) considered attitudes to health and the environment as discouraging the future demand of GM plants, nearly a third (31% and 28%, respectively) as encouraging. While the latter probably assumed that a new generation of GM crops might be acknowledged to bring benefits to human health and the environment, the former assumed that GM crops will be perceived as inferior in these respects.

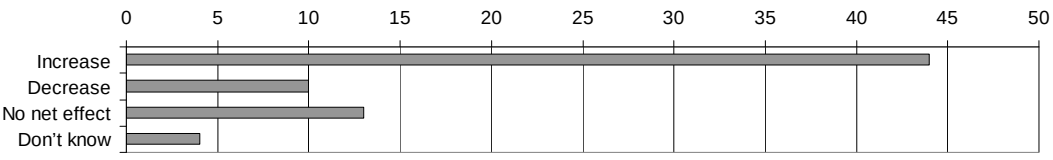
Overall, experts from industry had a higher-than-average tendency to expect different factors to encourage GM demand. This especially pertained to global trade (eight in ten compared with the average of five in ten for all respondents), world food demand and international trade regulation (for both: seven in ten compared with five in ten on average) and in particular concerning the differentiation of food products (five in ten compared with two in ten on average). Interestingly, fewer than half of the experts from industry expected GM plants for pharmaceuticals to play a role in encouraging demand for GM plants, compared to six out of ten researchers – perhaps because the development of such plants is still confined to the researchers' labs, whereas industry experts recognise the economic difficulties of such applications.

Some respondents also named other factors that might have an impact on the future of GM plants. One mentioned that if GM crops became significantly cheaper this might increase demand for them in times of rising prices for agricultural products. On the other hand, another respondent expressed the opinion that, as the average household income in the EU was rising, this could increase the demand for GM-free and organic products. Since the survey was carried out in late 2007 and the economic situation has changed meanwhile, this statement may be taken as highlighting the importance of the current economic context. For another respondent, “consumers’ perception of collusion between public administrations and multi-national companies will (continue to) minimise demand”. Food scandals and related fears (regardless of whether the food was of GM origin or not) might also hinder future demand for GM plants and products. The role of NGOs and the media was emphasised as well: depending on their power and credibility, they might influence public opinion on GM plants and food.

THE PLACE OF GM PLANTS AND FOOD IN EUROPEAN AGRICULTURE

Overall, a majority of experts expected most of the cited factors as encouraging demand for GM plants and food. But this does not directly indicate what the overall effect will be, as certain factors may outweigh others. We therefore asked whether the demand to introduce new GM plants in European agriculture will increase or decrease. Six out of ten experts expected an increase, less than one-fifth considered that it would remain stable, and only one-seventh expected a decrease (Fig. 2).

FIGURE 2: FUTURE DEMAND FOR NEW GM PLANTS IN EUROPEAN AGRICULTURE (*Question 1B; n = 71)*

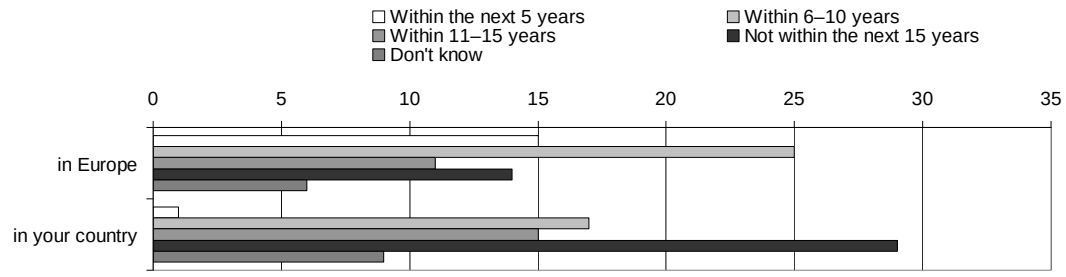


Question: Overall, would you think that the demand to introduce new GM plants in the European agriculture will increase or decrease?

It is of no surprise that respondents from the industry sector had the highest expectations regarding a growth in demand for GM plants and food (nine in ten), followed by the group of researchers (seven in ten).

Due to the uncertainty of the introduction of new generations of GM crops (see Sect. 4.2), we were interested to learn if the experts also predicted whether the existing "first generation" of GM crops (such as insect-resistant and herbicide-resistant plants) would be grown to a noticeable extent over the coming years. As shown in Fig. 3, more than half of the experts estimated that first-generation GM plants would be grown on more than 5% of the available European cropland within the next 10 years. This was a surprising result, knowing that only limited areas are currently cultivated with first-generation GM crops in Europe, and that no noticeable changes have occurred during the past years.

FIGURE 3: FUTURE CULTIVATION OF FIRST-GENERATION GM PLANTS IN EUROPE
(*Question 2; n = 71)*



Question: Do you think that the "first generation" of GM plants (such as insect-resistant (IR), herbicide-resistant (HR) and virus-resistant (VR) plants) will be grown in Europe to a noticeable extent (say more than 5% of the available agricultural crop land) in the next 15 years)?

It is a striking result of the survey that experts had a completely different view on the subject when asked about cultivation in their own country: only a quarter of them predicted that first-generation GM plants would be grown in their own country to a noticeable extent within the next 10 years (Fig. 3). This result, contradictory at first glance, was probably influenced by the national provenance of our experts. Amongst the countries represented, the only commercial planting of GM crops– on a very small scale – is in Germany. Many respondents probably expected countries which have shown a more positive attitude towards the use of GM crops in the past (e.g. Romania or Spain) to grow them to a larger extent in the near future.

In accordance with their view on the development of future demand in general, industry experts, and to a lesser extent researchers, entertained the highest expectations that first-generation GM crops will be grown to a noticeable extent in Europe and in their respective countries. All industry experts (except one who ticked 'Don't know') considered that first-generation crops will be grown in Europe within the next 15 years

(compared to four out of five overall), and three quarters (compared to half the experts overall) of them considered that they will be grown in their own country.

DISCUSSION

Overall, the general conditions for agriculture are changing. First, food supply is high on the agenda in response to increasing demand and jumps in food prices. The role of agriculture for food security and development is also back on the development agenda as two recent assessments show:

- World development report 2008 (World Bank 2007)
- International Assessment of Agricultural Knowledge, Science and Technology for Development (IAASTD 2008a + b)

The focus on food supply also has an impact on debates on GM plants both in Europe and worldwide. With regard to perspectives in developing countries, the views on the potential contributions of modern biotechnology towards productivity enhancement, improvements for small-scale farmers, and reaching the Millennium Development Goals, remain divergent – as has been the case ever since the 1980s. TA projects also came to differentiated and ambivalent conclusions, including that a number of important development goals could not be achieved through GM plants (e.g. *Denmark*, *Genetically modified crops in developing countries*). In the responses to the present survey, world food demand does not rank highest in encouraging demand for GM technologies. On the other hand, the survey indicates that a trend towards more efficient agricultural production methods will encourage GM-demand (Question 1).

Recent years have seen a dramatic increase in the importance of biomass as a renewable resource, especially for biofuels (for example EC 2006, GBEP 2007, Meyer et al. 2007, SRU 2007). This is illustrated both by the actual increase in biofuel production and by the formulation of ambitious goals for future biofuel use.

At the same time, crop breeding for bioenergy is more or less at its beginning. Reflecting this situation, experts considered the use of bioenergy and biomass to be a very important encouraging factor for GM introduction. But it has to be kept in mind that the biofuel policy itself is becoming increasingly controversial, as can be seen from the demand for a moratorium in biofuel use (for example EEA 2008).

Experts saw attitudes to the environment and to health as well as the structures and power relations in the food chain as discouraging factors for the future of GM plants and food in Europe, in line with the results from the TA project reviews.

In summary, the experts expected the demand to introduce new GM plants in Europe (Fig. 2) to increase. Accordingly, the majority of respondents expected a rise in the cultivation of first-generation GM crops that have in principle been available for a considerable time also in Europe (Fig. 3). Expectations concerning the time frame for introducing first-generation GM plants in European agriculture differ remarkably among different groups of experts. However, it is rather surprising to see that for many

of them, cultivation of first-generation GM plants will substantially increase in Europe, or at least in some European countries. These rather high expectations may reflect observations that the acreage of agricultural land cultivated with GM crops worldwide keeps increasing each year, and expectations that this trend will also involve some European countries.

In conclusion, experts see driving forces arising that will influence the demand for GM plants and food, and they expect the use of such plants in Europe to increase. Chapter 5 will discuss whether these expected developments could have consequences for GM regulation and for further TA projects.

NOVEL GM PLANTS, TECHNOLOGIES AND APPLICATIONS 4.2

BACKGROUND

The appearance of novel applications of GM crops has been announced and expected for many years. One main focus of scientific and political debate is on GM plants with modified properties for the user (so-called “output traits”, as opposed to agronomic or "input traits", which serve to optimise agricultural production). These plants are designed to produce pharmaceuticals or industrial raw materials (so-called molecular pharming); they are also expected to feature improved, especially healthier contents as a source of food. The latter could be particularly attractive to final consumers, while most of the other possible novel applications would serve industrial purposes in the first instance.

Recent interest has focused on options for using GM plants as a source for renewable energy production. The potential contribution of GM technology is seen in increasing the biomass yield in general or that of specific components such as fatty acids. Such plants may eventually be associated with environmental advantages and thus become more persuasive in public perception than the existing “first” generation of GM plant crops. On the other hand, some novel traits for new areas of application, such as the production of pharmaceuticals, may throw up serious new questions for risk assessment and management.

However, the suitability of genetic engineering to address such complex breeding aims as yield is controversial. It may also be put to the test by other advanced technologies such as smart breeding, which makes use of molecular genetics to support conventional breeding approaches.

RESULTS FROM THE TA PROJECT REVIEWS AND FUTURE ISSUES

Only two of the 29 projects reviewed overall explicitly dealt with new applications of GM plants – also called the second and third generation ("second generation"

describing those GM plants which are closer to commercialisation, and "third generation" referring to those being researched or at a very early stage of development):

- *Denmark, New GM crops – new debate*
- *Germany, Green genetic engineering – transgenic plants of the second and third generation*

One further report focused on relevant applications, but only marginally touched on the topic of GM plants (*Flanders, Industrial biotechnology* and *Functional Food)*, while another (*German, Gene technology Report)* predominantly covered technological questions (also in related areas of modern plant breeding).

The Danish citizens' jury assessed the new uses of GM plants as predominantly beneficial, but had different attitudes towards the use of GM plants for medical, other industrial, or ornamental purposes. One important demand made was that applications should not give rise to more harmful agricultural practices than the corresponding traditional modes of production (particularly concerning fertiliser or pesticide usage). Thus, a precondition for allowing the new plants was that the environmental consequences of new practices should be thoroughly assessed (*Denmark, New GM crops – new debate).*

Another challenge identified was the retention of a free consumer choice. Some reports even implied that GM products also for non-food and non-feed purposes could or should be labelled. In addition, public research should be strengthened to provide a counterweight to private research and development, as public research was considered necessary to maintain sufficient control of the new GM plants. The clearest message from the citizens' jury, however, was not about tangible advantages, disadvantages and conditions with regard to GM plants, but about the necessity of informing the public about these issues as part of an open and balanced debate (*Denmark, New GM crops – new debate).*

A major outcome of the TAB project, which was based predominantly on the analysis of scientific expertise, was that fundamental uncertainties remain regarding the developmental status of most GM plants for molecular farming as well as for the production of functional food, so that the economic potentials are very difficult to assess. In several cases, expectations of attainable product yields have not been fulfilled even after many years of development. In the course of maximising content, it seems that undesired side effects tend to emerge which then result in lower yields. While this does not make the concept (economically) unusable, it does affect the range of substances that can be produced on a commercially competitive basis.

In addition, approaches based on GM plants have to compete with well-established or more intensively investigated technologies in the chemical and pharmaceutical sector, and particularly in the food industry, where food ingredients are gained by chemical synthesis, microbial production or isolation from natural sources. The resource-intensive and comparatively long development period for new GM varieties, as well as

regulatory requirements, represent a disadvantage over more rapid and flexible alternatives. According to the TAB report, the most probable perspectives are localised in the field of pharmaceutical production, as a growing demand for biotechnological, high-value drugs and a need for additional production capacities can be deduced from recent market developments. With regard to the production of low-priced, so-called bulk chemicals, a major restriction was identified in the form of GM-specific regulation and management measures which increase the production costs (*Germany, Transgenic plants of the second and third generation*).

Since most GM plants modified for output traits are at an early stage, the risk discussion is still in its infancy and has so far concentrated on the question of how to reliably prevent gene flow or outgrowing and contamination of staple food. However, at least for GM plants producing pharmaceutical substances, the conditions for risk regulation (i.e. risk assessment, risk evaluation and risk management) are fundamentally different. Compared to existing GM plants with agronomic traits, they bear an inherent risk due to the possible medical and physiological impact of their new ingredients. At the same time such crops exhibit benefits (e.g. of a life-saving drug) which may be given weight if the approval procedure were amended in the direction of a comparative risk-benefit analysis (compare Sect. 4.5).

All in all, a thorough examination of the current European regulation was recommended to check its appropriateness for molecular farming. The overall conclusion of the TAB project was that, due to the limited emphasis on “molecular farming” within the debate on GM plants, there was an overall need at the EU and national levels for a more thorough consideration of opportunities and potential risks of GM plants modified for output traits (*Germany, Transgenic plants of the second and third generation*).

The report by the Berlin-Brandenburg Academy of Sciences and Humanities (BBAW) brought up the question of alternative novel methods or technologies for plant breeding *(Germany, Gene technology Report)*. "Smart breeding", the use of genomic information to empower and refine conventional breeding strategies, may be able to handle complex traits like yield or tolerance to abiotic stress (drought, salinity, etc.). At the same time, it uses molecular techniques without producing GM plants and thus avoids all aspects of GM-specific risk regulation and measures. "Cisgenic" approaches using only species-immanent traits for genetic modification are also on their way. Some experts and stakeholders ask whether cisgenics may blur the distinction between GM and non-GM plants, and one may ask if this technology will influence the public attitude towards GM technology.

PRELIMINARY CONCLUSIONS AND RESULTING QUESTIONS

Novel applications of GM plants have been announced for a long time, but have not yet appeared at all on the European market and only to a negligible extent elsewhere. So the basic question remains whether a technological breakthrough (i.e. a plant variety with new characteristics ready for marketing) can be expected in the next few

years. We asked for the experts' assessments of the availability of different traits, including a number of output traits, as well as new agricultural input traits.

Such "technical" availability does not mean that the GM plants can be introduced to the market – they still have to be authorised. At least for some novel output traits, it is obvious that serious risk questions have to be resolved, including the design of reliable risk management procedures (see below). Thus, a second question concerns the possible and expected authorisation of different categories of new GM plants as a prerequisite for their future market appearance.

The fulfilment of both requirements, the technical availability and the market approval does not automatically imply that a GM plant will actually be taken into use – this again depends on the demand by growers and the acceptance of possible users or, for pharmaceutical GM plants, the cost of the substance produced. Such acceptance and demand may vary according to the characteristics of the very heterogeneous categories of new GM plants. They depend on a variety of parameters such as the expected area of cultivation (which could be very small and possibly covered by glasshouses for pharmaceutical crops or special high-value chemical compounds) and the agronomical needs and measures (which could be more or less similar to established agricultural practices). Furthermore, how "close" the application is to the consumer will also play a role; uses as a source of food may be more sensitive than a very specialised "consumer-remote" purposes (e.g. phytoremediation, the extraction of toxins from the soil). These aspects could not be explored in detail in a questionnaire, but should be kept in mind in interpreting the answers received.

The usual scientific risk assessment procedures rely heavily on the concept of substantial equivalence, both in EU and US approval regimes. By proving that there are only minor differences between the GM plant and its conventional counterpart, the risk assessment focuses on the genes transferred and the specific traits they confer, and to a much lesser extent on the properties of the new plant as such. However, when the result of the genetic modification is a major change in the plant's physiology or a new synthesis of specific molecules in large amounts, GM plants are no longer equivalent to existing varieties. Therefore, their safety may need a more thorough or different type of investigation compared with existing "first-generation" GM plants. In the questionnaire, we asked the experts if they shared this view and, if so, in which areas they would possibly expect regulatory challenges.

RESULTS OF THE EXPERT SURVEY

AVAILABILITY – AUTHORISATION – DEMAND – ACCEPTANCE OF NEW GM PLANTS

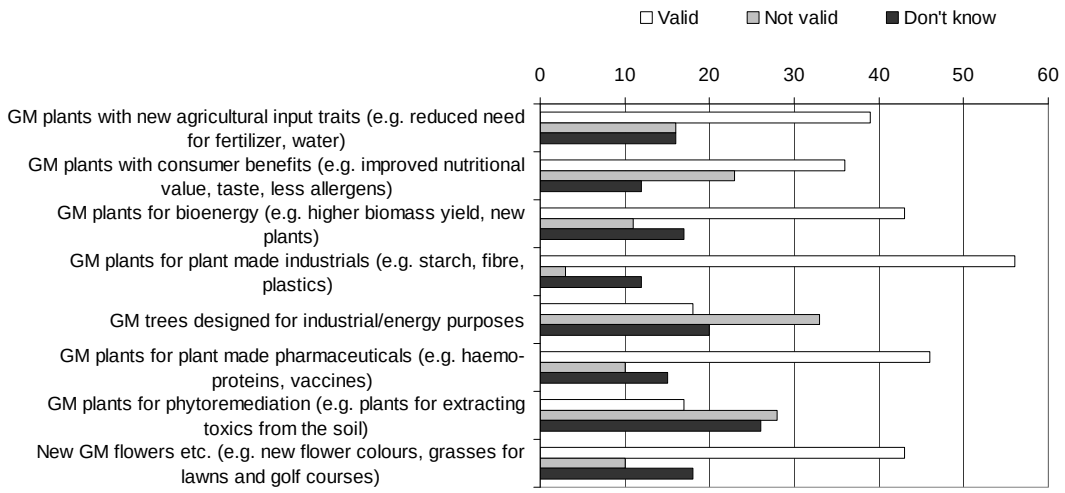
Overall, the respondents tended to expect new GM plants to be introduced in the coming decade. With the exception of trees for industrial or energy purposes and plants for phytoremediation, the majority of respondents expected all other categories of plants listed to be available and authorised for cultivation in Europe within the next

10 years. The experts did not add any other category to those listed in the questionnaire.

Asked whether the various plants *"will become available"*, "GM plants for plant-made industrials" scored highest (four in five, see Fig. 4), followed by plant-made pharmaceuticals, plants for bioenergy and new GM flowers (about three in five each). "GM plants for phytoremediation" and "GM trees designed for industrial/energy purposes" received the lowest support (about one in four), while "GM plants with consumer benefits" got support from half of the respondents, comparable to "new agricultural input traits".

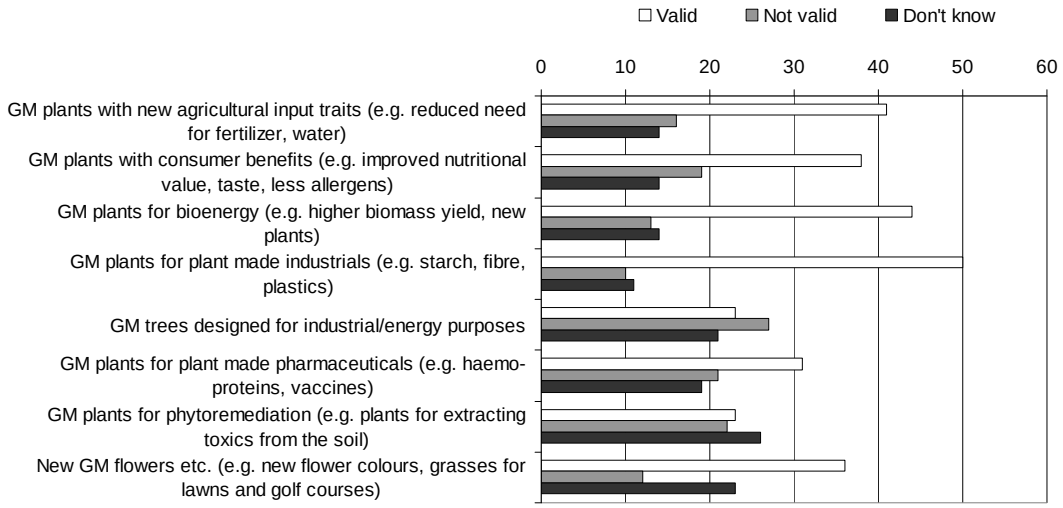
The answers to *"will be authorised"* (Fig. 5) show a similar pattern except for "GM plants for pharmaceuticals": They are regarded as less likely to be authorised although they would be available (less than half vs. three in five). This difference may reflect that such products can be supplied in most cases from restricted cultivation in greenhouses without authorisation for commercial planting. In general, one reason for the relatively low support for GM pharmaceutical plants, trees and plants for phytoremediation may be that they might be associated with different kinds of risk, which could be seen as requiring different assessment regimes (see Fig. 11).

FIGURE 4: AVAILABILITY OF NOVEL GM PLANTS
(Question 3A; n = 71)



Question: Currently there are several classes of new GM plants in development. Please check if you believe the statement: "Such crops will become available within the coming 10 years."

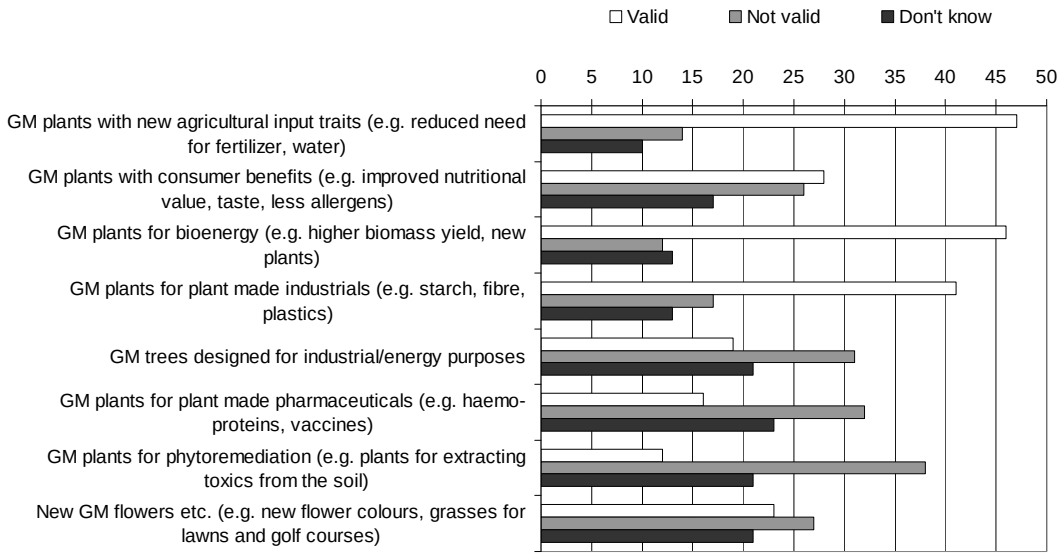
FIGURE 5: AUTHORISATION OF NOVEL GM PLANTS (*Question 3B; n = 71)*



Question: Currently there are several classes of new GM plants in development. Please check if you believe the statement: "Such crops will be authorised for cultivation in Europe."

The question of *"demand from farmers"* (Fig. 6) tapped into expectations concerning the interest and willingness to grow the respective GMP. By comparing with the question on *"acceptance with consumers"* (Fig. 7), we can deduce a possible conflict between a high demand from farmers compared to low acceptance from consumers anticipated for "GM plants with new agricultural input traits" (seven vs. three in ten). A similar, though weaker discrepancy arose for "GM plants for bioenergy" (seven in ten vs. half), and an opposite relation for "GM plants with consumer benefits" (two versus three in five). Maybe a reason for the latter is that respondents believed that crops with consumer benefits would only make up a niche market, so the average farmer would not benefit from it.

FIGURE 6: DEMAND FROM FARMERS FOR NOVEL GM PLANTS (*Question 3C; n = 71)*

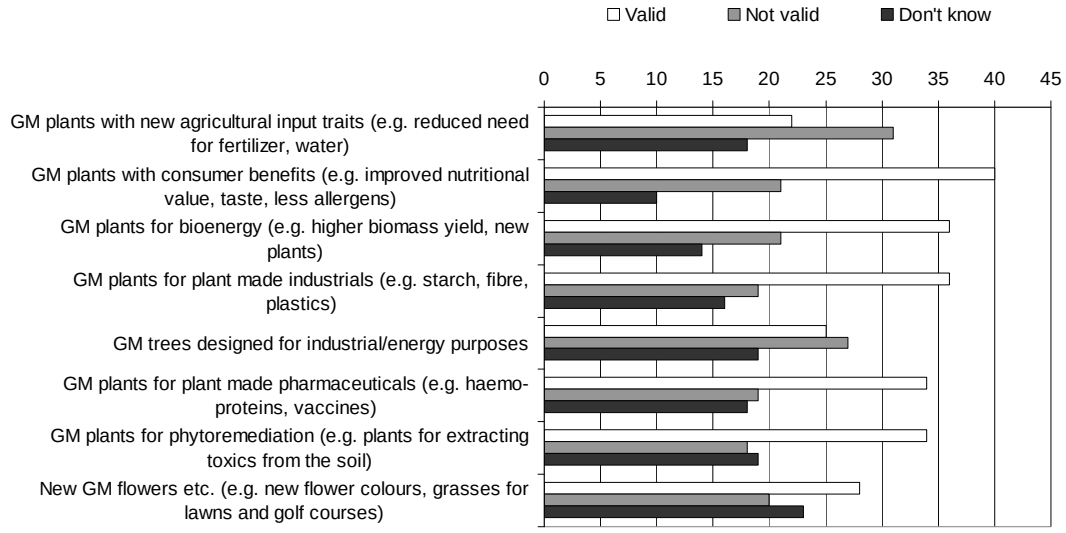


Question: Currently there are several classes of new GM plants in development. Please check if you believe the statement: "Such crops will find significant demand from farmers."

The assumed low interest of farmers in growing GM plants for pharmaceuticals is not surprising, because such plants will probably be cultivated, if at all, only on a contract basis. The high numbers of "Not valid" for "GM plants for phytoremediation", "GM trees designed for industrial/energy purposes", and "New GM flowers" also reflect their nature as non-agricultural plants which are not relevant for most farmers.

The relatively high expectation for consumer acceptance of "GM plants for bioenergy", "GM plants for plant-made industrials" and "GM plants for pharmaceuticals" is in line with the responses to Question 6 where a majority of experts perceived that GM non-food products would meet more positive public attitudes (see Fig. 12 in Sect. 4.3). It also fits with the cautious but affirmative vote of the Danish citizens' jury on these issues (*Denmark, New GM crops – new debate)*.

FIGURE 7:ACCEPTANCE WITH CONSUMERS OF NOVEL GM PLANTS (*Question 3D; n = 71)*



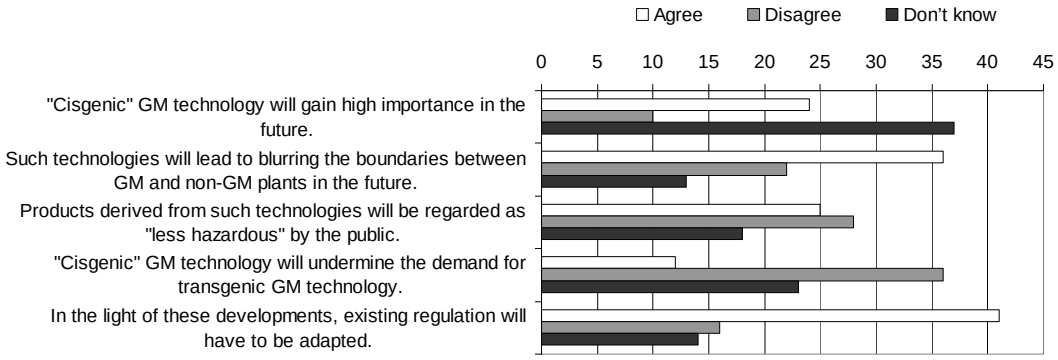
Question: Currently there are several classes of new GM plants in development. Please check if you believe the statement: "Products from such crops will find acceptance with consumers."

Concerning "*demand from farmers"*, several participants commented that "*Farmers will probably be willing to grow anything for which there is a demand, either from consumers or from industry."* Regarding "*acceptance with consumers"*, one respondent commented: "*Every single person is a consumer, so obviously this is not a homogeneous group. What percentage of consumers is needed to answer "valid" - 10%, 30%, the majority? I have interpreted this as acceptance by a majority of consumers. There will be a minority that will not accept any GM crops (this is about 15% of all consumers*)."

FUTURE IMPORTANCE OF SPECIFIC ADVANCED GENETIC BREEDING TECHNOLOGIES

Questions on the future importance and implications of smart breeding and cisgenic technologies are of interest because both have the potential to provide novel varieties that may be more acceptable to a sceptical public since the degree of "manipulation" may be perceived to be less severe.

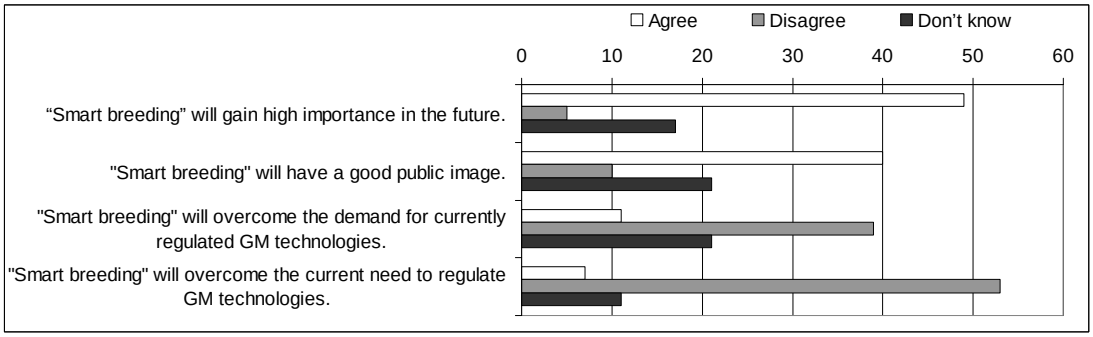
FIGURE 8:FUTURE IMPORTANCE OF “CISGENIC” GM TECHNOLOGY (*Question 4A; n = 71)*



Question:	In the future, technical developments such as “cisgenic” GM technology may become more important. While traditional “transgenic” plants result from gene transfers which use recombined DNA from other species, “cisgenic” plants result from gene transfers which use only recombined DNA from the same species. Please indicate if you agree or disagree with the following statements.

The importance of cisgenic GM technology does not seem to be very clear as responses show a high rate of “Don’t know” answers (more than half; Fig. 8). The statements that this technology “blurs the boundaries” and a “need for adapting existing regulation” ensues each met with quite high support from more than half of the respondents. On the other hand, the statement “Cisgenic GM technology will undermine the demand for transgenic GM technology” met with the lowest support, which indicates that respondents expect cisgenes to at best supplement, rather than replace, transgene technology.

FIGURE 9: FUTURE IMPORTANCE OF “SMART BREEDING” (*Question 4B; n = 71)*



Question:	“Smart breeding” is another new technical development. "Smart breeding" derives from traditional methods of plant breeding but includes tools on the basis of modern recombinant DNA technology such as molecular markers. Please indicate if you agree or disagree with the following statements.

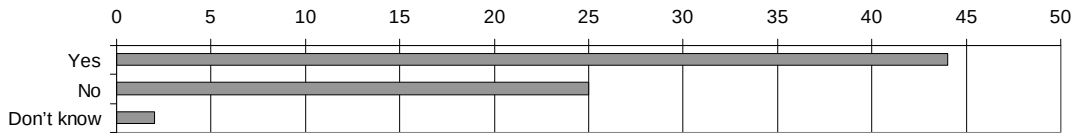
Whether the public would regard products derived from such technologies as "less hazardous" was controversial (one-third agree, slightly more disagree). In the written comments respondents emphasised that *"Most consumers will, if asked to distinguish, see cisgenics as less hazardous than transgenics, but that doesn't mean they will accept them in their back yard or on their dinner plates."* A similar consideration was: "*I guess cisgenic will be defined - publicly as well as in terms of regulation - as transgenic. Argument: rearrangement within the genome calls for precaution as well."*

Compared to cisgenic GM technology, many more (seven in ten) considered "smart breeding" to be important: more than half saw a "good public image" (Fig. 9). However, smart breeding is not considered an alternative to GM technologies (more than half disagreed), and it will not overcome the current need of GM plant regulation (three in four disagreed). One respondent noted *"that all these techniques will contribute to the development of plants for different purposes"*.

REGULATORY ISSUES OF NOVEL GM PLANTS FOR THE NON-FOOD SECTOR

Almost half of the experts agreed that novel GM plants for the non-food sector would pose new regulatory challenges, while one in four disagreed (Fig. 10).

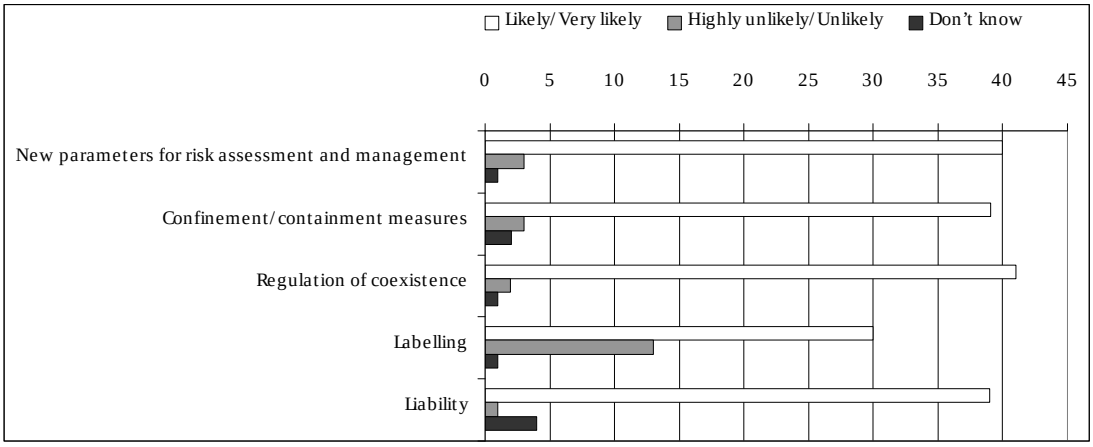
FIGURE 10: NEW REGULATORY CHALLENGES CAUSED BY NOVEL GM PLANTS?
(*Question 10A; n = 71)*



Question: Newly developed GM plants for the non-food sector (e.g. GM plants for plant made pharmaceuticals, for industrial raw materials, and for bio-energy) are sometimes said to have new properties compared to gm plants for food and therefore pose new regulatory challenges. Do you or don't you agree with the following statement?

Those who expected regulatory challenges were then asked what kind of challenge they would expect (Fig. 11). Aspects such as "new parameters for risk assessment and management, "confinement / containment measures", "regulation of coexistence" and "liability" were all regarded as very likely or likely to be on the agenda during the next 10-15 years by around nine in ten of the experts. In comparison, "labelling" was identified as a highly likely or likely issue by only seven in ten. This could reflect the fact that non-food/feed products may not necessarily have to be labelled.

FIGURE 11: AREAS OF NEW REGULATORY CHALLENGES OF NOVEL GM PLANTS
(*Question 10B; n = 44)*



Question: If you ticked "Yes" *[in question 10B]*, please assess which regulatory challenges non-food GM plants will raise in the next 10-15 years, and whether this will be very likely, likely, unlikely or highly unlikely. Please feel free to add other regulatory challenges not listed.

The experts did not add any other category to those proposed in the questionnaire, but in the written comments it was emphasised that *"Regulators also need to address issues such as ethics, sustainable development and societal utility"* and that *"In general, since most non-food GM plants presumably will produce high value products, there will be a natural interest to keep them confined from other crops in order to preserve the value of the products."* Another participant added that *"Answers refer primarily to plants producing pharmaceuticals. Some other non-food traits, e.g. for bioenergy, would not raise new regulatory challenges."*

DISCUSSION

Will new GM crops with novel properties be available, and will they come onto the market? Will new regulatory challenges arise, and what about alternative or complementary novel methods/technologies such as smart breeding and cisgenics?

Amongst the experts asked, the overall expectations that such new GM plants would be developed and in principle be available "within the coming 10 years" remained high. A more precise forecast was not requested, thus no conclusions can be drawn about when the experts expected such crops to be market-ready and authorised in Europe.

Interpreting the rough forecast for different categories remains difficult. As already mentioned, GM plants with improved output traits have been announced for many years, but no information is available on whether the technological development has been substantially accelerated. In some cases, high expectations could be due to

wishful thinking (or continuing fear) rather than informed judgement. The TAB report showed that many research and development projects in the past failed in their late stages (*Germany, Transgenic plants of the second and third generation*), which makes it difficult to forecast the fate of current projects. A plausible reason for the high expectations concerning industrial applications probably is the availability of a particular GM crop, the BASF starch potato "Amflora" – whose authorisation was applied for more than 10 years ago. However, the "Amflora" example also illustrates that industrial GM crops may have difficulty obtaining authorisation even in a case that has been extensively tested for a long time and assessed, according to the European Food Safety Authority (EFSA) GMO Panel, to be unlikely to have adverse effects. It is not clear whether this will change in the foreseeable future.

The pattern of the experts' expectations regarding demand from farmers and acceptance by consumers vis-à-vis GM crops with new input traits and functional food properties were basically in line with familiar opinions: respondents regarded farmers to demand more agricultural traits and consumers to demand improved nutritional value (irrespective of the factual rejection of GM foods in Europe until now). However, the acceptance of growers and consumers seem to diverge for other applications as well. One reason may be that certain types of crops are closer to the consumer, and thus more sensitive.

For food crops, there should be a strong relation between consumers' demand and farmers' production. In contrast, for plant-made pharmaceuticals, industrial substances and crops for bioenergy it is the pharmaceutical, chemical and energy industry that creates demand. On the one hand, this might change the role of farmers, who in the future might be working increasingly on a contract basis – a development that is also taking place with food production, as the requirements of identity preservation and quality control constantly rise. On the other hand, as the produce becomes refined to fuels, plastics or pharmaceuticals, their agricultural and thus GM origin becomes obscure. More "remote" value chains such as these may be less sensitive to GM opposition, although recent actions against the "Amflora" potato were similar to former campaigns against GM food crops.

The future role of cisgenics and smart breeding seems to be somewhat unclear. Although they were considered important for plant breeding in general, the majority of experts did not expect them to substantially reduce the demand for transgenic technologies. There might be a gain in popularity, however; and some existing regulations might need to be adapted in order to cover cisgenics.

GM plants for the non-food sector, and especially in the case of plant-made pharmaceuticals, were expected to pose various regulatory challenges. This confirms the results of the TAB report (*Germany, Transgenic plants of the second and third generation*). A majority of respondents considered it likely or very likely that new parameters for risk assessment and management, confinement and/or containment measures, regulation of coexistence and liability will be put on the agenda over the next 10-15 years.

Taken together, the appearance of new categories of GM crops remains difficult to predict. However, if they occur in the coming years, at least some of them will evoke novel regulatory questions.

PUBLIC ATTITUDES AND ACCEPTANCE 4.3

BACKGROUND

The history of GM plants in Europe is a history of strong debates between decision makers, experts and various stakeholders, including industry, consumer groups and environmentalists. Proponents of GM plants argue in favour of the environmental benefits of GM plants (less fertiliser, less pesticide, less tillage) and higher productivity perspectives. Opponents emphasise potential health and environmental risks as well as a variety of non-technical issues, such as the multiple purposes of agriculture, pending dependence on multi-national companies and questions of ethics and (food) culture.

Over the years, this debate has found resonance in and received inputs from the public in European states' to varying degrees. The ensuing reluctance to buy GM products has almost prohibited their commercial introduction. Public scepticism might have had an influence on the EU regulation on GM plants and food as well, which some claim to be rather restrictive. When considering the future of GM plants and food in Europe, it is thus important to reflect on the way public debate will evolve and, more specifically, whether or not agricultural GM technology and its products will find more acceptance over time.

However, it must be kept in mind that acceptance or the lack of it is the result of a process of shaping public opinion with many factors involved. Therefore, any such reflection must take into account numerous possible reasons for the perception entertained by the European public.

Overall, repeated European surveys[1] have identified growing scepticism throughout the 1990s and a slight change over the last couple of years. Regarding GM food, the majority still seem to be sceptical (Gaskell et al. 2006). Several explanations have been proposed. Firstly, since the so-called first-generation of GM crops was mainly developed in order to suit the needs of the producers, one line of explanation stresses the rational choice of consumers: since buying GM food products would not as yet bring clear individual benefits, and the potential risks claimed by opponents could not be entirely dismissed, consumers tend to remain sceptical. Consequently, with new GM plants delivering products which might be considered beneficial for the consumer, or products other than food or feed, some expect attitudes to change.

1 In particular, six Eurobarometer surveys on biotechnology in 1991, 1993, 1996, 1999, 2002 and 2005, see http://ec.europa.eu/research/press/2006/pr1906en.cfm

However, even if one takes into account consumer calculation of risks and benefits, this alone may not be sufficient to explain how attitudes are formed. Analyses of surveys have shown that, regardless of considerations of risk or personal benefit, if someone has moral objections to genetic modification this acts as a "veto" (Gaskell et al. 2006). Such objections can be directed, for example, towards the perceived role of GMOs as "tinkering with life", which would collide with a certain understanding of nature.

Such general arguments lead to another line of explanation that emphasises someone having a general opinion of GM plants (Lassen et al. 2002; Lassen and Jamison 2006). Reasons may be based on arguments of the general environmental effects, common welfare and/or democratic accountability. For example, such arguments could pertain to GM plants considered to reduce or create environmental risks either directly or through the way agriculture is conducted. Whether or not risk management will be able to mitigate risks is controversial, as is the question of whether coexistence will secure consumer choice or, if it fails, will result in negative effects for non-GM agriculture. Patenting may contribute to enhancing research to secure the world food supply, but it may also give rise to problems of equity and dependence on "big business". There are also links to voices criticising the way food scandals have been dealt with and how expert committees and regulatory bodies have failed to provide and act upon expertise, independent of special interests. Accordingly, the perceived lack of accountability has contributed to a reluctance to accept reassurance from experts that there is no risk (PABE 2001). This again is linked the debate on the risk issue, but at a different, societal level.

In other words, several lines of argumentation may explain the perceptions measured in a survey. In addition, it must be kept in mind that there may be a gap between the role of the citizen supporting or rejecting GM technology on the one hand and the role of the consumer purchasing GM food products or not in practice on the other, whereby one and the same person could take on both roles at different times.

RESULTS FROM THE TA PROJECT REVIEWS AND FUTURE ISSUES

A number of TA reports from various institutions, many of them involving lay panels or other forms of involving non-experts, have tried to shed light on the reasons behind past and present public perceptions and on factors that may influence them in the future, such as participation, communication and public debate. Project members used information from the following summary of some of the most important points to consider from the reviews of these reports in forming their hypothesis. Relevant TA projects reviewed were:

- *Denmark, Genetically modified foods*
- *Denmark, New GM crops – new debate*
- *Finland, Debate concerning the plant gene technology*
- *Flanders, New impulses for the debate on genetically modified food*
- *Germany, Green Biotechnology Discourse*

- *Norway, GM food*
- *Switzerland, Genetic Technology and Nutrition*
- *United Kingdom, GM dialogue*

Other reports mentioned public perceptions as a factor to be taken into account, such as

- *France, Co-construction*
- *Flanders, Industrial biotechnology*
- *Flanders, Functional Food*
- *Austria, Precautionary Expertise*
- *Germany, Transgenic plants of 2nd and 3rd generation*
- *Switzerland, The future of plant biotechnology*

Almost unanimously, the project reviews suggest that consumer attitudes, and the ensuing reluctance of retailers to put GM products on the shelves, have strongly influenced the economic performance of GM food. Consequently, the question of how attitudes will develop over the next 5-10 years is likely to be the key to any future success of GM crops (*United Kingdom, GM dialogue*). This applies to current GM plants for food, future developments, and GM crops for non-food purposes/applications. In some countries, consumers may even have become less confident and more sceptical over the years (*Norway, GM food*). This may also have to do with a loss of trust in the scientific community and in regulatory bodies and not only with the risks associated with the technology alone (*France, Co-construction*). There are contrasting experiences in Finland, however, where acceptance seems to have improved (*Finland, Debate concerning the plant gene technology*).

In general, it is difficult to determine whether acceptance has changed in practice. What can be said, however, is that perceptions are split: some reports emphasised strong dissent among members of stakeholder panels over risk, benefits and major definitions such as on the precautionary principle and ecological damage (*Germany, Green Biotechnology Discourse*).

Surveys over the last decade have repeatedly pointed out that consumers are quite sceptical towards food products from first-generation GM plants, as they do not see clear benefits for themselves, and also fear risks related to health and the environment. This argument was also emphasised in citizens' panels and consensus conferences (for example *Denmark, Genetically modified foods*). However, a Swiss panel of non-experts considered no danger to be proven, and although no final judgement could be made on the presence or absence of a risk, some members considered that GMOs should not therefore be banned (*Switzerland, Genetic technology and Nutrition)*.

Several reports quote expectations that acceptance of new GM food products could grow as future products may entail obvious benefits to consumers (for instance healthier nutrition or better food quality, *Germany, Green Biotechnology Discourse)*. Non-food products may also find more acceptance, as health issues are less sensitive, and new products may be associated with clear advantages. In particular, GM plants for medicines received support because of the importance of the product, in contrast to

ornamental flowers. Therefore, a "conditional yes" can be expected – which seems to depend on the perceived societal usefulness of the product compared with its possible risks (see also Sect. 4.2) *(Denmark, New GM crops – new debate*).

However, attitudes are not only the result of a simple balancing of (environmental or health) risks and (societal or personal) benefits. Citizens are also concerned with general issues such as equity regarding benefit allocation (*Flanders, Functional Food*) and justice, in particular with regard to developing countries (*Denmark, Genetically Modified Foods*). Several reports highlighted that attitudes towards nature play an important role, too *(Switzerland, Genetic Technology and Nutrition)*, and that ethical considerations should be taken more seriously (*Denmark, Genetically modified foods*). Finally, aspects of food culture may also influence perceptions (*Flanders, Functional Food*).

This said, however, non-experts also understand and evaluate national economic arguments such as concerns for the research area (*Switzerland, Genetic Technology and Nutrition*). However, economic benefits are not only considered to be associated with the introduction of GM technology, as in agriculture there may be disadvantages from using GM plants for the national agricultural system (*Norway, GM food*). For example, if the organic sector considered particularly vulnerable to contamination with GM plants is prominent in a country, economic losses from jeopardising this sector could be considerable.

More procedural factors have also been proposed as possibly influencing public attitudes, such as communication and participation in decision-making processes. Several reports point to the desire for broader participation and involvement of the public and stakeholders to help ensure that as many relevant questions as possible are addressed. Citizens call for an intensified dialogue between the general public and researchers, and some voted for the public to already be involved in the decision-making processes on GM plants when the technology is at the research stage (*Switzerland, Genetic Technology and Nutrition; Switzerland, The future of plant biotechnology; Flanders, New impulses for the debate on genetically modified food; Austria, Precautionary Expertise for GM Crops*).

Moreover, the importance of understandable, down-to-earth communication about GM plants was identified, although it was emphasised that the social acceptability of GM plants does not only depend on the level of information. In other words, more information does not necessarily mean more people will accept the technology. (*Flanders, New impulses for the debate on genetically modified food; Switzerland, The future of plant biotechnology in Switzerland*). This confirms the criticisms of many social scientists about the "deficit model" of the Public Understanding of Science approach.

PRELIMINARY CONCLUSIONS AND RESULTING QUESTIONS

Public attitudes are a major factor determining the prospects of new GM plants, both for food and non-food purposes. It is therefore important to gain more insight into the possible trajectories of developing public perceptions. However, since perceptions are a result of multi-factorial influences, it will be difficult to predict such a trajectory.

There are contradictory indications as to which direction the development will take. On the one hand, some countries have experienced a loss of acceptance, at least for products from first-generation GM plants. For some people, the label “GM” seems to be associated with deep-rooted aversion, regardless of any actual benefits. The risk issue, especially regarding the environment, has not been settled for good, and general questions of ethics and equity still hamper the prospect of the technology. Labelling and consumer choice might not be the solution for those who consider GM products unacceptable for the latter reasons. This indicates there will be little change from the status quo.

On the other hand, new products promise consumer and health benefits or aim to deliver products other than food, where health risks no longer play the same role. Over time, arguments related economic advantages or ecological benefits may gain a foothold. Such arguments have been brought forward to support the notion that acceptance may improve in the future. In addition, a habituation effect cannot be ruled out once products are on the market.

We conclude that for the time being, it is impossible to seriously predict how public attitudes will actually develop. However, for future regulatory decision-making and strategy building this is not the only important question to be asked. Rather, we think it equally or even more important to know what the experts who influence the shaping of public opinion and who advise regulators and other decision-takers deem to be the most likely development – almost irrespective of whether such a development comes about or not. The perceptions of experts will, for instance, ultimately have an influence on what decision-takers consider relevant for their decisions.

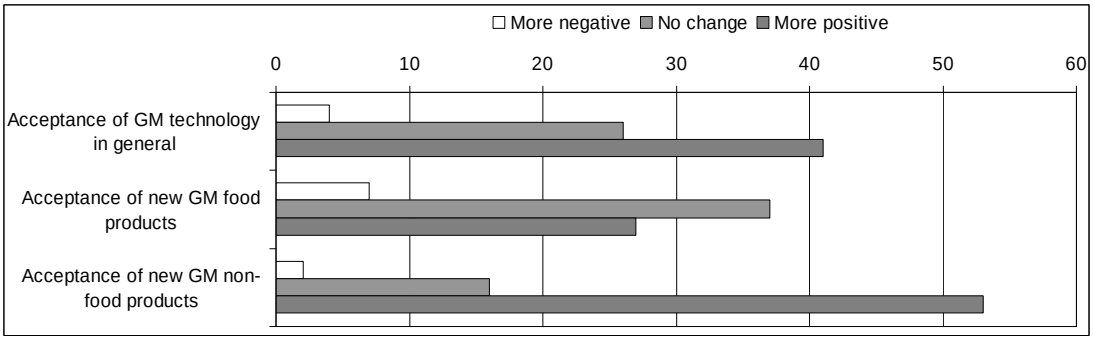
Following this rationale, we devised some questions for our expert survey aimed at challenging our preliminary conclusions on the development of public perceptions of GM plants in the future. If policy decisions are influenced by the way experts perceive what the public thinks of GM plants and food in Europe and how ordinary people might act in the future, the question is what do experts consider to be crucial in determining public perceptions. Is it risk or personal benefit? Do common welfare arguments play a role? Will future risk management succeed in assuring confidence? And is it the citizen or the consumer who will decide the future fate of GM plants and food in Europe?

RESULT OF EXPERT SURVEY

PUBLIC ATTITUDES OVER THE NEXT 10-15 YEARS

In order to address these issues, we put the question: *"Will public attitudes to GM crops and food change in the next 10 to 15 years?"* with three sub-questions, in which we asked for the experts' opinions on public acceptance of GM technology in general, new GM food products, and GM non-food products. This distinction is important, as acceptance may vary according to the type of products.

FIGURE 12: PUBLIC ATTITUDES (*Question 6; n = 71)*



Question: Will public attitudes to GM crops and food change in the next 10 to 15 years?

A (small) majority of experts expect a more positive attitude towards GM technology, with an important difference between food and non-food products (Fig. 12). Overall, three in four expected more positive attitudes towards new non-food GM products and only about one in three for new food products. Thus, a majority of experts consider the next generation of GM food products to be met with scepticism. On the other hand, a significant majority expect positive attitudes in relation to non-food products. It should be noted that for all items in the question, industry experts and those from universities and research institutes have higher expectations of a positive change than others.

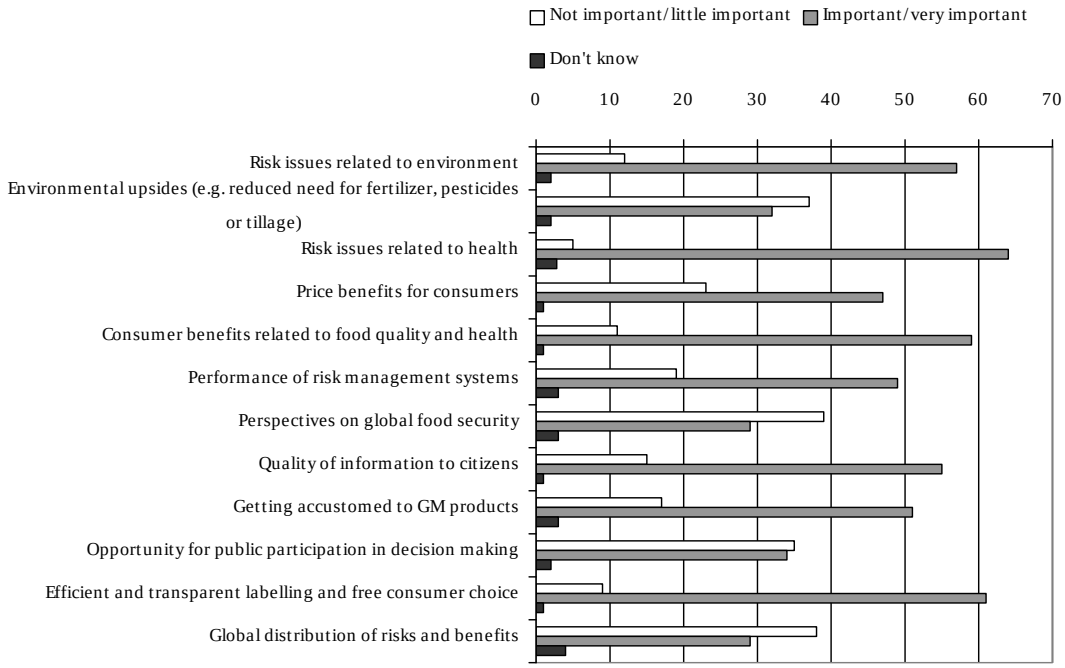
It is interesting to note that even though only one-third of the experts expect more positive attitudes for new GM food products, half of them expect these products to be on the market within the next 10 years (Fig. 3, Sect. 4.1). Obviously, some experts think that public attitudes will not prevent the marketing of new GM food products. Concerning new non-food products, the number of experts expect public attitudes to grow more positive is about the same as those who expect GM plants for bioenergy, industrials and ornamental flowers to be on the market within 10 years.

INFLUENCING FACTORS

In a second question, we wanted to know which factors may influence acceptance, regardless of whether positively or negatively: *"Currently the consumer acceptance of GM plants and food varies across Europe. Many factors have been associated with*

public acceptance. Please rank the factors in the list below in their importance for consumer acceptance over the next 10 to 15 years". The emphasis here was laid on consumer attitudes.

FIGURE 13: FACTORS INFLUENCING PUBLIC ATTITUDES (*Question 5; n = 71)*



Question: Currently the consumer acceptance of GM plants and food varies across Europe. Many factors have been associated with public acceptance. Please rank the factors in the list below in their importance for consumer acceptance over the next 10 to 15 years. Please feel free to add other factors not listed.

The answers indicate that risk will remain an important factor (Fig. 13): Nine in ten experts considered issues related to health risks as important or very important. Interestingly, two-thirds of the industry experts (compared to slightly more than half on average) considered them to be very important. At the same time, four in five (and all of the industry experts) found the factor "consumer benefits related to food quality and health" to be important or very important, suggesting that they might see a possibility that acceptance could improve in case such benefits would materialise.

In previous studies, "price benefits for consumers" were understood as genuine consumer benefits, but citizens did not necessarily look at the price as an important advantage (*Denmark, Genetically modified foods*). Similarly, in our study, experts did not regard price benefits to be as important in influencing public attitudes as food quality and health.

The results suggest that, for the consulted experts, public attitudes would mainly depend on personal health benefits or risks that are associated with GM products. The

high number of industry experts emphasising health and food quality supports the idea that industry is aware of the consumer focus on food safety and health issues.

In the same vein, experts considered environmental risk to be high on the agenda. Four in five considered "risk issues related to the environment" to be of major concern in the future, too. In Question 11 (see Fig. 19 in Sect. 4.5), "environmental benefit" was considered to be the most likely aspect to be included in future assessment procedures, which is somehow at odds with the finding that one of the four least-scoring factors for acceptance was "environmental upsides (e.g. reduced need for fertiliser, pesticides or tillage)." This suggests that most experts did not expect this argument, which is often brought forward by industry, to find any public resonance. It could also indicate that experts expect the public to be more concerned about risks to the environment from GM plants than to have confidence in such plants solving environmental problems.

Global issues were considered to be less important for consumer acceptance. Low values for "perspectives on global food security" and "global distribution of risk and benefits" may indicate that experts considered consumers to assess GM products from an individual or European perspective. Likewise, "opportunity for public participation in decision making" attracted low scores. Most directly this could be taken as dismissive of a deficit model, which would hypothesise consumer acceptance to correspond to the level of public participation. On the other hand, those who appreciate the role of such participation in creating acceptance also tend to be more enthusiastic about such participation in general (Question 15; see Fig. 23 in Sect. 4.7). Whether they expect this to result in higher or lower public acceptance remains, however, an open question.

In contrast, information and communication scored highly. Four in five experts considered "quality of information to citizens" to be important or very important, as did almost nine in ten for "efficient and transparent labelling and free consumer choice" (compared with two thirds for "performance of risk management systems"). Thus, they seemed to expect that consumers would focus on safety and on clear and reliable information in deciding whether to buy products, but not on active participation in decision-making.

GM plants have now been produced for more than a decade. A majority of experts seemed to expect that people could get used to GM products. Seven in ten experts (and, again, all industry experts) considered "getting accustomed to GM products" would be important or very important for consumer acceptance.

DISCUSSION

The survey results indicate that experts expect consumers to be sceptical towards GM food products, mainly for reasons of (a perceived lack of) safety for human health and the environment. Together with the finding that they consider consumer benefits to be important factors influencing acceptance, this may reflect a perception that the future of GM plants and products could mainly be a question of personal benefit and risk

balancing. This is in line with the finding in Sect. 4.2 that experts consider new GM food crops with consumer benefits to be on the market within the foreseeable future. Apparently, experts think that benefits such as food quality or health effects will foster consumer acceptance. A possible habituation effect is also expected to play a role, while price premiums are not considered to be equally important.

The emphasis on the individual consumer can also be deduced from the weight given to information and communication. This is unquestionably a necessary prerequisite for making an informed choice, both with regard to buying a product and making up one's mind on a political question. In the light of the reluctance to grant importance to the issue of participation in decision-making, many experts seem to conceive the question of acceptance as being resolved by the market – provided full information is granted to allow the consumer to make a rational decision on whether or not to buy – or by established politics.

Expectations are also high with regard to public attitudes towards GM non-food products. However, it is not quite clear how consumers will be able to make choices, for instance where biofuels produced on a GM basis are mixed with conventional fuels. Here, the aspect of the individual consumer making a personal and rational decision clearly has its limits, and the citizen balancing his own personal values is addressed. Citizens' deliberations may be equally rational, but they may also be influenced by more general considerations that do not necessarily concern individual benefits or risks alone.

In contrast to numerous TA reports, where time and again citizens have expressed the opinion that societal issues and ethical concerns should be addressed seriously, many experts seemed to be of the opinion that normative demands would become less important for future attitudes than individual benefit and risk balancing. Were our experts not aware of the societal dimension of the issue? We believe this is not the case: many of them come from countries known to harbour a critical public, such as Austria, Denmark, Germany, Norway and Switzerland, so it is more than likely that they have consciously perceived the ongoing public debate and more general societal and ethical questions.

However, recent survey results seem to indicate that consumers are not very aware of buying food that contains GM products, despite claiming to oppose the use of GM technology for food purposes (Consumerchoice 2008). This seeming discrepancy may relate to the "consumer" expressing buying preferences as opposed to the "citizen" expressing general value judgements. We interpret the opinion of the experts given above as pertaining more to consumer choice. From the point of view of industry and food retail, market acceptance might be considered to solve the problem of alleged public opposition to GM plants and food, while the political issues behind it are more related to values and might remain unaddressed.

From a TA perspective, the ethical and societal arguments frequently brought forward in participatory procedures as well as the results emerging from large surveys that indicate unease in significant parts of the population do not go away, even if some

products do find buyers. Rather, they indicate issues that may not only be related to GM plants, such as concerns about the behaviour of regulatory bodies and industry, deteriorating food culture, or increasing dependence on the interests of multi-national companies. These issues, which are related to citizens' concerns rather than those of the consumer, can probably not be comprehensively addressed in the restricted context of a debate on the risks and benefits associated with GM plants, but they also cannot be dismissed as irrelevant either.

4.4 FREEDOM OF CHOICE, COEXISTENCE AND LABELLING

BACKGROUND

For a considerable time, there has been public reluctance to buy agricultural products derived from GM plants. At the same time, the biotechnology industry has promised agricultural producers that the need for inputs will be reduced, yield increased, and environmental benefits provided. Thus, for political reasons, a compromise had to be found that would allow the introduction of such products on the market for producers and consumers without entailing any consequences for those who, for whatever reason, did not want to cultivate GM plants or buy these products. The latter should be guaranteed a continued supply of products that are GM-free, at least, for practical reasons, under a very low threshold level for unintended GM contens.

In a recommendation released in 2003, the European Commission issued guidelines for member states to ensure the coexistence of GM crop cultivation and conventional and organic farming. Since other regulations on admission to the market took care of environmental and health risk aspects and the labelling of GM products, the purpose of such provisions was merely to allow individual producers and consumers the freedom to choose whether or not to use those GM plants and products allowed onto the market. For farmers, this means that any influences from GM plants onto non-GM plants during production (such as through unintended cross-pollination and volunteering) and harvest (through contamination) must be minimised on a crop-specific basis.

In recent years, states have devised instruments to (a) require GM farmers and actors in the food chain to take practical segregation measures to minimise the chance of intermixing, and (b) make those who fail to take these measures liable for any losses incurred on others. Some states also (c) require actors to contribute to a common liability fund that compensates losses of more diffuse origin. There are thus a variety of measures in place that should guarantee freedom of choice, although some states have not yet fully implemented all required measures.

Controversies arose as to whether coexistence is feasible in practice and whether the ensuing burdens are distributed fairly. The risk of failure to maintain segregation may differ according to crop, but also according to agricultural practices or environmental conditions, and should be subject to regional variations. Some actors claim that

coexistence may only be feasible for certain crops, depending on their reproductive biology and/or for a certain scale of cultivation. Others claim that challenges relate mainly to institutional or procedural issues, for instance reaching a general agreement between farmers in a region whether or not to cultivate GM crops. Under the current EU legislation, there is no way of imposing a general decision to use or not to use GM crops in a certain area, as this should be left to individual choice. However, such provisions are up for debate.

Policies aim to maintain coexistence along the entire food chain to ensure consumers have free choice of products with or without GM. GM products must be traced and labelled in order to provide appropriate consumer guidance. However, distinguishing GM products from non-GM products for the purpose of labelling has inspired debate. For instance, there have been controversies over the amount of GM ingredients that can be tolerated in non-GM products. The threshold was set at 0.9%, provided that the ingredient in question has been through the EU risk assessment and authorisation procedure, and the admixture is unintended. In addition, some claim that labelling should not be restricted to the marketing of primary products from GM plants, but should also be mandatory for products where GMOs are used as inputs in secondary production, for example meat from animals fed on GM feed.

Finally, the relation between risk assessment, risk management and coexistence is not entirely clear. One interpretation is that these three measures supplement each other. First, it is mandatory to carry out an environmental and health risk assessment before a GM variety is admitted to the market. If any non-negligible risk can be demonstrated, the variety will not be authorised or appropriate measures will have to be taken to mitigate the risk. But even if no risk can be demonstrated, products from GM plants have to be segregated and labelled as such to allow freedom of choice. This rationale implies that while regulatory authorities would ensure that only crops that will be managed safely are admitted to the market, individuals should still be allowed to decide whether to use them or not. According to this interpretation, it would follow that the responsibility to contain risks falls strongly in the hands of regulatory authorities.

Alternatively, coexistence is not only enforced to enable freedom of choice, but also as a tool for risk management. First, coexistence measures would render it possible to trace back and contain risks that suddenly appear and which had not been anticipated during risk assessment. Secondly, there could also be cases where risk assessment concludes that a specific crop will be safe under certain conditions. Coexistence measures would then be necessary to ensure that the crop is kept under these conditions.

The latter approach would be all the more important if food crops were modified for non-food purposes. Such plants might give rise to undisputed hazards if they accidentally intermixed with food crops and entered the food chain. Some substances produced might be poisonous or at least inedible, so crops must be strictly segregated.

In addition, the possibility of the relevant genes being transferred and expressed should be kept to the absolute minimum.

Lastly, it is also reasonable to argue that safety is never absolute and that not all concerns can be catered for. Accordingly, coexistence and labelling can be seen as means to enable individuals to pursue their preferences regarding whatever risks may remain. Such risks can take on different meanings. Apart from individual health hazards, risks for the environment that would not necessarily infringe on the individual's personal interests could also be addressed, as could risks of other types (e.g. economic risks to farmers not applying GM crops) not subject to risk assessment.

To conclude, coexistence is intended to provide a way of performing different methods of agriculture in parallel and thus rendering the freedom of choice possible. However, there are indications that the feasibility of coexistence cannot be taken for granted. It remains to be seen whether GM agriculture does not preclude other forms, in particular organic farming. We therefore wanted to explore whether coexistence schemes can adequately provide freedom of choice for producers and consumers.

RESULTS FROM THE TA PROJECT REVIEWS AND FUTURE ISSUES

A number of TA projects in Austria, Denmark, Flanders, Germany, Norway Switzerland and UK explored coexistence and labelling. However, all projects explicitly dedicated to such issues were undertaken prior to the introduction of the relevant regulation. Thus, there is no ex-post assessment of the actual instruments set in place. Even if it cannot be deduced from these reports whether the instruments available adequately address the problem or not, particular points to consider emerged. The following summary is based on ten reports:

- *Austria, "GMO-free" claims and the avoidance of GMOs in feed*
- *Austria, Coexistence*
- *Denmark, Coexistence*
- *Flanders, New impulses for the debate on genetically modified food*
- *Flanders, Functional food*
- *Germany, Green Biotechnology Discourse*
- *Norway, Coexistence*
- *Switzerland, Coexistence*
- *Switzerland, Genetic Technology and Nutrition*
- *UK, GM dialogue*

In general, the reports underline the need to provide for free choice, not least in response to as yet unresolved risk claims and contradictory opinions on the potential benefits and detriments (*Denmark, Coexistence*). In some countries, coexistence seems to be considered a political solution to facilitate the introduction of GM plants (*UK, GM dialogue*). Free choice implies that correct labelling is provided and that the existence of conventional and organic farming must be guaranteed (*Denmark, Coexistence; Switzerland, Genetic Technology and Nutrition*). To this end, it is

mandatory for completely separate distribution channels to be installed (*Flanders, New impulses for the debate on genetically modified food).*

Several reports come to the conclusion that coexistence is feasible in principle, however, only under certain conditions (*Switzerland, Coexistence; Denmark, Coexistence; Austria, Coexistence*). The European rules for authorising GM plants are adequate in general, but may be leaky in some cases (*Flanders, New impulses*). Since the risk of spreading and intermixing cannot be eliminated, technical precautions must be taken and enforced. Such measures must be tailored to the crop type, the agricultural system and the geography – a point already emphasised in the European Commission's recommendations. Ultimately, it is necessary to consider the scope of cultivation of GM crops as well (*Denmark, Coexistence*). However, in many reports doubts are expressed as to whether coexistence will be possible for all crops. Even in cases where coexistence appears feasible, the necessary measures to maintain segregation between GM and non-GM plants and their products entail rather demanding crop-specific logistics along the entire production, processing and distribution chain (*Austria, Coexistence*).

The reports frequently highlight practical challenges related to establishing thresholds for unintended GM ingredients in non-GM products. Two fields are considered to be particularly problematic: contamination of organic products and of seed sold as non-GM (*Germany, Green Biotechnology Discourse; UK, GM dialogue*). In both cases, reports quote demands for threshold levels below those foreseen and close to the level of detection, which would be a considerable challenge to industry.

Since intermixing cannot be ruled out, according to many reports, systems of compensation and liability are considered imperative, and it was stressed that rules should be uniform across Europe (*Denmark, Coexistence; Norway, Coexistence; Switzerland, Coexistence; Switzerland, Genetic Technology and Nutrition*). Reports also raise questions about the considerable costs of commitments and measures to minimise the effect of segregation failure, such as extra checks and quality controls, which would raise the costs of non-GM products and would have to be borne by the GM sector (*Flanders, New impulses for the debate on genetically modified food, Austria, Coexistence*).

Some sceptical reports raise doubts as to whether coexistence as conceived by the European institutions would be feasible at all and, even if it were feasible, whether it would be worth the considerable social and economic cost entailed (*Austria, Coexistence, Norway, Coexistence*). In addition, and in the light of doubts about whether unilateral EU policies are possible at all, given the global market for seed, food and feed, any European regulatory approach might be doomed to failure (*Austria, "GMO-free"; Norway, Coexistence*).

Although the general impression from most of the reviews is that labelling is supported in principle, there are also questions over whether consumers can handle a possible information overload (*Flanders, Functional food*). In addition, different interpretations of the term "GMO-free" seem to exist in the public, and there are demands for

labelling not only primary products, but also derived, or secondary, ones such as meat from animals fed on GM crops (*Austria, "GMO-free"; Norway, Coexistence*).

Taken together, the reports seem to imply a conditional 'yes' in response to whether coexistence would be feasible, although a general consensus on this question between experts and stakeholders seems to be difficult to reach (*Germany, Discourse*). Elaborate, costly and rather far-reaching measures must be taken in order to guarantee segregation and labelling, and many there questions still remain unanswered regarding the practical implementation and the division of burdens.

PRELIMINARY CONCLUSIONS AND RESULTING QUESTIONS

The proper functioning of coexistence and labelling is a prerequisite for turning the concept of freedom of choice into reality. Despite criticism, it is still considered an appropriate answer to the concerns of both citizens and consumers, the interests of individual farmers who wish to perform very different forms of agriculture and the (often diverging) interests of trade and industry.

The question is whether coexistence is feasible and, if so, for which crop, under which conditions and at which costs. While the reports reviewed (theoretically) seem to provide a cautiously positive answer, the lack of experience so far and some incidence of contaminations that have occurred over recent years in other countries preclude a final judgement. Whether coexistence is now feasible and will be so in the future depends mainly on whether the instruments for coexistence can be shown to work for "first-generation" GM plants. In particular, it will be crucial to see whether all GM products that qualify for labelling in principle will also be so in practice. This, however, can only be assessed if the relevant products are placed on the market, which again is subject to the proper functioning of coexistence. It seems that we have a catch 22 situation regarding the answer to the question whether coexistence can function.

RESULTS OF THE SURVEY

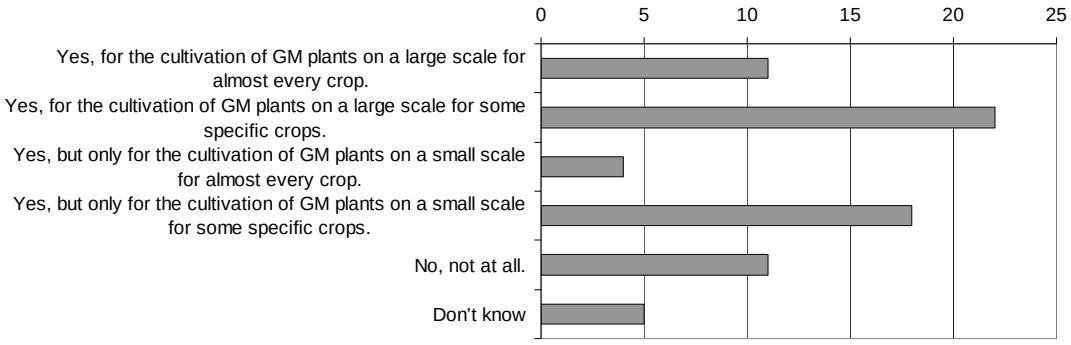
WILL COEXISTENCE WORK FOR FIRST-GENERATION GM PLANTS?

In the light of different answers given in the project reviews, we wanted to know whether experts thought that coexistence would work for "first-generation" GM plants (e.g. insect- or virus-resistant and herbicide-tolerant plants) over the next 15 years.

Overall, it emerged that opinions among the experts approached were split (Fig. 14): roughly one-third of the respondents thought that coexistence might work for some specific crops for large-scale cultivation, compared to one-quarter who considered it would work only for cultivation on a small scale. One in six expected that coexistence could work on a large scale for almost every crop, while a similar number thought it would not work at all. Experts from industry had more confidence in coexistence, with 8 out of 11 expecting that coexistence would work on a large scale.

In their comments, respondents further explained their views. A respondent who believed coexistence could work stated: "*Only for a few crop types in certain small scale farming regions will it be very difficult for GM crops to coexist.*" A more sceptical respondent referred to historical examples: "*Contamination is unavoidable, e.g. StarLink, US rice, etc. There are too many places where contamination could take place, so it is impossible to separate.*" Somewhere in between, another respondent argued crop-specifically: "*In my opinion coexistence might be possible for non-food potatoes but not for canola or sugar beet.*" A respondent who ticked the "Don't know" option enlarged the view from the purely technical to the organisational level: "*I'm sure that technically efficient measures can be devised for some crops in some places (and not for others). However, I'm less confident the industry is ready for such a clear commitment to the polluter pays principle*."

FIGURE 14: WILL COEXISTENCE WORK FOR FIRST-GENERATION GM PLANTS?
(*Question 7; n = 71)*



Question: Coexistence measures are a central part of risk management under GM-cultivation. Coexistence is also a central prerequisite for freedom of choice. Coexistence may be a challenge, depending on type of crop and location. Do you think that coexistence will work for the "first-generation" of GM plants (e.g. insect-resistant, herbicide-resistant and virus-resistant (VR) plants) in the next 15 years? (Please tick one possibility).

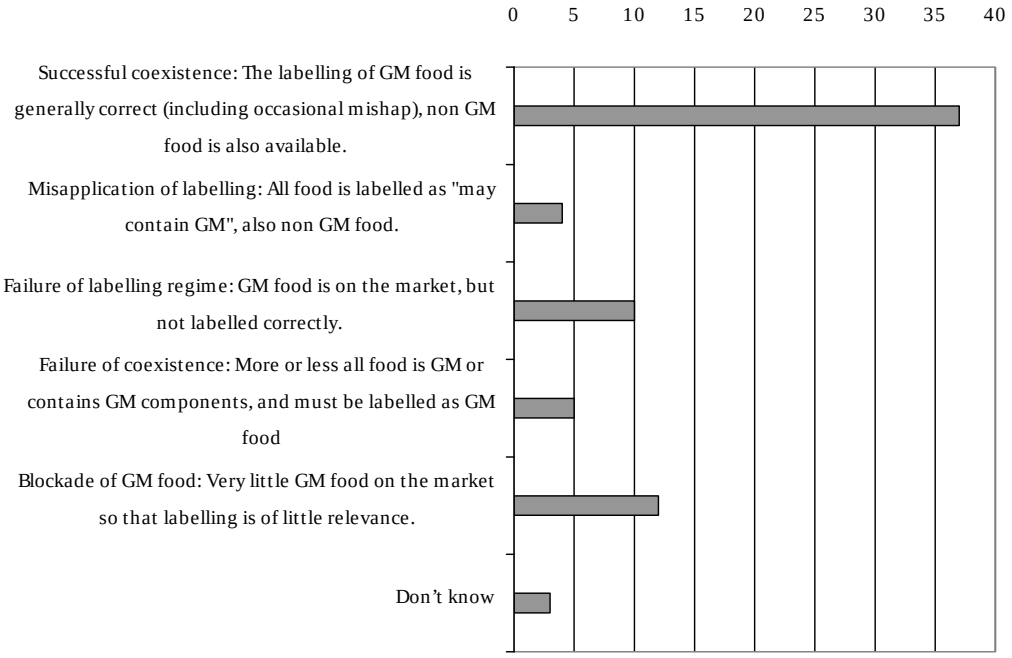
In conclusion, responses to this question indicated that the issue of coexistence has not been settled and a consensus has not yet been achieved.

CAN CONSUMER CHOICE BE MAINTAINED?

Question 9 (Fig. 15) was reciprocal as it covered a similar issue, this time viewed not from the producers' but from the consumer perspective. Referring to the close connection between coexistence and labelling, we asked the experts for their opinion on which of five different scenarios they expected to come true regarding the possibility of maintaining consumer choice. Notably, the majority of respondents believed that coexistence and labelling would work generally (Fig. 15). The second largest group of respondents, however, considered that GM food would only play a

marginal role in the future. The other alternatives offered were attracted fewer responses. Thus, respondents did not believe that European consumers are about to experience a lack of GM-free alternatives.

FIGURE 15: CAN CONSUMER CHOICE BE MAINTAINED? (*Question 9; n = 71)*



Question: Coexistence and labelling of GM food are closely connected. There are different opinions over how well the current EU regulations would cope with the extended use and growing of GM plants in Europe. Please indicate which scenario in your opinion is most likely. (Please tick one scenario)

To further analyse how respondents saw the relationship between coexistence and labelling we compared responses to Question 9 and Question 7. It was evident, for instance, that those who supported the scenario of successful coexistence/correct labelling in Question 9 had diverse perspectives on the feasible scale of GM-cultivation in Question 7. And vice versa: a high proportion of those who did not show any confidence in coexistence in Question 7 thought that GM food would generally be blocked from the market in Question 9.

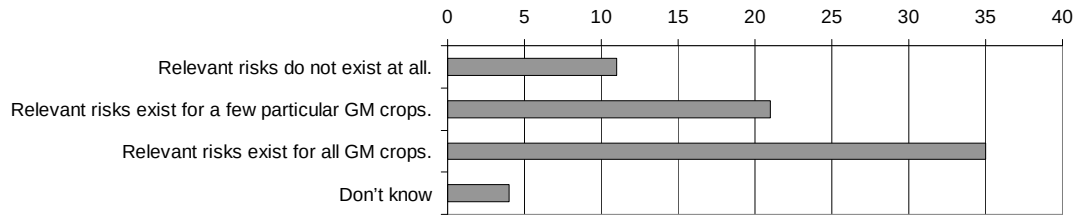
A respondent who ticked the "successful coexistence" option commented: "(….) *it is highly questionable whether non-GM food will be available in the future. Of highest importance is the question of seed and threshold levels for non-GM seed.*" Another expert stated that "*the reality is a blockade of GM food on the market, but one could have successful coexistence allowing up to 0.9% of approved GMs in products* (….)." In addition, one respondent questioned the wisdom of leaving everything to consumer choice alone: "*Labelling is important in relation to human health concerns but hardly addresses the environmental risks.*"

DO COEXISTENCE SCHEMES ADDRESS RISKS?

The latter remark brings us back to the discussion from the Introduction of whether coexistence and labelling merely provides for freedom of choice, or also is part of risk management. From this discussion we can deduce a controversy over whether current risk assessment, as a basis for coexistence schemes, will be able to contain all relevant risks. If not, risks not covered could possibly be passed on to third parties, which is considered problematic. In Question 8, therefore, respondents were asked to provide their views on whether there could be relevant environmental or economic risks that would not be contained by current risk assessment and coexistence schemes.

The majority of respondents believed that risks might occur that would not be contained by current risk assessment and coexistence schemes, while only one in six believed that such risks do not exist at all (Fig. 16). Almost half of the respondents thought that such risks might occur for all GM crops. To further explore the judgements of the sub-sample who believed risks remain, we asked how serious they considered such risks to be and whether they found it feasible to come to a fair distribution of risks and burdens. The question allowed multiple responses.

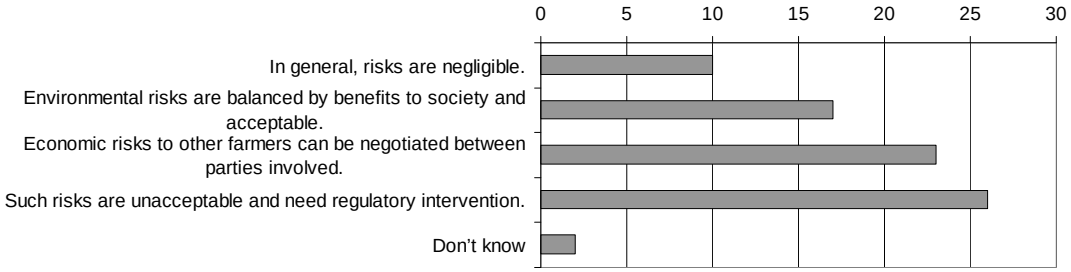
FIGURE 16: DO COEXISTENCE SCHEMES ADDRESS RISKS? (*Question 8A; n = 71)*



Question: For the cultivation of GM crops some experts have discussed whether there could be relevant environmental or economic risks (e.g. to farmers not applying GM crops) that would not be contained by current risk assessment and coexistence schemes. Please tick the statement that comes closest to your opinion.

Only one in eight responded that remaining risks are negligible, and, taken together with those who believe they do not exist at all (mentioned above), these two groups make up an total of 20 respondents (Fig. 17). At the opposite end of the spectrum, one in three (26) found the remaining risks to be unacceptable and to require regulatory intervention. The remaining respondents, approximately one in four, can be interpreted to judge that risks remain that should not be ignored but could be handled by current regulation.

FIGURE 17: HOW TO MEET RISKS? (*Question 8B; n = 56)*

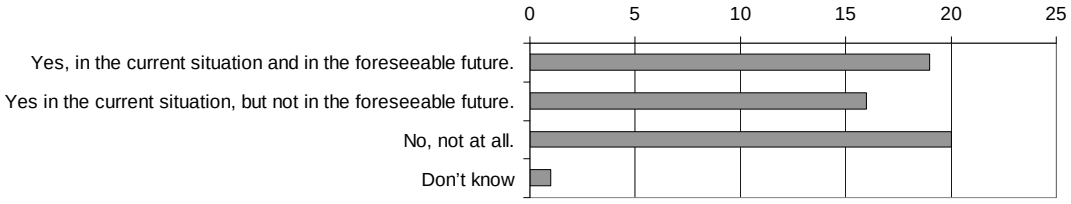


Question: If you think that relevant risks might exist [*in question 8A*], please tick those statements that come closest to your opinion (multiple answers possible).

The strong call for regulatory intervention contrasts with the rather lower rejection of coexistence and labelling discussed in previous sections. One explanation may be that saying "coexistence will not work at all", as in the previous section, is a more categorical rejection than saying "there are risks that would not be contained by current coexistence schemes, and such risks are unacceptable and need regulatory intervention", which permits solutions other than rejection.

Against this background, the next question explored whether the same sub-sample of 56 respondents deemed current regulations sufficient. One in three (of the sub-sample) agreed, while more than one in three found them entirely insufficient (Fig. 18). Somewhat smaller was the number of those who considered them adequate today but expected problems in the future.

FIGURE 18: ARE REGULATORY PROVISIONS SUFFICIENT? (*Question 8C; n = 56)*



Question: Do you think that current regulatory provisions are sufficient to deal with such risks [*see question 8B*], today or for the foreseeable future?

The 36 respondents who found current regulations insufficient, now or in the future, were further asked how these risks should be addressed. Rather than new regulation, stronger liability and new approaches to risk assessment were the most frequently mentioned remedies.

DISCUSSION

Can coexistence be considered a viable concept, and will it work? Without coexistence, no sensible labelling would be possible, and the freedom of choice could not be realised. Indications towards an answer in one or the other direction have been inconclusive so far.

Many experts believed that GM food will be labelled correctly and that non-GM food will continue to be available, indicating confidence in current systems of traceability and labelling. According to Question 7 (Fig. 14), most respondents in our expert survey expected coexistence to work in general, which is in accordance with the majority of the TA reports reviewed.

However, at the same time, both the reports and the expert survey indicated that coexistence might be rather intricate and dependent on many conditions. We can take this as a reason why a number of our respondents have no confidence in current coexistence schemes. Apart from those who bluntly reject the overall approach to coexistence for one reason or another, some respondents believe that coexistence could work for crops with a certain reproductive biology only and/or provided that certain precautions are taken, including a consideration of the scale of cultivation.

In conclusion, coexistence may be considered a viable concept, but one that would be difficult to realise for all crops and perhaps impossible under certain circumstances (INRA 2008). Agronomic research results show that it may depend on the individual case, the crop, the plant variety, the location and the agricultural context (neighbouring crops, field size, etc.) whether coexistence is deemed to work or not. Therefore, it is not surprising that answers to the initial questions are found to be contradictory.

Some light may be shed on the reasons behind this discrepancy by considering risk aspects, even if coexistence was intended as a means to escape from, or to circumvent, contentious risk debates. Despite widespread expectations that coexistence as such may be implemented, almost half the respondents expected current schemes for risk assessment as a prerequisite for coexistence to be insufficient to contain all relevant risks. Some may have thought the assessment might not be able to cover risks adequately, or they might have considered particular topics relevant that are not subject to risk assessment. In other words, under the auspices of coexistence the debate on risk has not come to a halt.

If current provisions are not considered to be sufficient, this points to the need to recalibrate approaches to assessing, authorising and/or managing GM crops. Some respondents put their hopes in a compensation system, which directs attention to the fair distribution of the benefits from cultivating GM crops and the burdens from unintended consequences. Therefore, a discussion of benefits and the aims of agriculture appears necessary.

BENEFIT ASSESSMENT AND AIMS IN AGRICULTURE 4.5

BACKGROUND

Ever since the need for assessing possible risks of GM plants became topical, criteria have been a point of discussion. Various reports have thrown up the question of whether today's assessment criteria are adequate. A particular point where opinions diverge is whether benefit should be taken into consideration, and if so, what "benefit" means.

The European regulation of GM plants only foresees an assessment of environmental and health risks. Nevertheless, the Norwegian regulatory approach also includes an obligation to consider "benefits to society". In the German law which aims to promote genetic engineering, benefits are at least indirectly included in the regulation. In this latter case, however, only risks to human health and the environment are currently considered in practice, while societal or moral concerns are considered impossible to assess objectively. Similarly, The Austrian law governing genetic engineering stipulated in its original form that genetic engineering applications should not be socially unsustainable, but this could not be translated into regulatory criteria.

Over recent years, and separate from debates on risk, a public debate has developed on the benefits of GM plants and food. Here different arguments have been introduced. On the one hand, it was argued that the first generation of GM plants provided benefits to farmers only (if at all), and that they carried no benefits for consumers. Accordingly, if uncertainties in risk assessment remained, they were considered unacceptable. This highlighted the question of the degree of risk that might be acceptable or conversely, what degree of risk could constitute a veto.

On the other hand, it was expected that a new generation of GM plants would bring benefits for consumers, such as increased nutritional properties, which should be weighed against potential risks. GM plants might also replace conventional plants and processes that were also not risk-free, or they might reduce other risks. Thus, at least in public debate, there is a discussion that benefits might possibly outweigh certain risks.

For policy-making, the problem is how to respond to demands for considering benefit or the lack of it in dealing with the issue of GM plants. One option would be to consider benefit at a political level, without formally integrating its assessment into the case-to-case authorisation procedures. This would imply general policies such as the decision to promote those GM applications that carry a consensus that they would bring societal benefit, or to promote alternative pathways if not. Currently, opinions seem to be deeply split on this issue.

Another possibility would be to explicitly devise a case-based assessment in the authorisation procedures for products, but there are few precedents for such an approach. So far, the most prominent example is with the authorisation of drugs, where such an approach follows acknowledged criteria for efficacy and lack of side effects and further involves a comparison with established drugs.

For transgenic crops, both the criteria and the comparator are contested. So far, the normative framework for regulating novel agricultural varieties is derived from the sum of current aims of the established practice in agriculture. This framework is in principle applied to GM plants as well; in other words, they must (at least) meet the same criteria as "conventional" non-GM plants cultivated in today's agriculture. However, even these conventional aims of agriculture are under discussion and continue to shift, as can easily be deduced from the debates surrounding the formulation of the European Common Agricultural Policy. New developments such as the quest for sustainable agriculture might interfere with more traditional aims such as high productivity.

In addition, tasks other than producing food have been assigned to the agricultural system, such as landscape protection or providing a basis for tourism, leading to increased importance for the concept of multi-functional agriculture. Such multiple tasks might also have an influence on how the risks or benefits of growing particular GM plants might be assessed in the future. Such very basic considerations have influenced the debate on GM, conventional and organic agriculture, and tap into a variety of issues in different countries. Therefore, specific domestic aspects cannot be discounted when the options for including benefit in the assessment criteria for GM plants are discussed.

RESULTS FROM THE TA PROJECT REVIEWS

Several reports from EPTA members came up with the issue of benefit assessment in various contexts. This summary is based on the following reports:

- *Denmark, GM crops in developing countries*
- *Flanders, Functional Food*
- *Germany, Green Biotechnology Discourse*
- *Germany, Risk assessment and post-marketing monitoring*
- *Norway, Sustainability and societal impact of GM food*
- *Switzerland, Future of plant biotechnology*

Three main questions come to mind that would be necessary to address: firstly, the kind of benefits discussed; secondly, the way such benefit could be assessed, and thirdly, the way the result of such assessments could be taken into account.

With regard to the kind of benefits, several potential ones have been assigned to GM plants. For example, certain GM crops are said to assist in ensuring sustainable agricultural production and food supply particularly in Third World countries (*Denmark, GM crops in developing countries).* On the domestic front, consumer benefits might arise from GM foods in the form of improved food products which lead to healthier nutrition (*Germany, Green Biotechnology Discourse).* There might even be scientific evidence of health benefits from GM functional food products to be taken into account. However, proving them might be difficult (*Flanders, Functional Food*), and a consensus over whether and what kind of a benefit could be expected seemed

difficult to establish (*Germany, Green Biotechnology Discourse*). An interesting perspective comes from a Swiss lay panel that established a link between benefits and a particular understanding of risk: accordingly, if the potential benefits from GM plants are not be realised in the future because research on them does not take place today, this might be considered a risk (*Switzerland, Future of plant biotechnology)*.

Various views were expressed on how to assess benefit. Here, the ruling normative framework determines the choice of criteria. However, few reports explicitly highlight the normative dimension arising from the multi-tasking nature of agriculture. The issue came up when a normative framework for desirable agricultural practice or sustainable agriculture was considered to be missing (*Germany, Risk assessment and post-marketing monitoring)*. The most elaborate investigation came from Norway, the country with most experience in discussing benefit criteria. It came to the conclusion that any kind of pragmatic benefit assessment would have to rely on checklists to be amended case-specifically according to the properties of the product and the contingencies of its production and use. Where the necessary information for such an assessment could be derived from, however, remained unclear (*Norway, Sustainability and societal impact of GM food)*. Benefits might also be assessed indirectly through comparative risk analysis: risks related to a new technology such as GMOs could be compared to the risks of the technology it is replacing, which might be considered a benefit (*Switzerland, Future of plant biotechnology).*

Thirdly, where a benefit can be established, how should this be taken into account in regulatory decision-making? Norway is the only country so far where benefit assessments have been officially integrated in the authorisation procedure for GM plants. Here, an assessment of societal benefit as well as of the contribution to sustainability is mandatory even for experimental releases; however, its implementation has not yet been fully accomplished (*Norway, Sustainability and societal impact of GM food)*. One question was whether benefits should be considered as an additional requirement or a factor that might soften up the requirement for the absence of risks for health and the environment.

Implicitly, and irrespective of whether benefits can be demonstrated in an assessment or not, the Swiss lay panel emphasised that the relation between scientifically established risk and societal preferences must already be balanced today. Since a zero risk level cannot be achieved, an acceptable level of risk had to be determined (*Switzerland, Future of plant biotechnology)*.

PRELIMINARY CONCLUSIONS AND RESULTING QUESTIONS

While the idea of taking benefits into account is attractive to many, the implementation of a workable system of assessment, the establishment of relevant criteria and of an acceptable way of incorporating the findings from such an assessment into regulatory decision making remain to be solved. In other words, the practical dimensions of benefit assessment must be determined. It is therefore unclear whether such

assessments will ever become reality. What are the criteria, if indeed there are any, against which benefit might feasibly be measured?

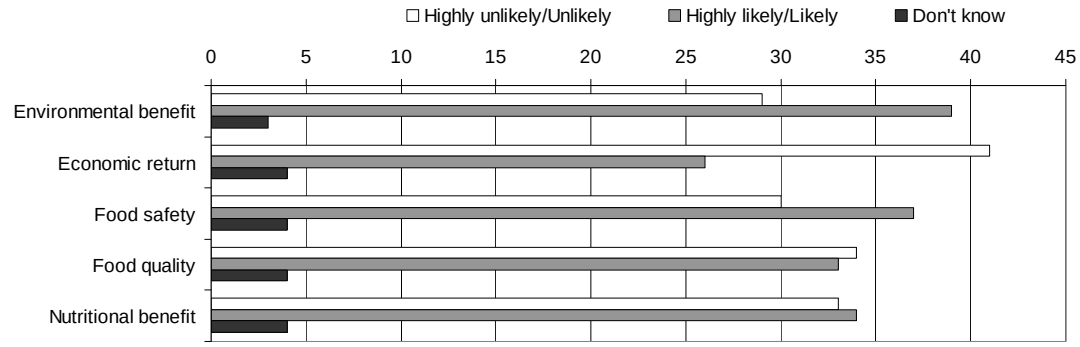
Closely linked to the question of whether and how to assess benefits is the question of aims in agriculture. A benefit can only be measured according to a particular aim, and what might constitute a benefit for one aim might be detrimental to another competing aim. Which aims will gain in importance in the future?

RESULTS OF THE QUESTIONNAIRE

BENEFIT ASSESSMENT

Different forms of assessment can be envisaged that take into account parameters other than environmental and health risks. We, therefore, wanted to know whether experts could consider criteria other than risk (in conventional terms), in particular whether it was considered acceptable and feasible to include benefits in the assessment of GM plants, as is the case with pharmaceuticals.

FIGURE 19: BENEFIT ASSESSMENT (*Question 11; n = 71)*



Question: So far, the assessment procedures for GM plants and food only takes into account potential risks. Some actors have advocated that also potential benefits should be taken into consideration as applied in areas such as pharmaceuticals. Below is a list of potential benefits that could be included in such considerations. Please assess how likely it is that in future different benefits will be considered for GM approvals. Please feel free to add other groups not listed.

The responses showed that experts were split over the likelihood that benefits would be considered for GM approvals (Fig. 19). A majority of respondents thought it likely that environmental benefits would be taken into such consideration, while the opposite is true for pending economic return. The experts were divided on the likelihood of taking food quality and nutritional benefits into consideration, while a slight majority considered food safety a probable field where benefits could be taken into account in the future.

Despite the substantial proportion of those who considered the consideration of benefits likely or very likely, many comments emphasised the regulatory difficulties

involved in such a step. One respondent expressed that "*there are a number of serious difficulties in the inclusion of extensive benefit analysis. However, it is something that clearly could be considered*." Another questioned whether licensing is the right place to include a benefit assessment: *"Regulators only take care of risks. The Market takes care of the benefits and the risks."* Obviously, for this expert benefits could only be conceived on a personal level amenable to market forces.

Benefits were clearly considered subject to interests and values, in contrast to health risks that were deemed unacceptable to everybody. A number of respondents highlighted that drug assessments were the only example in product regulation where benefits would be taken into consideration, and contrasts were drawn: "*In the health sector people are willing to take a risk if there is enough benefit. In GM crops people will not be willing to take any risk"* and: "*taking pharmaceuticals, we consider that we may have to take risks. Eating food is something different."* Medical benefits usually were seen as weighing heavier than possible side effects if people were to regain their health – but food consumption as an important part of everyday life was considered different, and risks deemed unacceptable.

Some comments addressed the issue of comparisons between conventional and GM crops. They proposed attributing a benefit to conventional crops compared with their GM counterparts due to the absence of uncertainty associated with the technology, all other parameters being equal. Support for such systematic and a priori suspicion of risk with GM crops, however, was only encountered sporadically among the comments. In addition, public perception remained a controversial problem. Although "*these initiatives may substantially improve public perception, and so potentially pave the way for profitable GM crop production"*, another expert stated that *"…in the current public perception setting, I don't believe that positive considerations would be taken into account."*

AIMS IN AGRICULTURE

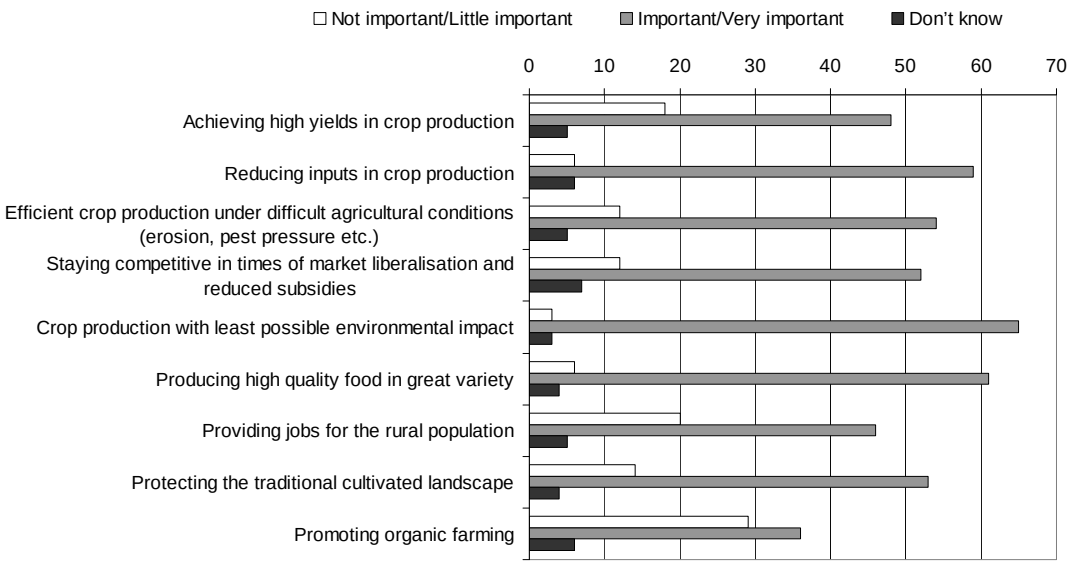
In order to determine whether a GM crop conveyed a benefit, it would be necessary to know which aims are assigned to agriculture at large. For comparative risk assessment, too, aims are important because comparisons must be drawn with established practices in agriculture. In Europe, these practices vary according to climate or soil, but also according to the tasks assigned to agriculture. For example, in addition to efficiently producing crops or providing jobs, agriculture is called to protect the traditional landscape and the natural environment. Thus, agriculture must pursue different aims, against which the performance of GM cultivation could be measured.

In the light of a certain lack of coverage in the reviews, we wanted to know which tasks of agriculture respondents considered likely to become salient in the foreseeable future. We presented a list of tasks and asked the experts to rank them.

In total, the majority of experts agreed that the aims for future agriculture proposed in the questionnaire would become salient (Fig. 20). For most aims, those who ranked the aim to become important outnumbered the others by at least two to one. The only

exception pertained to the promotion of organic farming, whose salience was doubted by two in five experts. This probably reflected the controversial nature of the debates on organic farming among proponents and opponents.

FIGURE 20: AIMS IN AGRICULTURE (*Question 12; n = 71)*



Question: In order to assess risks and benefits of GM cultivation, it must be compared to established practices in agriculture. In Europe, these practices vary according to climate or soil, but also to the tasks assigned to agriculture. For example, and apart from efficiently producing crops or providing jobs, agriculture should also protect the traditional landscape and the natural environment, among others. Thus, agriculture must pursue different aims, against which the performance of GM cultivation will be measured. Please rank the aims in the list below in their importance over the next 10 to 15 years.

The most unanimous vote was seen for crop production with the least possible environmental impact, which more than nine in ten expected to become important. Only slightly less popular with the experts was the production of high-quality food in great variety and reducing inputs in crop production. This again could be seen as relating to minimising environmental impact. Following this argumentation, there seemed to be a consensus among the experts that the general aim of sustainable agriculture would likely be a guiding principle in the future.

However, caution must be applied in interpreting the results since they may reflect different conceptions of the underlying basic terms. For example, environmental impact has always been difficult to define, and the future conditions of agriculture (such as pest infliction or drought) are difficult to foresee.

DISCUSSION

Experts were split over the likelihood that assessing benefits would be part of future assessment procedures, but a substantial proportion think it likely. Considering the doubts expressed in some comments, the question arises as to why there is such a support. One reason simply might have been the wording in the questionnaire, where the word “consider” rather than “assess” was used. This might have allowed an interpretation that topics were to be considered on a general level and not in the case-by-case assessment and approval procedure.

On the other hand, environmental benefits turned out to be considered more likely to be implemented than economic criteria, which might reflect a general emphasis on the aim of state action in sustaining the public good rather than safeguarding individual benefit. It might also indicate the implicit aim on the part of some experts to pass over problems of acceptance in a situation where the benefits of GM plants, in the opinion of some, might not be sufficiently appreciated.

This raises the question of who could be considered to benefit from the introduction of benefit assessments in some form. It could work in different directions; some may argue that if a GM crop does not bring additional benefits, this should veto the crop entirely. On the other hand, GM advocates would hope that the consideration of environmental benefits would strengthen their case.

The main question remains as to the level, if there is one, at which such state action should be implemented in order to make it both practically sound and politically legitimate. Should it be at a political level, with open commitments for particular forms of agriculture such as promotion of high productivity, large-scale production or of small-scale, diversified and/or organic farming where possible and desired? Or should it be at a regulatory level where formal procedures are incorporated? As comments suggested, the latter seems to be hampered by some rather basic problems. From a practical point of view, there are almost no examples of benefit assessment in product authorisation procedures to draw upon, apart from medical substances and devices. For the latter, societal benefits have always been linked to health gains, which can be established by scientific means.

From the perspective of political legitimacy, societal benefit is difficult to determine because of a lack of generally accepted criteria. Usually, marketable products are considered to deliver personal benefits in the first place, and the market is considered to be effective in determining such personal benefit and providing the appropriate signals to producers. In contrast, societal benefit, if accepted to be different from the sum of individual benefits, is a much less obvious concept. If it is considered at all, it is often deemed subject to political preferences rather than market forces, and generally accepted methods to determine such benefit are difficult to establish. It remains to be seen whether a suitable regime can be found that will live up to the expectations entertained by some with regard to benefit assessment.

The normative framework at the basis of any benefit assessment depends on the acknowledged aims in agriculture. From the survey, it appeared that reducing the input and impact on the environment while sustaining food quality and variety were expected to become salient in the future. Such a result is not very surprising, as the aims mentioned can be considered part of the sustainability propagated as the overall frame for future European agriculture (and in other world regions). Nevertheless, the clear result is noteworthy; reducing input and environmental impact while sustaining high quality is obviously considered almost indisputable among the participating experts. By contrast, the promotion of organic farming has attracted more doubts. It seems to be too controversial an approach for a future paradigm for agriculture. This suggests that conventional farming will remain a central starting point for a more sustainable agriculture.

Nevertheless, it remains a matter of a broader debate whether the aims experts regarded as likely to be dominant in the future would become so in reality. There are many competing aims, including those directed towards mostly economic parameters, which may become more dominant in the future. If GM plants are to find a place in European agriculture, they will have to fit into the aims pursued by a future agricultural system. Thus, their future is dependent on the developments of this system rather than on particular pieces of legislation alone.

GLOBAL ASPECTS OF GM REGULATION 4.6

BACKGROUND

The trade in agricultural (and food) products has increased substantially over the last 20 years with the expansion in trade by leading export and import countries and with new countries participating in the globalisation of markets. In the current round of multi-lateral trade negotiations in the WTO, the so-called Doha Development Agenda (DDA), major objectives include the further opening of the market and the relationship between WTO rules and multi-lateral environmental agreements. Discord on agricultural issues was one of the main reasons why DDA negotiations have not yet been successfully concluded.

The practice of GM regulation in the EU was previously already challenged before the WTO. In 2003, the United States, Canada and Argentina complained about the delay in approving and marketing new GM crops (the so-called de facto moratorium) in the EU, which was considered to go against WTO rules. The WTO dispute settlement panel came to the conclusion that the EU had violated the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) (WTO 2006) by

- An alleged general EU moratorium of approving GM products for commercialisation,
- Product-specific SPS measures,
- EU Member State safeguard measures against GM products.

The EU defended its regulatory regime with reference to its Cartagena Protocol on Biosafety commitment, which takes a precautionary approach to regulating GMOs. The WTO dispute settlement panel rejected the precautionary defence of the EU and ruled that the Cartagena Protocol is not relevant if disputants are not party to the agreement. In this way, the panel accentuated the schism between the WTO and the United Nations system. However, there could have been an alternative: The panel could have declined to rule, given the lack of consensus on risk assessment and risk management options in multi-lateral agreements (Suppan 2006). This means that at certain times different systems of international agreements can come to different conclusions regarding risk regulation. There is reason to believe that conflicts between differing agreements and approaches on trade and risk regulation will be with us for some time.

Substantially, the WTO ruling could be seen as indicating that only those restrictions that are rooted in the demonstration, if not proof, of particular risks would be acceptable within international trade regulations. This highlighted not only the different approaches taken by the US and its allies, on the one hand, and the EU, on the other: It also became obvious that among EU member states, the implementation practice differed to some extent, despite a common regulatory framework, so that some Member State’s practices came into conflict with WTO rules.

RESULTS FROM THE TA PROJECT REVIEWS AND FUTURE ISSUES

The solution to such controversies remains open. Although this could turn out to be an important topic for future regulation of GM plants in Europe, most TA reports over recent years have only addressed international issues in passing. The reports reviewed also concentrated on the debates and regulation in their own countries of origin and in the EU. A small number of reports assessed the risks and opportunities for GM crop use in developing countries. In all cases, the global aspects of GM regulation were not the main focus. Nonetheless, a number of reports did address the global increase of GM crop acreage, the question of international trade conflicts, the development of international GM regulations and the different approaches to risk assessment and regulation in some way. The following points are based on information from six reports

- *Austria, The Role of Precaution in GMO policy*
- *Germany, Green Biotechnology Discourse*
- *Norway, Reconvening the lay people's panel on GM food 4 years after*
- *Norway, Sustainability and societal impacts of GM food*
- *Switzerland, Genetic Technology and Nutrition*
- *UK, GM dialogue*

In the first place, regulatory challenges were identified in the context of international dependencies and international harmonisation. One of the challenges identified was how the EU would respond to the WTO dispute panel's findings on the implementation of GM crop regulations in the EU (*UK, GM dialogue).*

Furthermore, there was a demand for laws and regulations to be co-ordinated at the international level *(Norway, Sustainability and societal impact of GM food*). Two countries within Europe that are not EU member states, Switzerland and Norway, maintain a close relationship, but retain regulatory approaches to GM plants that differ in some respects from those in the EU. Proceeding from the specific regulations in Norway and Switzerland, reports from these countries identified challenges for their unilateral policies:

- As an open question, it was discussed to what degree a unilateral Swiss policy is possible, and to what extent there is a need to use of GMOs in Switzerland *(Switzerland, Genetic Technology and Nutrition).*
- The criteria of sustainability and societal benefit in the Norwegian legislation appear to be unique and raise questions of access to relevant information about the products and the willingness of applicants to provide such data just for Norway. In consequence, Norway cannot fully undertake the relevant assessments, and due to this lack of documentation, Norwegian authorities may end up not authorising any given product. However, the EU might not consider such terms legitimate for rejecting an authorisation, which might be necessary under Norway's commitment as member of the EEA. Thus, a number of questions regarding the harmonisation of regulation within the EU/EEA remain. *(Norway, Sustainability and societal impact of GM food).*

Another considerable challenge identified is to find ways to proceed from the precautionary principle to an applicable approach and concrete actions, and to define its relation to the risk assessment framework. The precautionary principle should not be used as a technical barrier to trade or a tool for protectionism (*Austria, The Role of Precaution in GMO policy*). The further definition and operationalisation of the precautionary principle was specified as a task in various reviews (*Austria, The Role of Precaution in GMO policy; Germany, Green Biotechnology Discourse).*

One argument taken up by several reports was that the "sound science" approach (as prevalent in US policies), with its tendency to delay safety obligations until the causal chain between a harmful impact and its source has been fully established, runs counter to the precautionary principle. This underlies several pending or already manifest conflicts between the US and EU (as materialised in the WTO dispute). The EU could possibly build on a "de facto coalition" with developing countries in favour of the precautionary principle in order to strengthen its position and promote its understanding of precaution (*Austria, The Role of Precaution in GMO policy).*

In summary, conflicts involving WTO regulations in the context of applying the precautionary principle and/or sustaining unilateral safeguard measures were identified as important future challenges for current European regulation.

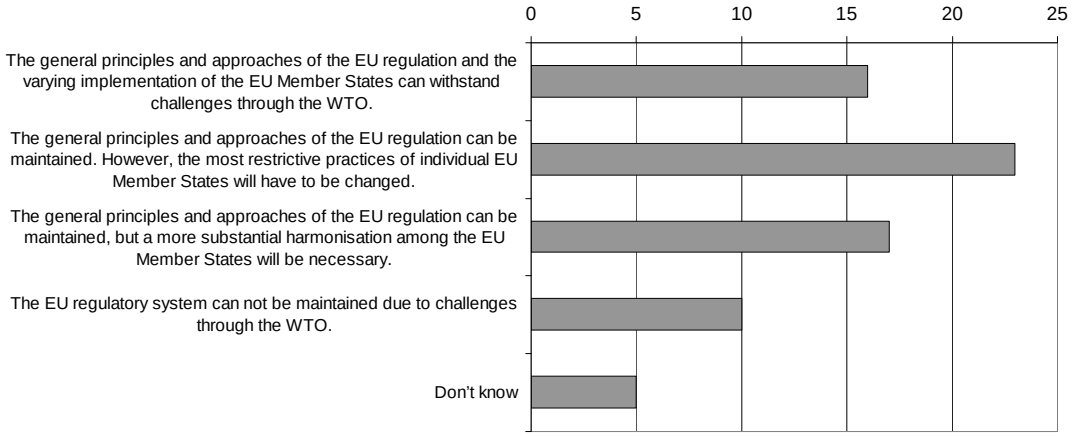
PRELIMINARY CONCLUSIONS AND RESULTING QUESTIONS

It is probable that in the future, more types of GM crops will be released, both in exporting countries and in Europe. Therefore, there is a possibility that, in the future, the US and other countries might continue to challenge the current EU regulation which is based on the precautionary principle and the case-by-case risk assessment and authorisation that is so far mandatory. To explore the judgments of the experts, two questions on global aspects of GM regulation were included in the questionnaire. One question pertained to the consequences *for* the EU regulation and the other to the consequences *of* the EU regulation, in other words, on its future robustness and on its future influence on non-European countries.

RESULTS OF THE EXPERT SURVEY

In the light of the increasing global use of GM crops and WTO conflicts, and with regard to the consequences for EU regulation, the experts saw a good chance that the EU regulatory system for GM crops and foods might survive (Fig. 21). Only a minority (one out of seven respondents) thought that the EU regulatory system could not be maintained due to future WTO challenges, etc. Nearly four in five were convinced that at least the general principles and approaches of the EU regulation could be maintained.

FIGURE 21: ROBUSTNESS OF THE EU REGULATORY SYSTEM (*Question 13A; n = 71)*



Question: It is probable that more types of GM crops will be released both in export countries and in Europe. The current EU regulation, based on the precautionary principle and case-by-case risk assessment and authorisation, might be challenged by the US and other countries also in the future. Please give your judgement on how robust the EU regulatory system will turn out to be to challenges for example at the WTO in the next 10 to 15 years. (Please tick one possibility)

This question also addressed the topic of varying implementation of the EU regulation in the EU Member States and what this means in the context of WTO challenges (Fig. 21). One in four respondents assumed that the varying implementation by the EU Member States could withstand challenges from the WTO, while more than half of the experts (40 respondents) expected that restrictive practices of individual EU Member States would be challenged. Of the latter, 23 respondents (or one-third of all respondents) found that the most restrictive practices of individual EU Member States would have to be changed, while 17 answered that more substantial harmonisation among the EU Member States would be necessary. Together, this can be interpreted as an indication that some amendments on national level and/or more harmonisation on the EU level could move onto the political agenda over the coming years.

The written comments give some insight into the assumption underlying these assessments. The compatibility of the general principles and approaches of the EU regulation with international regulations and the political standing of the EU are not the only reasons for the expected robustness of the EU regulatory systems. At least in some cases, changes to the GM regulation systems in other countries, a change (or the need for a change) in WTO rules and/or a decreasing influence of the WTO were assumed, as highlighted by the following comments:

> *"The need to develop a regulatory frame which is addressing the regulatory needs of the public is not only a European topic. It may even be that the US will change its risk regulation frame."*

"The influence of the WTO will probably decrease in the future. The political system is moving to a multi-polar world with neoliberal globalisation losing influence."

"Better change the WTO regulations to take into account the demand of citizens thus democratise decision making also in the context of WTO."

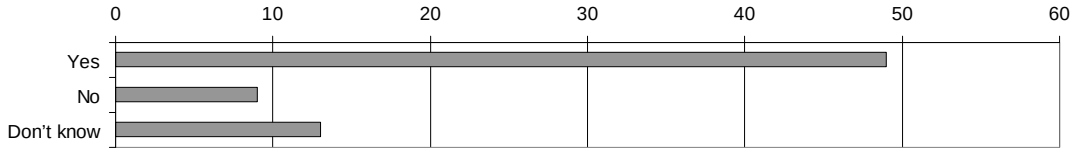
However, some respondents considered the restrictive practices of some EU member states as "politically" driven (and thus discrediting the system), in contrast to sound science:

"While the EU regulations with their basis on scientific appraisal are well accepted in many countries, the de-facto blockade by the Member States discredits the EU process."]

The differing emphasis in these comments highlights the fact that considerable uncertainties are seen in the future development of multi-lateral agreements and global governance as well as in the EU's role here, and not only in the GM regulation proper.

With regard to the question on the consequences of EU regulation (Fig. 22), nearly seven in ten experts believe that it will continue to be influential on a global scale. This is in line with the assessment of the EU regulation to be generally robust.

FIGURE 22: THE FUTURE ROLE OF THE EU LEGISLATION (*Question 13B; n = 71)*



Question: The EU legalisation has been a model for regulations in some other countries. Will the EU regulation continue to be influential in the future? (Please tick one possibility)

The EU labelling regime is thought to be particularly influential:

"Food labelling in particular is emerging as a regulatory field where governance beyond Europe moves towards EU principles and standards (not traceability, which is too expensive to implement elsewhere)"

"The EU model will remain very influential, especially through its labelling regime. This regime has an impact all over the world, for products that will be imported into the EU."

The opinion that the EU's GM regulation will influence those of other countries does not in itself indicate whether this is regarded as a positive or negative feature. But that can be illustrated by the following comment: *"I can only add: Unfortunately!"*

DISCUSSION

Will the EU be able to uphold the principles of its regulatory approach, in particular the precautionary principle? And can individual countries, even as Member States of the EU, proceed with their own interpretation of the EU regulation through an "adapted" implementation of EU rules?

Challenges clearly arise from conflicts inside the EU that are based on different implementations and policies in various Member States, who have repeatedly been shown to exploit their remit within allowed tolerance of the EU regulatory or even outside it. Therefore, the EU regulatory approach is not as consistent internally as it may appear from the outside. Experience so far could suggest that this will not be easily overcome; however, a majority of experts considered a challenge to be probable and many thought that action would ensue. The survey shows that an amendment of the most restrictive practices by individual EU Member States and/or more substantial harmonisation of the implementation of EU regulation could come onto the political agenda.

While countries such as Norway and Switzerland are not full members of the EU, large portions of the relevant EU regulation nevertheless have a strong influence. Either it is mandatory, through the EEA (Norway), or de facto hard to circumvent, due to bilateral agreements and strong trade relations. Experiments in these countries are, therefore, interesting to follow up. So far, their special regulatory approach has survived for quite some time, despite the obvious discrepancies. Perhaps this is a way of flexibly adapting the GM regulation to national peculiarities without openly diverging too far from the common EU path.

The regulatory variation in the microcosm of the EU (although it covers quite a large and important area) might be considered enhanced at an international level. Different approaches between the EU and the US (e.g. regarding the role of functional equivalence and the precautionary principle) have so far been reconciled in a pragmatic rather than a conceptual way. This does not seem to cause grievances unless there is a particularly painful instance, as has been the case with the "de facto moratorium" in the EU. The experts seemed to have different opinions of whether the EU approach is more adequate or not.

Nevertheless, the majority of experts interviewed considered the EU approach to be robust in the future as well. Overall, they seemed to think that conflicts with WTO agreements would probably not be enough to change the EU regulation on GM plants and foods. Whether this was mostly due to the international de facto power relations in this question or on a perceived conceptual superiority is not addressed here. However, even some of those who did not seem to approve of the EU approach considered it to be quite viable. This can also be seen in the amount of influence they considered the EU regulatory approach would continue to have at an international level in relation to other (developing) countries.

This prompts the question as to what will happen in those future challenges that the majority of experts anticipated. If the EU approach turns out to be sustainable, something must happen to the rules that the challenge will be based upon.

POLICY FIELDS 4.7

BACKGROUND

If one proceeds from the picture that emerged from the project reviews and the expert survey so far, the question is what can be learned from this and where do we go from here? In particular, we were interested in identifying and assessing policy options.

While this is common in many TA exercises, particularly if they include public or stakeholder participation of some sort, it is especially difficult in this case. The long-lasting debate has quarried robust interests and firm opinions, which pose great challenges to political decision-making and demands a very subtle way of proceeding. We therefore decided to leave the question of policy options open. Rather, we identified several policy fields at a very general level where action could be taken, and to ask the experts to give us their opinion.

The last part of this analysis is therefore slightly different from the former. The issues addressed in earlier sections were the future of GM plants in Europe and what is most likely to happen in relation to challenges for policy and research. In this final section, we turned to more normative issues related to policy fields.

RESULTS FROM THE TA PROJECT REVIEWS

Many TA project reports come up with a list of options for actions to be taken not only with respect to policy but also with respect to identifying fields for further TA studies. The following summary is based on information from six reports:

- *Austria, Precautionary Expertise for GM Crops*
- *Denmark, New GM crops – new debate*
- *France, Co-construction of a research programme*
- *Norway, Sustainability and societal impact of GM food*
- *Switzerland, Genetic Technology and Nutrition*
- *Switzerland, The future of plant biotechnology in Switzerland*

In many of the project reviews, a variety of policy options were identified subject to the focus of the study and the form of TA that was chosen. In general, many reports took up the point of interaction with the public, which is certainly an important issue, but not one that comes immediately to the forefront in the present context of challenges for European GM policy.

The other options for state action that came up can be grouped on a very general level according to different policy fields:

- Amendment or implementation of existing regulation;
- Institutional reforms including the taking different actors on board;
- Research policy

Subject to the general assessment of whether or not the European framework was sufficient in particular aspects, various stakeholders in the project reports called for amendments or adaptations to existing rules and pieces of legislation. Demands expressed in those reports where public participation was essential often pertained to considering uncertainty aspects and issues of benefit and risk distribution and ethics in a broader sense (*Norway, Sustainability and societal impact of GM food*) or some sort of benefit for society (*Switzerland, The future of plant biotechnology in Switzerland*).

Institutional reforms have been a major issue ever since the debate on GMOs started. More recently, the EU has engaged in institutional reforms in order to render risk assessment and management more credible and less prone to influence by national policies (Levidow et al. 2005), which resulted, for instance, in setting up centralised agencies such as EFSA. In contrast, demands by stakeholders for more participation on their own part in decision-making have been issued frequently. In addition, public involvement in various guises has also been discussed (*Austria, Precautionary Expertise for GM Crops*).

Almost every project review stipulated the need for research on issues that are not very likely to be taken up by the private sector. Research funding was often mentioned in discussions on other issues such as coexistence or risk management as a precondition to gaining necessary insights. Many of the challenges identified indirectly concerned the role of publicly funded research. It is seen as a means to maintain sufficient control over new GM plants and as a balance to private research and development (*Denmark, New GM Crops – New Debate; Switzerland, Genetic Technology and Nutrition*). From this perspective, public research could disentangle the outcome of R&D activities and applications (*France, Co-construction of a research programme*). The need for free and unbiased public research was also stressed as a means to determine the possibilities of scientific research and to recognise the limits of knowledge (*Switzerland, The future of plant biotechnology*); Public research could define research priorities in terms of identified agronomical problems that are considered politically relevant (*Switzerland, The future of plant biotechnology*).

PRELIMINARY CONCLUSIONS AND RESULTING QUESTIONS

Unease over whether the assessment of GM plants and food is adequate has long been prominent. In particular, the question of who to ask and involve in the assessment and decision-making process has never been resolved. Another contested field is how gaps should be bridged between national methods of implementing general frameworks

and/or differences between divergent international frameworks. Closely linked to such questions is the problem of institutional reform at both EU and national levels.

A second area of concern is the role, magnitude and direction of publicly funded research. Although many stakeholders support an increase in the proportion of such research, it is not clear what the money eventually should be spent on. Preferred research aims may be linked to more general stances with respect to the desirability of GM or non-GM solutions.

RESULTS OF THE SURVEY

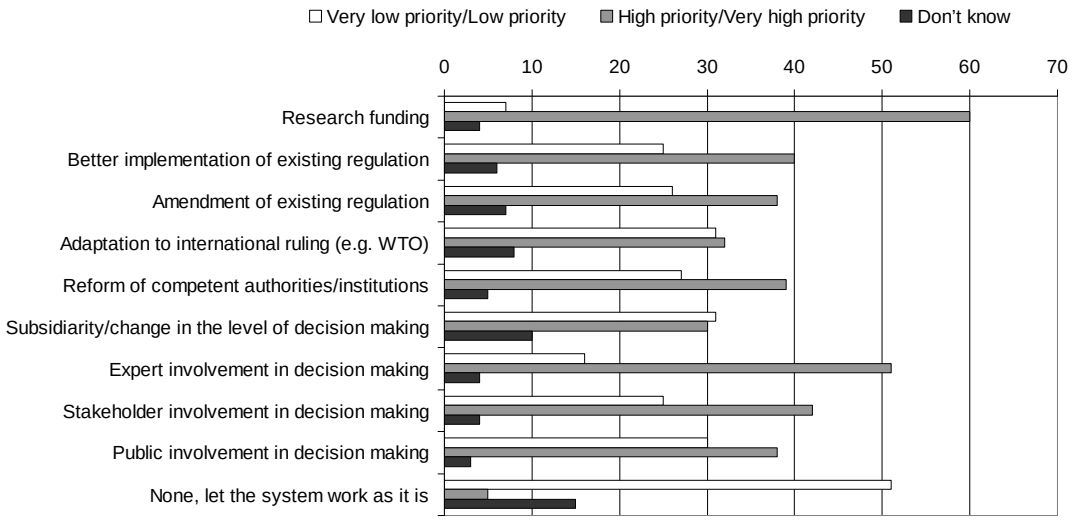
In order to identify areas of action for government institutions, we listed possible actions and asked respondents to indicate whether these should be prioritised.

The answers revealed that around three-quarters of the experts would not like to just let the system work as it is (Fig. 23). This certainly can be interpreted as an indication that respondents are not very content with the status quo.

The major field identified was research funding, which was prioritised by almost nine in ten respondents. This is, however, no surprise in the light of the fact that the majority of the experts were researchers themselves.

Other types of action that received priority (by slightly more than half of the respondents, although one-third did not approve) related to better implementation of regulations and, to a lesser extent, to amending such regulations. Regarding the direction of such an amendment, one may draw conclusions from other survey questions. In preceding sections, we have seen that a number of respondents were not confident with current approaches to coexistence and liability, and that they supported the development of new parameters for risk assessment and management, especially with an eye to future non-food GM crops. In addition, some respondents explicitly commented that regulation must be simplified and streamlined.

FIGURE 23: PRIORITISATION OF POLICY FIELDS (*Question 15; n = 71)*



Question: In order to meet challenges that have been explored in this questionnaire, it could be necessary for government institutions to take further action. Please prioritise the areas below in which you consider action needs to be taken. Please feel free to add areas of action not listed

Adaptation to international (WTO) rulings and the issue of subsidiarity received ambiguous support, with those who would prioritise the field equalling those who would not. Obviously, the issue of international harmonisation versus letting countries pursue their paths is something the group of experts had conflicting opinions about.

With regard to institutions, a majority prioritised the reform of competent authorities/institutions, which might indicate a measure of discontent with institutional performance. In terms of who else should be involved in the decision-making process, there seemed to be some enthusiasm for the involvement of experts, which again is not very surprising. However, stakeholder involvement also received priority from a majority of respondents, and even involving the public was not rejected on the priority list.

Looking at the way responses are distributed over the different categories of respondents, experts from universities/research and those from governmental agencies follow the general trend of being most supportive of 'research funding' and 'expert involvement in decision making'. Experts from industry also support 'expert involvement in decision making', but also 'adaptation to international ruling'. Taken together, the remaining group of experts (from agricultural organisations, environmental and consumer organisations and 'others)' are more supportive of 'stakeholder' and 'public involvement in decision making', although even in these groups there is strong support for 'research funding'.

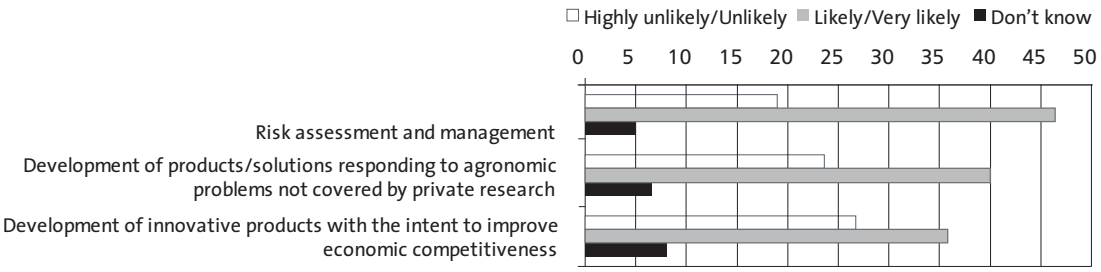
A comparison of how respondents prioritise expert involvement with how they prioritise public involvement also reveals interesting insights. Out of the 50

respondents who said that action to involve experts in decision-making should have high or very high priority, almost half said that action to involve the public should have low or very low priority. On the other hand, out of 36 respondents who said that action to involve the public should have high/very high priority, less than a third said that expert involvement should have low/very low priority. In contrast, there is a tendency that those who think stakeholder involvement should be prioritised also think the same about public involvement. In addition, higher enthusiasm for public involvement in decision-making also tends to go along with higher appreciation for the role of such involvement in forming consumer acceptance (Sect. 4.3).

On the topic of research funding, the high priority assigned requires better clarification of the type of research the experts might have had in mind. In particular, how do the experts see the role of publicly funded research: as a counterbalance to private research, basically oriented towards risks and the restriction of possible negative effects or as a means to improve the economic competition of the region by developing innovative products? In the survey we presented three options to the experts and asked them to judge the likelihood that they would become an objective of publicly funded research in their own country over the coming years.

The answers showed that two-thirds of the experts considered risk assessment and management to be a likely objective, and more than half that it would be filling in the gap left open by private research. A similar number found the aim of developing (innovative) products to be a likely candidate for publicly funded research (Fig. 24). The distribution of answers did not differ according to the experts' backgrounds (research, industry, government, NGO).

FIGURE 24: OBJECTIVES OF PUBLICLY FUNDED RESEARCH (*Question 14; n = 71)*



Question: In view of new developments in the research on GM plants, what will be the objectives of publicly funded research in your country in the coming years? Please feel free to add other objectives not listed.

DISCUSSION

Only a small minority of experts indicated a preference for leaving the current management system for GM plants and food alone and letting it work as it is. Thus, this is a call to policy makers to take action. The overwhelming majority of respondents supported a call for more research funding. While we cannot directly draw

conclusions on what directions such research should take, preceding sections have revealed a number of topics that may be worthy of attention (see also below).

Apart from research funding, respondents encouraged stronger involvement of experts and, to a lesser degree, stakeholders but also the public in decision-making. Some respondents tended to encourage the first while discouraging the latter, and vice versa. This may indicate different opinions regarding the general ability of non-experts to make informed judgments in such complex and controversial matters. The demand for a stronger role for experts could be interpreted as indicating that, according to many respondents, current policies were not sufficiently funded in science. Respondents also prioritised a better implementation of existing regulations as well as some amendments. The nature and direction of such amendments remains an open question, however. The same can be said about the reform of competent authorities/institutions. Nevertheless, in the light of the discussions in preceding sections, the interested reader might be able to draw his or her own conclusions.

Regarding the role of publicly funded research, the experts expressed the opinion that its scope will probably be rather broad over the coming years. Accordingly, it could be an instrument for supporting regulation of topics such as risk assessment, but maybe also coexistence, screening, labelling, etc. where commercial research would perhaps not be directed. At the same time, experts did not rule out that publicly funded research could also be an instrument in research and innovation policy in order to improve economic competitiveness. Interestingly, the distribution of opinions in this question did not differ very much regardless of the experts' background (university/research institute, industry, NGO), which might indicate there is a consensus among experts from different fields on this point.

CONCLUSIONS 5.

EPTA members and many other European institutions have carried out numerous research projects and written many reports on issues concerning GM plants and food. The present report is the result of a collective effort of eight EPTA member institutions who used their combined knowledge to gain more comprehensive and substantiated insights than each could reach alone. By analysing past TA results and supplemented by an expert survey, we tried to identify challenges for the European system of GMO regulation in the years to come. The aim was to find out

- Whether and how the situation had changed in recent times due to different general conditions,
- What kind of technical, societal, regulatory and political challenges could be identified,
- Where future areas of action could be located, and
- How TA (institutions) could address these issues.

In the following section, we present a selection of our main findings, together with some implications as we see them, which may touch on areas of action relevant for policy. We do not claim that these are particularly novel but, taken together, they may shed a different light on an issue many stakeholders consider to have been talked to death.

DEMAND FOR ACTION

An overall conclusion from our results is that the regulatory system for GM plants and food in Europe does not seem to be fully prepared to meet all existing and foreseeable future challenges. This notion is seriously supported by the experts' survey, as most experts asked expressed some degree of discontent with the status quo regarding GM plants and food in the light of the challenges ahead. Only five of the 71 respondents supported the statement “let the system work as it is”. This suggests that many consider it necessary to take action.

New solutions or fundamentally new views do not seem to be immediately at hand, nor are there any indications that these might develop in the near future. However, analysis of the survey results in comparison with the review findings provided us with valuable hints. These allowed us to corroborate and supplement results from past research exercises and reports, as well as from our ongoing technology-monitoring activities. Overall, we identified five main challenges for policy making on GM plants and food, and discuss possible TA contributions related to these.

CHALLENGE 1: NEW DRIVING FORCES FOR GM PLANT INTRODUCTION 5.1

The general overall conditions for agriculture are changing, and this may influence the future of GM crops. Nevertheless, it remains difficult to draw conclusions for future developments. For instance, the TA project review results did not reveal a single or major driving force for or against GM technology implementation. However, our expert survey confirmed a recent development in scientific and public debates (see Sect. 4.1): not only is the demand for food on the agenda, but also that for biomass as a renewable resource. Such added emphasis on biomass per se may increase the incentive to use GM technology.

Productivity gains through raising agricultural efficiency or mitigating pest pressure have traditionally been perceived to promote the use of GM technology, whilst the ever more globalised trade of food products contributed to its distribution across the world. The experts considered that these factors would also be influential in the future. Indeed, such a future seems realistic: in parallel with a rising demand for bioenergy and biomass, the majority of experts expected that GM plants will be available and authorised for cultivation in Europe for such purposes within the next 10 years. Non-food uses such as these may be less sensitive to avoidance by sceptical consumers: firstly because the products are less sensitive than our diet; secondly because they involve new value chains where it is the industry, rather than consumers, who make up the (direct) demand. However, regulatory challenges and controversies concerning biosafety may be intensified (see Sect. 4.2).

At the same time, the overall aims that society sets for agricultural practice will have a profound influence on the chances of new GM crops in the future. Nine in ten experts regard methods for crop production with the least possible environmental impact to be an important aim for the next 10-15 years. They also expect the production of high-quality food in great variety and the reduction of input into crop production to be important, which again can be seen as related to the environmental impact to be minimised. We can, therefore, deduce a strong emphasis on sustainability and on reducing input and impact on the environment while sustaining food quality and variety.

RESULTING AREA OF ACTION

The general conditions for European agriculture keep changing, and the driving forces for GM plant introduction are closely linked to these changing conditions. Global challenges to agriculture make it necessary to reconcile various and sometimes conflicting demands: rising world food demand and replacing fossil fuels; volatility of market prices and sustaining rural income; decreasing arable land area and preservation of biodiversity, to name but a few. In the light of these factors and the quest for sustainability as an overall aim, conflicts in terms of goals are unavoidable – as one expert commented, we need “sound decision making between conflicting

interests towards sustainable development." The question is therefore which kind of sustainable agriculture Europe will develop over the next few decades. Most probably, this answer will shed more light on the prospects of GM plants in Europe than any specialised regulatory debate over the use of GM technology and its products. In some ways, the question of "GM – yes or no?" could become less important than the question "What are the aims and duties of our agricultural sector?" (see Sect. 4.5). This implies a range of more specified questions such as "What role should European agriculture play for non-food – compared with food – production?" or "Which aims other than agricultural production should be pursued?" or "What are the conditions under which particular tasks should be fulfilled?"

The most important area of action, therefore, is agricultural policy. This has always been a highly controversial field, so it is no wonder that stakeholders and scientists have different views on the future shaping of agriculture and the role of GM plants and products. Considerable efforts have already been made on exploring and discussing sustainable agriculture. However, in the light of changing conditions, it will be necessary to resume the discussion.

Challenge 1: New driving forces for GM introduction

In addition to continuing encouraging and discouraging factors of the past, the increasing demand for bioenergy and biomass poses new challenges. This will change the agricultural framing conditions.

Resulting area of action: Agricultural policy

> *The possible future role of GM plants could be determined in a broad societal dialogue on future sustainable European agriculture in a regional and global context.*

5.2 CHALLENGE 2: NOVEL GM PLANTS, TECHNOLOGIES AND APPLICATIONS

Several classes of novel GM crops are currently under development in Europe as well as in other countries. The majority of experts thought that most would be available and authorised for cultivation in Europe within the next 10 years, with the exception of trees for industrial or energy purposes and plants for phytoremediation.

Newly developed GM plants for pharmaceuticals and other non-food applications will be important, but could pose regulatory challenges. Nearly all experts consider it likely or very likely that new parameters for risk assessment and management, confinement and/or containment measures, regulation of coexistence and liability will be put on the agenda over the next 10-15 years. We can, therefore, conclude that the discussion on adequate criteria for risk assessment for novel GM plants will be ongoing for the foreseeable future.

Traditionally, health aspects of GM food have primarily been discussed in terms of risks. However, some future GM plants are designed to bring health benefits, for instance through improved nutritional value or pharmaceutical substances. Most respondents expect that in the medium term such consumer benefits will appear and proceed to influence acceptance with GM plants. A third of respondents expect that attitudes to health may encourage, rather than discourage, the demand for GM plants and food. However, at the same time new risks may appear from gene flow or outgrowing and contamination of ordinary food staples. Such uncertainties over health risks from novel plants must be seen in relation to problems of coexistence (see Challenge 4).

Experts were ambivalent in answering the question of whether benefits should be included in assessment procedures. Previous research by EPTA members has shown that stakeholders have different expectations when discussing the inclusion of benefits: some hope that such a move could allow small uncertainties over risks to be balanced against benefits, others claim that neither for farmers nor for consumers is there any real benefit and that small uncertainties over risks are not tolerable.

New technologies such as cisgenics or smart breeding are said to blur the distinction between GM and non-GM and to meet with less resistance from a sceptical public. The survey shows that these are considered important for plant breeding in general, but the majority of experts do not regard them as alternatives to GM technology as such. Some existing regulations might need adaptation to cover cisgenics, however.

RESULTING AREAS OF ACTION

As for every field of technology development, research policy is the area of action. The European research landscape of GM plant development is fragmented, and some member countries have redistributed their national activities towards other fields. However, survey results suggest that, firstly, there is a demand for more public sector research on new GM plants. As one expert commented, “more of the technology development needs to come back to the public sector and open-source technology protection (need to be) developed.” Secondly, plants that are newly developed could be checked as early as possible whether they meet European agricultural aims and current coexistence schemes. How to meet this challenge appropriately also needs to be dealt with at the European level.

Even though experts do not expect new developments in plant breeding to be a substitute for GM technology, different approaches must compete for research funds. To set priorities, it is not only necessary to assess technical performance but also the chances of newly developed plants satisfying the intricacies of public debate (see Challenge 3). In this way, the relationship between genetic modification and new ‘intermediate’ technologies such as cisgenics and smart breeding could be clarified.

The second important field is GM regulation policy in the EU. Many proposals have been made to improve, streamline or enhance regulatory policy, to the degree that the balance achieved is sometimes considered too fragile to challenge. However, as the

general framework keeps changing, regulatory revision is probably necessary. Properties of newly developed GM plants for the non-food sector could make it necessary to consider amendments and additions in risk assessment and risk management parameters, confinement and/or containment measures, regulation of coexistence and liability. In addition, the question of benefit evaluation might be put on the political agenda. Taken together, the status quo of regulation might again be up for revision.

Challenge 2: Novel GM plants, technologies, and applications

Several classes of new GM plants will probably be available and authorised for cultivation in Europe within the next 10 years. This poses a number of research and regulatory challenges.

Resulting area of action: Research policy

> *The aims of public sector research could be better aligned with European agricultural aims.*
> *The most promising GM and non-GM approaches could also be selected in terms of public acceptance.*

Resulting area of action: GM regulation policy

> *The regulatory framework for non-food GM plants could be reconsidered.*

CHALLENGE 3: PUBLIC OPINION – STILL A DECISIVE FACTOR 5.3

In many European countries, public attitudes are considered an important factor influencing both the use of GM technology and its development. Therefore, influences on consumer acceptance must be analysed in order to assess whether public attitudes are changing, and if so in which direction. The majority of experts thought that a more positive attitude towards GM technology is likely over the next 10-15 years. This is mainly be due to the potentially growing acceptance of new GM non-food products, while the (lower) acceptance of GM food products will remain unchanged (see Sect. 4.3).

However, it is uncertain whether the expectations towards overall higher acceptance will prove to be realistic. Non-food GM plants can also raise environmental and health concerns, especially where doubts exist over the performance of coexistence schemes (see Challenge 4). In the light of recent debates on whether biofuels are a sensible option for reducing carbon dioxide emissions or whether they compete with food production, expectations that plants for renewable bioenergy will elicit more positive public perceptions may turn out to be overoptimistic.

In the past, developments that were seemingly unrelated to the issue of GM plants and food have made their mark on the debate and influenced acceptance. This shows that public perception is multi-faceted and that it is not only a matter of the technology at stake or of consumer risks or benefits. Neither is consumer acceptance a matter of specific technological knowledge of particular products. Rather, the whole context of food production and regulation as well as the relationship between actors in the food chain, from the farmer to the end consumer, determine the fate of potential products. Attempts at deliberately guiding public perception by influencing a single factor have proved to be futile.

In conclusion, both old and new topics, expectations and arguments can be expected to make their mark on public debates and influence public attitudes in the future. Whether and how the overall public acceptance of GM plants will change remains unclear.

RESULTING AREA OF ACTION

Although consumer benefits are important, public attitudes are subject to many influences, including ethical concerns, and the area of action is less clear than for other challenges. For the time being, little indicates increasing acceptance. It cannot be taken for granted that with new consumer-oriented GM products, and with bioenergy as a new track of GM plant production, the public perception of the GM technology will change.

The challenge of public opinion is closely linked to other challenges such as the future role of GM plants in European agriculture (see Challenge 1), a realistic evaluation of benefits and risks of new GM crops (see Challenge 2), and the performance of coexistence schemes (see Challenge 4). Accordingly, both consumer protection policy and a variety of other fields from agricultural policy to GM regulation come into the picture – it is a truly cross-sectional task. An ongoing dialogue between consumers, scientists and various stakeholders over potential chances and possible problems might help to avoid disappointments and the emergence of scandal stories.

Challenge 3: Public opinion – still a decisive factor

Against the background of established arguments, new topics, expectations and concerns can be expected to influence public debates and public attitudes in the future. Although there is a difference in acceptance between food and non-food products, it remains unclear whether and how the overall public acceptance of GM plants will change.

Resulting area of action: Consumer protection policy and cross-sectional tasks

> *An open dialogue on potential chances and possible problems could be enhanced.*

CHALLENGE 4: COEXISTENCE AND LABELLING UNDER A GROWING USE OF GM PLANTS IN EUROPE AND THE WORLD 5.4

In the European regulatory system, authorisation of a GM plant is based on a scientific risk assessment. In addition, coexistence must be allowed for, and appropriate labelling is required, in order to guarantee consumers the freedom of choice. The concept of coexistence can be considered an answer to the political demand for freedom of choice, but it also influences the parameters of scientific risk assessment. As the two pillars for the authorisation and management of GM crops build on different rationales, they might not always be easy to reconcile.

Until now, only first-generation GM plants with herbicide tolerance and/or insect resistance have been grown in some European countries, often on small areas and for a relatively short time. Therefore, robust experience with the EU regulation on coexistence is still some way ahead. There is still thus some uncertainty whether the concept of coexistence will prove viable under all circumstances.

Reports from many EPTA members come to the conclusion that coexistence is feasible in principle. In support of this finding, only a minority of experts believed that coexistence will not work at all for first-generation GM plants. In line with this, most respondents expected them to be cultivated in Europe at least in the medium term.

When it comes to more detailed questions, however, experts are divided. Will coexistence work for some crops only or for a broad range? Can it work only on a small scale or also for large-scale cultivation (see Sect. 4.4)? The practical context seems to be more important than feasibility in principle. A caveat also pertains to the type of risk that coexistence measures address. Half the respondents believe current schemes are insufficient to contain all economic and environmental risks – depending on what is deemed relevant. Again, experts are split over how to process remaining risks – weigh them up against societal benefits, seek economic compensation, or rely on regulatory intervention?

Coexistence measures aim at implementing freedom of choice, and half of the respondents believed that GM food will be labelled correctly and that non-GM food will continue to be available. The others expected different negative scenarios such as the misapplication of labelling or the entire failure of coexistence and the ensuing blockade of GM food.

Controversies over coexistence can sometimes be traced back to differing degrees of confidence in systems of risk assessment and authorisation. Some doubts arise as to whether institutions involved in such an assessment are fully independent from vested interests – for example, one expert suspects that “EFSA … is just established to put its rubber stamp on all GMOs.” Crossing the boundaries of conventional expertise and interest representation is sometimes considered a remedy. However, experts have different opinions on whether more scientific expertise or more stakeholder or public participation (or all three) should be implemented.

In addition, misfits between parts of the regulatory system and politics are highlighted. For example, one expert calls for "the conflict between the scientific decisions and the political actions” to be resolved.

RESULTING AREAS OF ACTION

Overall, questions remain over the concept of coexistence as a core element of European GM plant regulation, which also concerns the limited use of GM plants in Europe so far. Coexistence and labelling are considered to function reasonably well under certain conditions. However, there are doubts that this will be the case for all cases of GM crop cultivation. Despite regulation and an extensive debate in the past, problems in the future cannot be excluded with specific crops and large-scale cultivation. Therefore, continuous monitoring and perhaps a revision of coexistence rules are required.

As the implementation and warranty of coexistence is intimately bound up with approval procedures for GM crops in general, further possible areas of action are related to basic aspects of risk assessment and/or management of GMOs. Reports from EPTA members have highlighted that the expertise involved in regulatory decision-making and the way parts of the regulatory system work together may come under scrutiny. A number of comments addressed the independence from vested interests of bodies involved (such as EFSA) as a prerequisite for public and stakeholder trust. A practical solution could be to incorporate a broader spectrum of scientific opinions and to enable a broader representation of interests, including those of civil society, and of different forms of expertise such as citizens’ knowledge.

Moreover, disentangling science (embodied in risk assessments by EFSA and national authorities) and political decision-making (on the EU and national level) has been a major aim of regulation, but it does not seem to have been accomplished in a fully satisfactory way. Therefore, a way must be found to better define the requirements of scientific evidence and the room for manoeuvre in politics.

A further, recurrent problem is the remit for political decision-making at the national level, e.g. on restricting or promoting the use of GM plants in a particular area. This issue is discussed in the context of Challenge 5.

Challenge 4: Coexistence and labelling under growing use of GM plants in Europe and the world

In Europe, GM plants have been grown on relatively small areas and only for a short time. Therefore, there is still a lack of robust experience with the EU regulation on coexistence. With specific crops and large-scale cultivation, problems cannot be excluded in the future.

Resulting area of action: GM regulation policy

- *Aspects of GM regulation on the requirements for maintaining coexistence and freedom of choice might have to be revisited.*
- *Incorporation of different types of expertise and interests could enhance and demonstrate independence from vested interests.*
- *The relation of science and policy could be better defined, with a clear remit for policy also on the national level.*

CHALLENGE 5: INTERNATIONAL TRADE RULES AND DOMESTIC DECISION-MAKING 5.5

The recent WTO conflict between the US and its allies and the EU has put pressure on some aspects of the European regulatory practice concerning GM plants and food. It made clear that the future shaping of international trade rules will greatly influence GM regulation in the EU. However, European ideas on how to regulate such issues might also be influential outside Europe and affect international agreements as well.

Apart from the concrete instance mentioned, the global increase in acreage covered by GM crops, pending international trade conflicts, the development of international GM regulations and the different approaches to risk assessment and regulation in various countries could turn out to be a challenge in the future, too. The question is whether the European regulatory system will be able to cope with this.

Despite the outcome of the WTO conflict, the experts saw a good chance the European regulatory system surviving, even in view of increasing global GM crop use. Most are convinced that at least the general principles can be maintained, but many think that restrictive practices of individual EU Member States will have to change and more harmonisation among the EU Member States will be necessary (see Sect. 4.6).

Accordingly, the robustness of the EU regulatory system is based on the perceived compatibility of general principles and approaches of the EU regulation with international trade regulations as well as on the political standing of the EU. In

addition, some experts consider a change to the GM regulatory system in non-EU countries or a change of WTO rules possible or at least desirable.

RESULTING AREAS OF ACTION

International trade policy is the obvious area of action. However, the trade conflict surrounding GM plants and food only pertains to one of several arenas within the WTO regulations. Therefore, not only those areas specific to GMOs might be considered at stake, but also the possible integration of environmental and social standards into WTO regulations. The relation of treaties, conventions and agreements reached under the auspices of different supra-national bodies (e.g. WTO and UN) will have to be clarified in order not to thwart the aims of these different agreements,. This is, however, beyond the scope of national influence and the issue of GM plants.

With regard to GM regulation policy, problems are said to have arisen from discrepancies between the implementation of the European regulatory framework in different Member States. Two possible solutions come to mind: giving more leeway to national sovereignty (often captured under the term ‘subsidiarity’) with respect to GMO regulation, or enforcing harmonisation among member states also with regard to minor details. In the past, the compromises reached did not always deliver fully satisfactory results, and many experts consider further harmonisation and/or institutional reforms necessary. It remains to be seen how far subsidiarity can be upheld under the auspices of WTO rulings.

Challenge 5: International trade rules and domestic decision-making

Uncertainties about the compatibility of the European GM regulation with international trade regulations remain. At the same time, international trade rules may be up to reforms.

Resulting area of action: International trade policy

> *Reconciling discrepancies between various international treaties could be intensified.*

Resulting area of action: GM regulation policy

> *National implementation could be harmonised, including institutional reforms.*

UPCOMING ISSUES FOR TECHNOLOGY ASSESSMENT 5.6

Over the years, technology assessment has made great efforts to clarify particular aspects of agricultural biotechnology, one of the most prominent technological fields that TA has ever dealt with. Not only with respect to technical analyses but also regarding public involvement, this issue has featured prominently among TA themes for two decades. Thus, one may question whether there is any particular shortcoming since almost every issue has already been focused on.

Nevertheless, some upcoming issues may prove to warrant increased attention from the point of TA. At least four developments call for renewed interest and novel approaches:

> First, there are a number of *technological developments that extend the use of GM plants* beyond the current range of applications, such as energy plants, plants for nutritionally enhanced products or for producing pharmaceutically active substances. Furthermore, crops of a new generation with enhanced agricultural traits such as drought resistance and other low-input properties throw up questions of enhanced survival capabilities (and thus invasiveness) together with improved yield under difficult environmental conditions. They are said to be much more common in a future determined by climatic change, so they might pose novel challenges for risk assessment.
> Second, apart from technological novelties, *changed general conditions for agriculture* continue to challenge established practices and aims. The example of fuel production from renewable resources, initially hailed as a tool to save fossil fuels and to mitigate carbon dioxide release, has shown that the general framework can change over a very short time. Volatile food prices and a depletion of staple stocks have re-opened the debate over whether it will be necessary to boost food production not only in developing countries but also in areas where overproduction has been a problem.
> The third area is decision-making. On the one hand, there are recurring conflicts about institutions and levels of decision-making, for instance between the EU bodies and Member States, and about singling out what belongs to the science of

risk assessment versus the politics of risk management. On the other hand there is the repercussion of international politics, including the WTO conflict, on national agricultural production. Trade liberalisation, globalised trade in food and feed, and international rules for the use of technology (or its prevention for example through patents) can challenge established practices at very short notice.

- Fourth, public attitudes towards GM plants and food may change in the future. This might not only influence the strategies of relevant actors such as farmers, food retailers, or NGOs, but also impact future political decisions. The direction of such a change, however, is impossible to predict. In the past, many factors not immediately related to GM technology as such but to broader social and cultural issues have been shown, or suspected, to influence public perception. In addition, national differences are obvious, and with a larger number of Member States the diversity of the European landscape of public perceptions might even increase.

Taking past experiences with R&D on transgenic plants into account, new forms of co-ordinated involvement of experts, stakeholders and citizens need to be organised in the process of the development of new generations of plants. The task of TA is to help clarify technological solutions and their societal implications. TA is one area that could contribute to developing new forums to open negotiating channels between actors who have found it hard to speak to each other or arrive at sustainable compromises.

Further discussion is needed on the TA approaches that are required and suitable. It largely depends on the expertise and experience of the TA institutions involved. This could be an indication to seek transnational co-operation, for example under the auspices of EPTA.

Relevant issues for TA identified:

- *Assessment of novel GM plants, especially those with enhanced agricultural traits*
- *Assessment of technological solutions offered or demanded to meet changed framework conditions for agriculture, and their societal implications*
- *Identification of impacts of international treaties and trade liberalisation and of possible solutions to meet them*
- *Understanding social and cultural factors influencing technological developments, their embedding into society and the ways implications such as risks and benefits are perceived*

These issues require the development of new forums for dialogue and a better co-ordinated involvement of experts, decision makers and the public in issues related to GM plants and food.

REFERENCES

Consumerchoice (2008): Do European Consumers Buy GM Foods? Final report http://www.kcl.ac.uk/consumerchoice

EC (European Commission) (2006): Biofuels Progress Report. Report on the progress made in the use of biofuels and other renewable fuels in the Member States of the European Union. Commission Staff working document, SEC(2006) 1721/2, Brussels, Belgium

EEA (European Environment Agency – Scientific Advisory Board) (2008): Suspend 10 percent biofuel target. http://www.eea.europa.eu/highlights/suspend-10-percent-biofuels-target-says-eeas-scientific-advisory-body

Gaskell, G., Stares, S., Allansdottir, A., Allum, N., Corchero, C., Fischler, C., Hampel, J., Jackson, J., Kronberger, N., Mejlgaard, N., Revuelta, G., Schreiner, C., Torgersen, H., Wagner, W. (2006): Europeans and Biotechnology in 2005: Patterns and Trends, Final report on Eurobarometer 64.3, A report to the European Commission's DG Research, Brussels, http://www.ec.europa.eu/research/press/2006/pr1906en.cfm

GBEP (Global Bioenergy Partnership) (2007): A Review of the Current State of Bioenergy Development in G8 + 5 countries. FAO/GBEP, Rome

IAASTD (International Assessment of Agricultural Knowledge, Science and Technology for Development) (2008a): Executive Summary of the Synthesis Report. http://www.agassessment.org/docs/SR_Exec_Sum_280508_English.pdf

IAASTD (International Assessment of Agricultural Knowledge, Science and Technology for Development) (2008b): Global Summary for Decision Makers. http://www.agassessment.org/docs/Global_SDM_060608_English.pdf

INRA (Institut National de la Recherche Agronomique) (2008): Results of the European SIGMEA project on the co-existence of GM and non-GM crops, http://www.international.inra.fr/partnerships/with_the_private_sector/live_from_the_labs/results_of_the_european_sigmea_project_on_the_co_existence_of_gm_and_non_gm_crops

James, C. (2007): Global Status of Commercialized Biotech/GM Crops: 2007, ISAAA Brief No. 37. ISAAA: Ithaca, NY

Lassen, J., Jamison, A. (2006): Genetic technologies meet the public: the discourses of concern. In: Science Technology & Human Values Vol. 31, No. 1, 8-28

Lassen, J., Madsen, K.H., Sandoe ,P. (2002): Ethics and genetic engineering - lessons to be learned from GM foods. In: Bioprocess and Biosystems Engineering Vol. 24, No. 5, 263-271

Levidow, L., Carr, S., Wield, D. (2005): EU regulation of agri-biotechnology: precautionary links between science, expertise and policy. In: Science and Public Policy, Vol. 32, No. 4, 261–276

Meyer, R., Grunwald, A., Rösch, C., Sauter, A. (2007): Chancen und Herausforderungen neuer Energiepflanzen. Basisanalysen. TAB (Büro für Technikfolgen-Abschätzung beim Deutschen Bundestag), Arbeitsbericht Nr. 121, Berlin

PABE (Public Perceptions of Agricultural Biotechnologies in Europe) (2001): Final Report of the PABE research project, funded by the Commission of European Communities, http://csec.lancs.ac.uk/pabe/docs.htm

SRU (Sachverständigenrat für Umweltfragen) (2007): Klimaschutz durch Biomasse. Sondergutachten – Hausdruck. Berlin

Suppan, S. (2006): The WTO's EC-Biotech Products ruling and the Cartagena Protocol. Institute for Agriculture and Trade Policy, Minneapolis

World Bank (2007): Agriculture for Development. World development report 2008. Washington DC

WTO (World Trade Organisation) (2006): European Communities - Measures Affecting the Approval and Marketing of Biotech Products. Reports of the Panel. DS291, DS292 and DS293. http://www.wto.org/english/news_e/news06_e/291r_e.htm

ANNEX 1: LIST OF TABLES AND FIGURES

TABLES 1.

FIGURES 2.

ANNEX 1: LIST OF TABLES AND FIGURES

ANNEX 2: LIST OF PROJECT REVIEWS

In brackets:
[Short titles]

The full texts of all project reviews are available on the project website as Annex 3 (http://www.eptanetwork.org/EPTA/projects.php?pid=150).

Austria:

- Review of the Austrian Federal Environment Agency monograph "Ecological Monitoring of Genetically Modified Organisms" (2000)
  [Austria, Ecological Monitoring of Genetically Modified Organisms]
- Review of the EU funded international research project "Precautionary Expertise for GM Crops" (2004)
  [Austria, Precautionary Expertise for GM Crops]
- Review of the monograph "Risk Assessment of GMO Products in the European Union. Toxicity assessment, allergenicity assessment and substantial equivalence in practice and proposals for improvement and standardisation" (2004)
  [Austria, Risk Assessment of GMO Products in the European Union]
- Review of the Austrian Agency for Health and Food Safety "Feasibility Study on 'GMO-free' claims and the avoidance of GMOs in food" (2005)
  [Austria, "GMO-free" claims and the avoidance of GMOs in food]
- Review of the study "Coexistence" on behalf of Federal Ministry of Health and Women (2005)
  [Austria, Coexistence]
- Review of the Federal Environment Agency conference "The Role of Precaution in GMO policy" (2006)
  [Austria, The Role of Precaution in GMO policy]

Denmark:

- Review of the DBT project "Genetically modified foods" (1999)
  [Denmark, Genetically modified foods]
- Review of the DBT project "Genetically modified crops in developing countries – challenges for the development aid" (2003)
  [Denmark, Genetically modified crops in developing countries]
- Review of the DBT project "Co-existence between GM crops and non-GM crops" (2004)
  [Denmark, Coexistence]
- Review of the DBT project "New GM crops – new debate" (2005)
  [Denmark, New GM crops – new debate]

Finland:

- Review of the Finnish debate between public administration, researchers and general public concerning the plant gene technology
  [Finland, Debate concerning the plant gene technology]

Flanders:

- Review of the viWTA Public Forum "New impulses for the debate on genetically modified food" (2003)
  [Flanders, New impulses for the debate on genetically modified food]
- Review of the viWTA-project "Functional foods. State of the art" (2006)
  [Flanders, Functional foods]
- Review of the viWTA project "Industrial biotechnology in Flanders: State of the art" (2006)
  [Flanders, Industrial biotechnology]

France:

- Review of the INRA Project "Co-construction of a research programme" (2002)
  [France, Co-construction of a research programme]

Germany

- Review of the TAB project “Genetic engineering, breeding and biodiversity” (1998)
  [Germany, Genetic engineering, breeding and biodiversity]
- Review of the TAB project “Risk assessment and post-marketing monitoring of transgenic plants” (2000)
  [Germany, Risk assessment and post-marketing monitoring]
- Review of the German “Diskurs Grüne Gentechnik” (Green Biotechnology Discourse) (2002)
  [Germany, Green Biotechnology Discourse]
- Review of the project “Genetic Engineering and organic farming” (2003)
  [Germany, Genetic engineering and organic farming]
- Review of the TAB project “Green genetic engineering – transgenic plants of the second and third generation” (2005)
  [Germany, Transgenic plants of the 2nd and 3rd generation]
- Review of the Berlin-Brandenburg Academy of Sciences and Humanities project “Gentechnologiebericht” (Gene Technology Report) (2007)
  [Germany, Gene technology Report]

Norway:

- Review of the project "Reconvening the lay people's panel on GM food 4 years after" (2000)
  [Norway, GM food]
- Review of the Project "Public meeting on coexistence" (2004)
  [Norway, Coexistence]
- Evaluating the criteria of sustainability and societal impacts in relation to GM food – the work of the Norwegian Biotechnology Advisory Board
  [Norway, Evaluating the criteria of sustainability and societal impacts in relation to GM food]

Switzerland:

- Review of the TA-SWISS PubliForum "Genetic Technology and Nutrition" (1999)
  [Switzerland, Genetic Technology and Nutrition]
- Review of the RIBIOS Forum "The future of plant biotechnology in Switzerland" (2003)
  [Switzerland, The future of plant biotechnology in Switzerland]
- Review of the "Report on the Coexistence of different GM and non-GM agricultural cultivation systems" of Agroscope Reckenholz-Tänikon Research Station ART (2005)
  [Switzerland, Coexistence)]
- Review Co-ordination Meeting of Institutions Offering Biosafety-Related Training and Education Programs (2004)
  [Switzerland, Biosafety-Related Training and Education Programs]

United Kingdom:

- Review of UK projects since 2000
  [United Kingdom, GM dialogue]

ANNEX 3: REVIEWS

AUSTRIA 1.

ECOLOGICAL MONITORING OF GENETICALLY MODIFIED ORGANISMS (2000) 1.1

BACKGROUND OF THE PROJECT

Context

On March 12th, 2001, the European Union (the Parliament and the Council by the co-decision procedure) adopted Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms. As a significant part of this Directive there is a Monitoring Plan sketched to be further elaborated in Guidance Notes. These supplementing Guidance Notes have been adopted by decision of the Council on October 3rd, 2002.

The present research was realised and finished between these two dates and addresses the need for further elaboration of the monitoring system, presenting preliminary proposals to be discussed on a national Austrian basis and EU-wide, afterwards.

The Austrian situation in the domain of green biotechnologies is characterised by a quite restrictive legislation, regional efforts to completely forbid GMOs and a broad GM-critical consensus between the political parties, farmers, interest groups, NGOs and the public. Already in the 1990s with the Directive 90/220/EEC in force, Austria pushed for a monitoring instrument. Basically, there were and there are two fundamental positions on the EU-level: those who demand an extensive monitoring of the approved GMOs, arguing that it is impossible to know every relevant effect of the product in a risk assessment ex ante; and those who understand a product which is approved after an exhaustive risk assessment as fully admitted. The critique of the latter on monitoring is that it is not affordable and even if it would be one cannot know what parameters exactly to trace – one cannot detect and measure anything which possibly could be of relevance. Austria maintained its pro-monitoring attitude and the present paper has to be read in this stable policy-line.

Demanding institutions

This study was financed by the Austrian Federal Ministry of Agriculture, Forestry, Environment and Water Management. As documented in the Third Report of the Austrian Genetic Engineering Commission (Gentechnikkommission), the study was also demanded and partly financed by the Austrian Federal Ministry of Health and Women. The paper was published in the monograph series of the Austrian Federal Environment Agency. The authors are, partly, from this agency and, partly, scientists from outside (University of Vienna, Austrian Federal Office and Research Centre of Agriculture). The main author Andreas Traxler has no institutional affiliation.

Guiding questions

How can we deal with the uncertainty about potential environmental effects of GMOs? What proposals can be made for the guidance notes to amend and complete Annex VII of the Directive 2001/18/EC with a framework concept for ecological monitoring that satisfies the needs of the EU and the Member States?

BASIC DATA ABOUT THE PROJECT

Type of project:

This project is a survey on ecological monitoring and the translation (to present it to a larger audience) of an abridged version of a more extensive monography (containing more Austrian-specific details) of the Austrian Federal Environment Agency (published in 2000). The methods used are basically a review of the legislative texts and scientific publications on the subject, and an exposition of Austrian ecological protection targets. Two case studies (GM maize and GM oilseed rape) were used in the original German version to delineate the requisites of an ecological monitoring device. However, the focus lies on the elaboration of a method, more than on applying already established methods.

Topics:

At first, the survey presents the EU-wide legal provisions on GMO monitoring. Then, the framework concept and the guidelines for monitoring of GMOs are sketched. There are criteria elaborated, the questions of financing and public participation are addressed and a terminology is elaborated. In a next step, the authors introduce the monitoring parameters and test methods they recommend.. After suggestions for Austrian specific ecological protection targets, the authors conclude with some words on biogeographical regions in Austria.

Duration:

The longer version in German language was published and presented in the year 2000, this paper in 2001. The project work took approximately a year.

MAJOR OUTCOMES OF THE PROJECT

Central findings

The study's analysis of the respective legislative acts on GMOs brought the authors to the conviction that ecological monitoring is one of the few methods to increase GMOs' environmental safety. It is the only way to detect unforeseen effects, to possibly prevent adverse effects in time, and to get to learn about the ecological risks of GMOs. There is a broad agreement, also in the EU (see directive 2001/18/EC) and between the interest groups, that it is a necessary instrument to control possible risks of the release of GMOs. However, there is uncertainty on how to implement it. Representatives of the industry, on the one hand, and ecologists, on the other, have quite

divergent views on the nature, extent and duration of the investigations to be carried out in a monitoring tool.

From the authors' point of view, ecological monitoring must be planned and carried out by ecologists in co-operation with molecular biologists and cannot be accepted as a burdensome necessity involved in the release of a GMO.

In line with the EU directive's indications, there should be a case-specific monitoring (limited in time, hypothesis-based) and general surveillance (nation-wide long-term monitoring without time restrictions, designed to observe the effects of all consented GMOs). The present monography also suggests a monitoring of the state-of-the-art (collect and structure international monitoring results; periodically adjust current monitoring plans in terms of methodology and subject matter) and an ecosystem monitoring (because of the high costs, it would be feasible only at few locations; however, this could unearth important findings and initiate interdisciplinary environmental monitoring on an integrated basis). A list of guidelines for ecological monitoring for releases and for the placing on the market is compiled in the study. The paper votes for the participation of the public (to improve acceptance and increase objectivity) and a broader and interdisciplinary integration of scientific fields and interest groups.

There is a great amount of monitoring parameters and test methods proposed by the contributors, which reflect the inconvenience of not knowing what to detect and assess, exactly. It seems that with the recommended ensemble, there should be reached an integrated, holistic vision able to catch problematic effects on the ecobiological system on various points and as fast as possible: There are standard parameters (biomass, phenology, cover values, vegetation structure, etc.) and methods of plant ecology proposed, furthermore biochemical, ornithological and entomological monitoring methods, and soil analyses.

The ecological protection targets should be stipulated by each individual Member State – the present survey attempts this for Austria.

Options for action

Amend Directive 2001/18/EC in line with the aspects prompted by the Austrian position. Each notification for the deliberate release or placing on the market of GMOs must contain a detailed monitoring plan on a case-by-case basis.

Identified future issues

The survey claims that the following points have to be clarified for future GMO notifications with regard to efficient ecological monitoring:

- determination of the executing institutions
- definition of threshold values
- definition of ecological damage (the term is not sufficiently defined: is it "damage" if a native plant population is suppressed or already if there is a GMO-occurrence in ruderal biotops?)

- establishment of a national and international information network (with a central coordination office for the GMO-monitoring as collector and administrator of monitoring data and findings)

These issues should be discussed at the earliest possible stage:

- planning of a nation-wide, representative monitoring network for animals and plants
- definition of the ecological targets likely to be affected by GMOs
- financing

IMPACTS AND FOLLOW UP OF THE PROJECT

According to the press release of the Austrian Federal Environment Agency, the frame monitoring concept was developed to be placed at the EU-level in the discussion on the monitoring guidelines complementing directive 2001/18/EC. These guidelines were published in 2002 by decision of the Council of the European Union. Only a comparative study of the two documents and the positions of other Member States and the relevant interest groups could clarify the concrete influence of the Austrian proposal.

CHALLENGES IDENTIFIED

The development of this monitoring concept, according to the authors, does by no means give a "clean bill of health" for releasing or placing GMOs on the market. Moreover, ecological monitoring is necessary and a useful tool – however, it does not work wonders: it is expensive, time-consuming, and methodologically limited.

LITERATURE

Traxler, A., Heissenberger, A., Frank, G., Lethmayer, C., Gaugitsch, H. (2000): Durchführung von Untersuchungen zu einem ökologischen Monitoring von gentechnisch veränderten Organismen. Umweltbundesamt, Monographien Band 126, Wien http://www.bmgfj.gv.at/cms/site/standard.html?channel=CH0810&doc=CMS1085490251342

English version (2001): Ecological Monitoring of Genetically Modified Organisms. Austrian Federal Environment Agency, Wien http://www.umweltbundesamt.at/fileadmin/site/publikationen/M147.pdf

AUTHOR OF THE REVIEW

Helge Torgersen

PRECAUTIONARY EXPERTISE FOR GM CROPS (2004) 1.2

BACKGROUND OF THE PROJECT

Demanding institution (initiator):

The research project "Precautionary Expertise for GM Crops" was funded by the European Commission, Quality of Life programme. It was the third in a series of EU funded projects on policy problems associated with the regulation of GMOs in several EU member states, co-ordinated by the Open University, Milton Keynes.

Context:

Background for this project was the increasing need of changes in regulatory procedures regarding GM crops. When Member States blocked the EU–level regulatory procedure in 1999, new legislations were adopted to meet their demands. New procedures were supposed to provide a mechanism to ensure full traceability and labelling of GMO crops and to enhance the application of the precautionary principle on a national level. Although the precautionary principle was widely invoked for dealing with uncertain risks by Member states, criticism remained considering the principle as a pretext for political agendas. One important reason was that largely, a generally accepted coherent view on the scope and modes of application of the principle was considered to be lacking.

The project analysed the different approaches to the precautionary principle and their consequences for regulatory measures as they appeared from regulatory actions by some Member States as well as from statements made by various stakeholders. Particularly the broader accounts leave the scope wide open for different interpretations. As a result, disagreements about the practical meaning emerged. The main goal of the study was to accommodate different views and give guidelines for the implementation of the principle. Thus it was an attempt to construct a comprehensive concept of the precautionary principle in the context of agricultural biotechnology.

The main guiding questions were:

- How do current European practices compare with different accounts of the precautionary principle?
- How are risk research, risk assessment and risk management linked in practice?
- How do stakeholder groups attempt to influence regulatory measures within or
- beyond formal procedures?
- How do expert advisory bodies mediate between regulatory science and public-scientific controversy?

BASIC DATA ABOUT THE PROJECT

Type of project:

The project was performed as an inter-disciplinary policy research exercise, aiming at comparative evaluations of national policy events, investigated by the national partners, and developments on the EU level researched by the co-ordinator.

The research activities mainly consisted of an analysis of relevant documents as well as interviews and workshops with key actors, involving a wide range of stakeholders.

Duration / start and closing date:

Work was performed within the years 2002 -2004, with the final report in 2004.

Topics of the project:

The investigation focused on the practical application of the precautionary principle in the member states with respect to transgenic crops.

Participants:

- D. Wield, S. Carr, L. Levidow, S. Oreszczyn, Open University, Milton Keynes, UK (Co-ordinators);
- H. Torgersen, A. Bogner, Institute of Technology Assessment; Austrian Academy of Sciences, Vienna, Austria;
- B. Gill, K. Boschert. Ludwig-Maximilians-Universität München, Germany;
- J. Toft, Roskilde University Library, Copenhagen, Denmark;
- C. Marris, P.-B. Joly, St. Ronda, Institut National de la Recherche Agonomique, Ivry, France; Ch. Bonneuil, Centre Koyré d'Histoire des Sciences et des Techniques, Grenable;
- L. Lemkow, D. Tàbara, D. Polo, Universitat Autònoma de Barcelona, Spain.

Subcontracts (consultants):

- P. Schenkelaars, Schenkelaars Biotechnology Consultancy, The Netherlands;
- J. Tait, University of Edinburgh, UK.

Events:

- National stakeholder workshops were held in all participating countries (UK, A, D, DK, F, SP, NL) and on the EU level. Workshops proceedings were distributed and, in part, published.

MAJOR OUTCOMES OF THE PROJECT

Central findings

The project places emphasis on the different understandings of the concept of precaution. As the different reports of the member states show, the concept is very contentious in its details and led to many conflicts among experts. In practise, the differ-

ent accounts have a strong impact on regulatory procedures. Narrow and broader accounts differ in three general respects – uncertainties in risk assessment, the trigger for management measures, and the scope of action (including alternative solutions). Despite institutional reforms regulatory disagreements continue, for instance, over the criteria for evidence, definitions of harms and means to manage uncertain risks.

One main outcome of the project is that different accounts should not be seen as fixed types but as dynamic tensions within the regulatory procedures. It is important to note that precaution has obtained its practical meanings through regulatory conflicts, more than by explicit interpretation or application of an a priori principle.

The project draws the conclusion that the diversity of views of member states is not considered impeding coherent policy or decisions. Through dynamic tensions among different accounts regulatory expert-procedures identified and addressed more scientific uncertainties than before. Thus, the precautionary principle helps to raise new questions about various unknowns in risk assessment. It shall be a flexible policy framework offering stronger means for shifting and clarifying regulatory criteria.

Options for action

The project analysed the need of common regulatory standards on EU level in order to handle existing expert conflicts. The establishment of the EFSA was an important step towards harmonizing the different understandings trough objective scientific advice. It is designed to override and reconcile national regulatory differences. However, the project made clear that on the EU-level different views are not being respected unless they are based on relevant scientific arguments. According to EFSA, Member States shall supply the necessary data and explain their scientific basis for different options within their risk management.

Identified future issues:

In future, this might stimulate more transparency in framing uncertainty and assigning a burden of evidence. Since many risks are not clarified yet, a great burden is born on science and expert judgements. Consequently common regulatory standards shall provide a more rigorous and transparent basis to deal with legitimacy problems.

Another future issue identified by this project is the broader participation of the public and stakeholders. The involvement of diverse stakeholders, including critical scientists and NGOs, can help to ensure that as many relevant questions as possible are addressed.

IMPACTS AND FOLLOW UP OF THE PROJECT

In every participating country as well as on the EU level a workshop with stakeholders such as regulators, scientists, industry and NGO representatives was held, where comments were collected and incorporated into the final report. These workshops took on different shapes in every country; in Austria, it was held as a “meeting on neutral grounds” between regulators from different ministries and scientists in order to explore policy future options.

The results of the project were published in a special issue of the scientific journal Science and Public Policy (32/4, 2005) and, individually, in various other scientific journals by several project team members.

CHALLENGES IDENTIFIED

The relation between scientific advice and political decision making on GM plants remains precarious despite agreed policy principles such as precaution. Rather than suggesting a once-and-for-all procedure with fixed and scientifically unambiguous criteria for the assessment of new GM plants, the authorisation, application and marketing of such plants and their products remain politically sensitive and open for negotiation. The issue turns out not to be able to be dealt with on the basis of science and law only, so that changes in the decision making due to political considerations will have to be taken into consideration in the future as well.

LITERATURE

Special issue on precautionary expertise for EU agbiotech regulation. Science and Public Policy 32(4), August 2005

AUTHOR OF THE REVIEW

Helge Torgersen

RISK ASSESSMENT OF GMO PRODUCTS IN THE EUROPEAN UNION. TOXICITY ASSESSMENT, ALLERGENICITY ASSESSMENT AND SUBSTANTIAL EQUIVALENCE IN PRACTICE AND PROPOSALS FOR IMPROVEMENT AND STANDARDISATION (2004) 1.3

BACKGROUND OF THE PROJECT

Context

Toxic and allergenic properties are considered focal aspects in the assessment of potential health risks of GM food. In contrast to other regulatory contexts such as chemicals, plant pesticides and food additives, detailed requirements for toxicity and allergenicity assessment have not been put into concrete terms until recently. During the time this study was carried out there was no detailed guidance available at all[1].

However, a number of genetically modified plants (GMPs) had already been authorised under Directive 90/220/EEC and the Novel Food Regulation. The authors state a distortion between the provided guidance for risk assessment and the complex situation characterised by rapid scientific progress, varying interpretation of EU regulation by the national authorities, and pressures from industry and public interest groups. The assessment practice resulting from this constellation is described as being time-consuming and inconsistent.

Demanding institution

The present monograph was funded by the Austrian Federal Ministry for Agriculture, Forestry, Environment and Water Economy and the Austrian Federal Ministry for Health and Women. The research that provided the basis for this document (two preceding studies in German language) was financed by the Austrian Federal Ministry for Work and Labour and by the Austrian Federal Ministry for Health and Women. Parliamentary documentation states that this compilation was carried out by order of the Austrian Federal Ministry for Health and Women.

Guiding questions

Which risk assessment practices exist regarding potential toxic and allergenic properties of GMPs? How would a consistent toxicity and allergenicity risk assessment approach look like? Which shortcomings can be identified in current risk assessment? Out of this review of the state-of-the-art, which proposals may be given in the context of recent regulatory developments for guidance documents etc.?

1 The authors mentioned the guidance document of EU's Scientific Steering Committee (SSC) that lists toxicity and allergenicity of gene products as issues to be considered. At present, there is the EFSA GMO panel's Guidance Document for the assessment of GMPs published in April 2004 (as an updated version of the SSC document) and actualized in 2006. This document more extensively addresses the aspects of toxicity and allergenicity.

BASIC DATA ABOUT THE PROJECT

Type of the project, methods

The present monograph is an abridged and condensed but updated English version of the content, conclusions and recommendations of two earlier research projects carried out in German language with the main goal to review the practice of risk assessment procedures on GMPs in the EU.

The practice of toxicity and allergenicity assessment was scrutinised in a range of Directive 90/220/EEC and Novel Food Regulation dossiers. Relevant dossiers were selected, investigated and their respective assessment procedure described. The different approaches to risk assessment were compared and evaluated. A literature review on the concept of substantial equivalence was also implemented. Based on this, the study elaborates proposals aiming at improvement and standardisation of risk assessment procedures. Surveys on toxicity and allergenicity assessment in regulatory documents covering GMPs in Europe and the US provided information which was included in the conclusions and proposals.

Topics

- current practice of toxicity and allergenicity assessment
- its shortcomings
- requirements for a comprehensive toxicity and allergenicity assessment
- proposals for improvement and standardisation of risk assessment regulation and practice

Duration

The two studies that form the basis of the present English version were conducted between 2000 and 2003. The English paper was first published in July 2004.

Participants

The current English version is authored by a subset of the original project team which consisted of scientists from the Austrian Federal Environment Agency, the Inter-University Research Centre for Technology, Work and Culture (IFZ) Graz, the ARC Seibersdorf Research GmbH, the Research Center for Biotechnology, Society and the Environment at the University of Hamburg and a range of individually contracted experts.

The subset of this team and, hence, the authors of the updated English version are: Armin Spök (IFZ), Heinz Hofer (ARC Seibersdorf), Petra Lehner and Rudolf Valenta (contracted), Susanne Stirn (University of Hamburg), and Helmut Gaugitsch (Austrian Federal Environment Agency).

Events

In the course of the investigation, various internal project workshops were held.

Prior to publishing the English version an international conference was held in autumn 2003 in Vienna, where the outcomes of the two preceding studies were discussed and a fundament for the updated English version was laid. Besides some of the studies' authors, a representative of the European Commission (Andreas Klepsch) and a member of the environmental NGO Global2000 gave lectures.

MAJOR OUTCOMES OF THE PROJECT

Central findings

With regard to the toxicity and allergenicity assessment procedures and the use of the concept of substantial equivalence, the study points out significant shortcomings in the dossiers based on Directive 90/220/EEC, as well as in the Novel Food Regulation dossiers:

- The formal structure of the risk assessment approach is not based on and does not clearly distinguish between exposure assessment and hazard assessment (which are both necessary). The claims of substantial equivalence are frequently based on trials and analysis that are not properly designed.
- Assessments and conclusions drawn often cannot be entirely verified given the lack of details.
- Although the overall approaches in risk assessment are similar in the dossiers, differences became evident at the level of details – this fact points to a lack of details in the guidance documents.
- Safety conclusions are often based on indirect evidence and/or assumption based reasoning, and they are partly based on questionable methods, approaches and assumptions.
- Unintended effects of genetic modification are usually not investigated and even dismissed. Significant differences found in compositional analysis are disregarded.

Options for action

Proposals were developed aiming at further improvement and standardisation of risk assessment:

- The structure of risk assessment approaches and dossiers should be standardised.
- The role of substantial equivalence for risk assessment should be further clarified.
- Significant differences in the results of analysis of the same GMPs should at least trigger repetition of the analysis.
- Dossiers should be "stand-alone" documents, including full reports of available safety studies, quoted literature, statistical evaluation sheets for compositional analysis, and thorough description of methods applied.
- The direct testing of toxic or allergenic properties should be preferred compared to indirect testing and assumption based reasoning.
- Testing should be extended to include whole-plant/whole-food testing.

Identified future issues

The authors mention that some of these proposals have already been included in most recent guidance documents. Others might require further discussion and even additional studies – the particular minimum set of toxicity endpoints, for example. Some proposals might require further improvement of testing methods or even the development of new methods.

IMPACTS AND FOLLOW UP OF THE PROJECT

Parliamentary debate

Austria refers to the study in an EU meeting of the Standing Committee on the Food Chain and Animal Health, claiming a comprehensive toxicological risk assessment as described in the study. In the Austrian Parliament there is no immediate discussion of the study. However, it details and shapes the Austrian position on GMP risk assessment issues.

Scientific recognition and public perception

An article based on the present study and written by some of its authors (together with other scientists) was published in the International Archives of Allergy and Immunology (137/2005).

Furthermore, the work is cited in Science, Technology & Human Values (32/1), in a Press Release of the Institute of Science in Society, and in a Nature Biotechnology correspondence. It was presented on the Third World Network's website and mentioned as additional material by the Third Meeting of the UNEP Ad Hoc Technical Expert Group on Risk Assessment.

CHALLENGES IDENTIFIED IN THE PROJECT

At the time of this English paper's publication, the 2003 SSC guidance document was the state-of-the-art standards on GMP risk assessment. As mentioned, it contains some of the proposals made by this study, as, for example, the need of complete dossiers containing all information required for a full risk assessment. Other aspects, however, remain unclear, ambiguous, or disregarded: Good Laboratory Practice is only demanded for toxicological studies. The SSC guidance is ambiguous with regard to the toxicological testing of the introduced proteins. The possibility of secondary effects is acknowledged, but in a more limited way than in this monograph. Further guidance for homology studies than the indications given by the SSC document is needed. Unlike the case-by-case basis favoured by the SSC guidance notes, this paper proposes compositional analysis for all processed products.

Taking into account these differences, this monograph sees the challenges in addressing the shortcomings still remaining. If this is not accomplished by further and better regulation, risk assessment practice on toxicity and allergenicity is still to be called deficient.

LITERATURE

Spök, A., Hofer, H., Lehner, P., Valenta, R., Stirn, S., Gaugitsch, H. (2004): Risk Assessment of GMO Products in the European Union. Toxicity assessment, allergenicity assessment and substantial equivalence in practice and proposals for improvement and standardisation. Austrian Federal Environment Agency. Wien

AUTHOR OF THE REVIEW

Helge Torgersen

FEASIBILITY STUDY ON »GMO-FREE« CLAIMS AND THE AVOIDANCE OF GMOS IN FOOD (2005) 1.4

BACKGROUND OF THE PROJECT

Context

The study bases its predications regarding to the feasibility of a correct use of the label "GMO-free", on the one hand, on the definition according to the Codex Alimentarius Austriacus and, on the other hand, on the EU-regulation 1829/2003 concerning the (not required) labelling of animal feed and comestibles as GMO.
The public debate on GMOs in Austria was a more critical one compared to other EU Member States. Moreover, it was characterised by an unusual common understanding between political representatives, social movements and significant parts of the agricultural sector. This constellation led to a more restrictive handling of the label "GMO-free" in Austria. For example, the Austrian label requires additional standards concerning the application of production facilities, the fabrication of additives, and feeding.
The study was carried out while the use of GM-seeds in Austria and other EU Member States was prohibited by regulations of the EU-Council. Hence, the possibility was excludable that in Austria and large parts of the EU there would be GM-seeds employed. In case of additives, the situation in the year 2005 was already different: some of them were almost exclusively accessible from sources involving GM-micro-organisms.

Demanding institution

The Austrian Federal Ministry of Health and Women, the Austrian Federal Ministry of Economics and Labour and the AMA Marketing GesmbH assigned the Austrian Agency for Health and Food Safety with the realisation and coordination of this feasibility study.
The study was realised in cooperation with the University for Natural Resources and Applied Life Sciences and was continuously evaluated by Prof. Maurer, head of the former Ludwig-Boltzmann-Institute for Organic Farming and Applied Ecology and now chairman of the new Bio Research Austria Institute.

Guiding questions

- Is there a transfer of GMOs from animal feed to derived food products?
- Are the raw materials and additives for feed production available?
- From the viewpoint of nutritional requirements, is the use of GMO-free feeds feasible?
- Does a GMO transfer happen via bee products?
- What strategies and efficient monitoring exist to avoid GMO contamination?
- From an economical viewpoint, is the use of GMO-free feeds feasible?

BASIC DATA ABOUT THE PROJECT

Type of project

The present project is a feasibility study that tries to estimate the existing possibilities (taking into account nutritional requirements, economical factors and constraints, etc.) to accomplish the requirements established in the legal frameworks in Austria and the EU. A broad inquiry into Austrian and international scientific studies and publications forms the basis of this study. The study investigates legislative texts and economical measures (market prices; amounts of consume and production of seeds, etc.), and undertakes some basic calculations to estimate the differential costs for the production of food applying GMO-free feeds.

Topics

The topics addressed by the study are basically the legal situation for the denomination of a product as "GMO-free" in Austria and the EU, the necessities to meet the legal requirements and control their compliance (monitoring) and the additional costs of gaining the "GMO-free" label. Besides, the world agricultural product market is taken into consideration regarding the availability of indispensable import products.

With these concrete topics the main problematic of the feasibility of GMO-free products appropriate to the current legal frameworks is addressed.

Duration

The study was commissioned in late autumn 2004, finished and published in November 2005.

Participants

- Austrian Agency for Health and Food Safety: Leopold Girsch (project management),
- Institute for Seeds: Natascha Balarezo (internal project coordination), Christine Kargl
- Institute for Animal Feed: Veronika Kolar, Thomas Kickinger, Herbert Würzner
- Vienna Institute for Comestible Testing: Rainer Bernhart, Klaus Riediger
- Risk Assessment: Roland Grossgut, Daniela Hofstädter
- Institute for Apiology: Rudolf Moosbeckhofer
- Biochemistry Competence Centre: Hermann Hoertner, Rupert Hochegger

Subcontracts

- University for Natural Resources and Applied Life Sciences (Institute for Marketing and Innovation): Siegfried Pöchtrager, Josef Penzinger, Stefan Großauer
- Evaluation: Ludwig Maurer

Events

The study was presented to a broad range of interest groups at the end of 2005. On November 2nd, 2005, there was a press conference at the Austrian Agency of Health

and Food Safety in Vienna. In the following weeks until February 2006 there were presentations, for example, for the Chambers of Agriculture of Austria, Upper Austria, Styria and Lower Austria and other communities of the agricultural sector.

MAJOR OUTCOMES OF THE PROJECT

Central findings

- No evidence was found in the international scientific literature stating that even traces of transgenic DNA were detectable in foods derived from animal production after feeding GM-feed.
- 90% of the imported soy used for feeding in Austria is transgenic. The global share of GM-soy is still increasing. However, following the requirements from the EU directive 1829/2003, in a short- and medium-term raw materials for animal feed production which do not have to be labelled as GMOs will be available. With respect to the provisions established by the Austrian Codex, protein substitutes for soybean extraction meal produced in Austria and the EU will be available. It has to be said that these substitutes can only be used to a certain limit and no forecast can be given for the development of the raw material markets. In terms of the additives for animal feed production, there are products available which do not require labelling in accordance with the EU-directive but would so according to the Austrian law.
- Feasibility of the usage of feed labelled as GMO-free: following the EU directive, it is feasible in a short- and medium term; following the Austrian Codex, it is feasible only for cattle but not for pigs, poultry and turkey (because of the necessary additives)
- The content of pollen in honey is usually noticeably below the labelling threshold levels in accordance with the EU-directive.
- Monitoring and strategies to avoid contamination: self-control of the companies; separated and closed production processes; appropriate cleaning; more provisions in monitoring and surveillance for the Austrian label
- The use of animal feed containing soybean extraction meal labelled as GMO-free or not requiring labelling leads to additional costs of up to over 8%. These costs vary considerably depending on the line of production (beef, pigs, etc.). In the future, by-products from bio-fuel production that contain protein and are available in Austria and the EU will be commercially employable as a protein supplying substitute for soybean extraction meal.

Options for action

- enhance the production of substitutes for soybean (for example, from bio-fuel production)
- try to assure a reliable labelling in the world market's production chains
- try to safeguard Austria's share of Brazilian and US GMO-free soybeans

Identified future issues

- monitor the world raw material market's development and the share of available and affordable GMO-free products
- integrate more aspects into the calculations of the additional costs

IMPACTS AND FOLLOW UP OF THE PROJECT

Parliamentary debate

The Federal Minister of Agriculture, Forestry, Environment and Water Management mentioned in a parliamentary inquiry presented by the Green Party in the year 2006 that the present study was presented to the ministerial working group on genetic engineering. Moreover, he cited the study's insights into the additional costs and technical needs for contamination prevention. In another parliamentary inquiry in 2004, also presented by the Greens, the same Minister explains the financing and planning of the study. He says, inter alia, that there was (as usual) an interchange on the planned contents with the relevant experts, on beforehand. Also in the regional Parliament of Salzburg the study was subject of a parliamentary inquiry.

Interestingly, the study was cited in a parliamentary debate in the German Bundestag by Christel Happach-Kasan (FDP). She exposed and interpreted the study's finding that GM-free pig and poultry breeding is quite impossible because of the additives needed. Not using genetic engineering technologies would lead to a higher mortality in the animal stocks. There was disagreement expressed by the German Greens.

Public perception

After the press conference on November 2nd, 2005, there was ample recognition of the study in local media and partially in the German-speaking world. The Austrian Press Agency published an article delivered by the Agrarian Information Centre. The ORF (the Austrian public news channel) reported, too.

Furthermore, the study was mentioned by the Austrian Federal Chamber of Commerce. Details were cited by the Austrian Chamber of Labour, Greenpeace, Austrian agricultural communities such as BioAustria, the German Information Service on Genetic Engineering (Informationsdienst Gentechnik) and other German citizen's action committees.

The public perception of the study is characterised by the conclusion that GMO-free production of comestibles is feasible, principally, but there are some costs to take into account. However, there are also new opportunities for the Austrian agriculture, especially concerning the production of GMO-free substitutes for soy from bio-fuel.

Scientific recognition

A research paper of the Austrian Federal Ministry of Health and Women on the need to label GMOs already pointed to the study in 2005, before its finishing.

CHALLENGES IDENTIFIED IN THE PROJECT

The development of the international market for reliable GM-free seeds and feed can not be predicted and lies outside the Austrian room for manoeuvre. The availability of GM-free additives is already quite limited.

LITERATURE

Austrian Agency for Health and Food Safety/University for Natural Resources and Applied Life Sciences, Vienna (2005): Feasibility Study on "GMO-free" claims and the avoidance of GMOs in food.

AUTHOR OF THE REVIEW

Helge Torgersen

COEXISTENCE (2005) 1.5

BACKGROUND OF THE PROJECT

The cultivation of genetically modified crops is growing steadily and fast in the ultimate years, mostly in North and Latin America. In the EU there is already an extensive set of legislation on the regulation, admission and limitation of GMO cultivation, import etc.

In 2003, the European Commission released the Recommendation No. 2003/556/EC on guidelines for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming. The Commission underlined that these guidelines should focus on economic consequences of GMO cultivation given that ecological and health aspects are already taken into account in the GMO admission procedure. The scope of the guidelines spans from the agricultural production to the first point of sale – higher levels of elaboration are not considered. In addition, national catalogues of measures, as to be defined by the member states, should allow for every country's specificities regarding topography, climate, the agricultural structures and the production systems. The Commission's Recommendation together with the country's implementation strategies should ensure that the compliance with the threshold values for non-GMOs is not impeded by the diversity of the producing regions, the productive systems and technical matters.

The Austrian situation in the domain of green biotechnologies is characterised by a quite restrictive legislation and a broad GM-critical consensus between the political parties, farmers, interest groups, NGOs and the public. Seeds in the initial examination have to be free of GM contaminations to be authorised in Austria. In the follow-up examination a threshold value of 0,1% is fixed.

BASIC DATA ABOUT THE PROJECT

The present study was conducted (under the guidance of Prof. Georg Grabherr) by Kathrin Pascher and Marion Dolezel from Vienna University's Department of Conservation Biology, Vegetation Ecology and Landscape Ecology between the end of 2003 and March 2005 on behalf of the Austrian Federal Ministry for Health and Women (Section IV). The overall goal of the document is to define rules and measures providing a general framework for coexistence of GM-, conventional and biological crops for the specific Austrian case as demanded by the Commission's Recommendation. The authors argue that measures for the cultivation of GM-crops would assure the farmers the possibility of planting just the crops they want to, as well as the consumers the security and freedom of choice they look for.

Following the Commission Guidelines which establish that the measures have to be crop-specific, the study focuses on maize, oilseed rape and sugar beet – for the authors primarily expect these crops to be commercially cultivated as GMOs in Europe.

Sources of GM-contaminations are outlined and evaluated, then the measure proposals for the reduction of these contaminations are given and experiences from other countries with coexistence of the mentioned crops are incorporated.

The project was realised in terms of a scientific study from an eco-biological perspective. In the course of the project, the authors attended a series of conferences and lectures, amongst others the 1st European Conference on the Coexistence in Denmark, a conference on GMO Risk Assessment in Vienna, other forums on coexistence in Austria and a Conference of the European network of GMO-free Regions.

There were basically two methods applied: Firstly, a theoretical evaluation of the problematic of coexistence and contamination by means of a review of existing studies of a European and non-European institutions and authorities (FiBL, Union of Concerned Scientists, BUWAL, JRC, MAFF, MAF), literature databases, organisational websites (saveourseeds.orf, transgen.de, biosicherheit.de, ucsa.org, etc.), personal contacts to Austrian authorities, organisations and firms (AGES, Saatbau Linz, ZAMG, Chambers of Agriculture, etc.), and conference attendance. Secondly, GMO-crop growing was simulated for different Austrian regions. The amount of field losses due to the necessary belts of isolation (to avoid exogamy) was simulated for random and clustered repartition of GM-crop fields in the cases of maize, oilseed rape and sugar beet.

MAJOR OUTCOMES OF THE PROJECT

The study's outcome is a catalogue of measures to prevent contamination with GMOs and to delineate the exigencies of a reasonable coexistence.

In the case of **maize**, the use of barriere-plants or of varieties with different flowering dates will not be sufficient to reduce GMO contamination rates to 0,9%. Isolation distances of at least 200m seem to be the only viable measure to guarantee this quota. However, if GM proportions grow beyond 10% and if a threshold value of 0,1% in the harvest is to be realised, cultivation, harvest and post-harvest processes have to be thoroughly separated and cross fertilisation completely avoided. Not even isolation distances of one to several kilometres could assure this due to other factors that until now couldn't be exhaustively studied – the establishment of large-scale GMO free zones would be the only possible way to guarantee these low threshold values.

Imports of basis seeds and possible cross fertilisation are the crucial points for contamination control in **oilseed rape**. Necessary measures for the consumption production are, therefore, a purity control of the imported basis seeds, long growing intervals of at least 8 to 12 years (to reduce volunteers of oilseed rape) and isolation distances of 4 kilometres (allowing for the flying distances of pollinating insects). Regional and continuous examinations of their effectiveness could facilitate more flexible isolation distances. The management of the segetal weed flora, barriers with non-GM oilseed rape and the removal of bee hives near the fields seem to be viable measures, too. Transportation routes should be as short as possible. However, the creation of a closed seed production area would be the most effective measure. Considering the specificities of agronomic and topographic structures, climatic particu-

larities, the necessary extent of the isolation zones, regional occurrence of volunteers, etc., the authors argue that coexistence of oilseed rape will not be feasible in Austria.

Sugar beet for consumption is not flowering. Hence, the unwanted hybridisation events affect seed production areas. To achieve a threshold value for GM contamination of 0,5% much larger isolation distances than the currently widespread 300, 600 or 1000m would be needed. The highest risk is currently posed by imported seed. Reliable choice and control is needed; moreover, suitable cultivars, coordination of farmers, at least 2 kilometres of isolation distance, control of bolters, weed beets, volunteer beets and Beta-forms. Pollen barriers should be used and a crop rotation of at least eight years guaranteed.

Beyond these crop specific arguments the study presents measures to avoid **technical contamination** at cultivation and harvest. The technical processes of GM and conventional or organic field crops should either be completely separated or strict guidelines for adjustment, operation and cleaning measures should be provided and demanded. Seeding and harvesting machines have to be cleaned before and after their application for GM crops. Losses during the transport must be prevented, hoppers cleaned and controlled, contracts established (e.g. between vicinal farmers on location of their fields or on the requirements and criteria for a joint use of machines), etc.

IMPACTS AND FOLLOW UP OF THE PROJECT

A Green Party's delegate to the National Assembly asked the Federal Minister of Health and Women and the Federal Minister of Agriculture, Forestry, Environment and Water Management in a written parliamentary request about the costs of coexistence in Austria. As an initial point he cited the present study which, in his interpretation, comes to the conclusion that the coexistence of GMOs and conventional and biological products is possible, if at all, only with high technical and organisational efforts.

The study is also cited by further studies of the Federal Ministry of Health and Women and the Austrian Agency for Health and Food Security, the network of GMO-free regions and an Upper-Austrian text introducing this region's characteristics and the structure of its economy. In a slightly different reading some of the study's findings are presented in an information letter of *Les Professionels des Semences et de la Protection des Plantes*, a French syndicate of the seeding industries. They mention that the study posits the possibility of coexistence always respecting the right isolation distances. It is just rape where coexistence doesn't seen viable in Austria.

CHALLENGES IDENTIFIED IN THE PROJECT

The study's tenor is that coexistence is possible in some cases but not in all. And even if it is possible this would lead to economical and social costs and much regulatory work on a national base. The mentioned feasible measures to assure coexistence

are presented in a sceptical light. The whole issue of coexistence seems to be a problematic one since it is at least an expensive endeavour and potentially impossible, at the end. The reader could get the impression that the study provides and tries to provide scientific arguments underpinning GM-critical positions.

LITERATURE

Pascher, K., Dolezel, M. (2005): Koexistenz von gentechnisch veränderten, konventionellen und biologisch angebauten Kulturpflanzen in der Österreichischen Landwirtschaft – Handlungsempfehlungen aus ökologischer Sicht. Bundesministerium für Gesundheit und Frauen, Sektion IV, Band 2/05, Wien http://www.bmgfj.gv.at/cms/site/standard.html?channel=CH0810&doc=CMS1113391269254 English summary: http://www.bmgfj.gv.at/cms/site/attachments/6/4/4/CH0810/CMS1113391269254/summary_-_coexistenz.pdf

AUTHOR OF THE REVIEW

Helge Torgersen

THE ROLE OF PRECAUTION IN GMO POLICY (2006) 1.6

BACKGROUND OF THE PROJECT

Context

In the year 2000, the European Commission published the so called Communication on the Precautionary Principle. This document proposed guidelines for the handling of scientific uncertainty. Since then, precautionary language and criteria have been integral part of the respective legislation, for instance, in the Deliberate Release Directive concerning GM crops or the Biosafety Protocol. Today, the Precautionary Principle (PP) is firmly established in European law.

Notwithstanding, the principle has not ceased to be contentious and much less to be interpreted in different ways. Besides the narrow account of the European Commission's document, there are broader ones from other sources like the European Parliament, experts, member states and stakeholders. The project "Precautionary Expertise for GM crops" (see section 1.2) studied varying understandings and applications of the PP within and between 7 European States. The scenario in Austria could be sketched as characterised by a wide GMO-critical political consensus between government, stakeholders and the public, despite divergent concepts of precaution.

Demanding institution

The present conference was initiated jointly by the Austrian Federal Ministries of Agriculture, Forestry, the Environment and Water Management and of Health and Women. The Federal Environment Agency was responsible for realisation. The conference took place in the frame of the Austrian EU-Presidency in the first half year of 2006. The actual and possible development of the PP in GMO policy was examined from legal, scientific, and political perspectives as well as on the basis of case studies at national, EU and international levels.

Guiding questions

- What different interpretations of the PP exist?
- Is there room for the principle in the EU legislative framework and how is it specified?
- What are practical experiences with the principle?
- What is the scientific background to be taken into account?

BASIC DATA ABOUT THE PROJECT

Type of project and duration

The project was an international and interdisciplinary expert conference held at the Hofburg in Vienna with the participation of experts and stakeholders from a scientific and a political background. It took place on the 18th and 19th of April 2006.

Topics

Relevant aspects of the precautionary approach towards regulation of GMOs were addressed. The main topics discussed were possibilities and limits of precautionary measures within the existing legal framework, the scientific background of precautionary approaches, as well as the practical experiences of putting to use the principle.

Some of the contributions' subject areas were how EU legislation on GMOs relates to and gives room for the PP, how and where it is discussed controversially, how it is interpreted in the CEE countries and what were practical experiences with the use of the principle, as well as the question of risk assessment.

Participants

Approximately 135 scientists, state and interest group representatives

Speakers: (in order of appearance):

- Hugo-Maria Schally (Chairperson), DG Environment, European Commission
- Christine von Weizsäcker, Germany
- Kathryn Tierney, DG Environment, European Commission
- Liina Eek, Ministry of the Environment, Estonia
- David Wield, Open University, UK
- Eric White, Legal Service, European Commission
- Thomas Jakl (Chairperson), Ministry for Agriculture, Forestry, Environment and Water Management, Austria
- Brian Wynne, Centre for the Study of Environmental Change, Lancaster University, UK
- Jürgen Zentek, Freie Universität Berlin, Germany
- Christopher Pollock, Institute for Grassland and Environmental Research, UK
- Margaret Mellon, Union of Concerned Scientists, USA
- Katja Moch, Öko-Institut Freiburg, Germany
- Michel Haas (Chairperson), Ministry for Health and Women, Austria
- Brian Wynne on behalf of David Gee, European Environment Agency
- Harry Kuiper, GMO-Panel EFSA, RIKILT – Institute of Food Safety, The Netherlands
- Jan Husby, Norwegian Institute of Gene Ecology, Norway
- Simon Barber, Plant Biotechnology Unit, EuropaBio
- Helmut Gaugitsch, Federal Environment Agency, Austria

IMPACTS AND FOLLOW UP OF THE PROJECT

It was concludingly addressed by Helmut Gaugitsch that there is a need for a follow-up. A good starting-point would be the discussion on the PP and ways towards its application. Kathryn Tierney (EU Commission) enunciated that the debate on GMOs and the PP would continue at the EU Environmental Council in Luxembourg in June 2006.

There was no parliamentary debate on the conference. However, it was presented by the authorities as an asset in the Austrian EU-presidency 2006 to address the issue in such an international expert conference, bringing forward the respective EU-wide discussion. The national press (Der STANDARD, 20.4.2006) reported in a short statement. The Institute for Applied Ecology (Freiburg/Germany), the USDA Foreign Agricultural Service, biotrin.cz and the Biosafety Information Centre mentioned the conference on its website.

MAJOR OUTCOMES OF THE PROJECT

Central findings

As Helmut Gaugitsch in his closing remarks points out, there is broad consensus around an understanding of the PP as one of the central aspects of European GMO legislation. It was described as a tool that allows countries to adopt the level of protection that was felt necessary, even in the absence of scientific certainty. However, it remains questionable whether there is a common understanding of the PP and the way it can or should be implemented.

Regarding the question whether the PP is a risk management issue only, it became clear that risk assessment on its own is an important prerequisite for decision making but not enough as it is inadequate to assess uncertainty, by definition cannot assess ignorance and also falls short of acknowledging any benefits. As Bryan Wynne expressed it, precaution should rest on the recognition that knowledge is always limited. The assumption that the need for precautionary policy can be subjugated to preliminary risk assessment is misconceived.

The PP should contribute to protection and not protectionism and should be used to gain further scientific knowledge. It was stated that the PP can be a possible instrument of scientific innovation.

There were also voices who proposed a modification of EFSA's format and inner EU-communication on orientations toward the PP. Others, again, expressed the opinion that Europe-wide universalist approaches to the PP, maybe, will not work (considering that some regions see commercial benefits in being GM-free etc.). There will not be a single understanding and application of the PP. Particularly "ecologically sensitive" areas will have different approaches, for example.

Eric White from the European Commission's Legal Service claimed that the PP is alive and perfectly compatible even with the WTO.

Options for action and identified future issues:

- continue to discuss the concept of the PP in the national, EU and international level towards application and action
- discuss the different national and EU wide conceptions of the PP to get to a more common understanding
- elaborate mechanisms to include statements on the application of the PP in GMO product notifications

- improve, harmonize and standardize the risk assessment instruments nationally and EU wide (should include guidance on which kind of data should be included in notifications and the methodology to generate them), keeping a balance between clear guidance and case-by-case sensibility
- in order to gain further knowledge on GMOs and to address uncertainty and ignorance, research projects could and should take approaches as the PP more into account
- enter into a dialogue with stakeholders (and involve them) at the national and the EU level and between them; risk communication should be improved and a system for public participation needs to be set up

CHALLENGES IDENTIFIED IN THE PROJECT

A considerable challenge identified is to find ways from the PP to an applicable approach and action and to define its relation to the risk assessment framework. The PP should not be used as a technical barrier to trade and a tool for protectionism.

There lies a twofold challenge in the concept of PP as it is present in nowadays' legislation and practice: On the one hand, the PP has to be elaborated and discussed on general grounds, looking for ways to apply and regulate it. On the other hand, the various interpretations of the principle have to be consorted.

The EU legislative framework has to be fine-tuned to provide for a higher degree of transparency and thus to fulfil the expectations on decision-making.

It was argued that the "Sound Science" approach (firmly present in the US policies), with its accents on delaying safety obligations until causal chains of harmful impacts are fully proven, runs counter the PP – with this, originating a possible and already manifest conflict between the US and Europe (see the current WTO dispute). The EU could possibly use the "de facto coalition" with the developing countries in favour of the PP, to enforce its position and foster its understanding of protection.

LITERATURE

Federal Ministry of Health and Women (Ed) (2006): Conclusions of the conference "The Role of Precaution in GMO policy", 18.-19. April 2006, Vienna http://www.bmgfj.gv.at/cms/site/standard.html?channel=CH0810&doc=CMS1145612477419

AUTHOR OF THE REVIEW

Helge Torgersen

DENMARK 2.

GENETICALLY MODIFIED FOODS (1999) 2.1

BACKGROUND OF THE PROJECT

The DBT- project *"Genetically modified foods"* from 1999 was carried out due to the apparent scepticism among the Danish population. At that time, genetically modified foods were about to enter the Danish market, but it seemed that the Danish consumers did not associate any direct advantages with them. However, it was impossible to reject that benefits would eventually emerge in step with the development of the technology.

At that time, legislation on genetically modified foods had not yet been completed within the EU and the potential benefits and risks considering GM foods were still associated with much uncertainty. Thus, the aim of the project was to provide a multi-faceted public debate on GM foods in order to enhance the dialogue between decision makers and the public.

BASIC DATA ABOUT THE PROJECT

The project was designed as a consensus conference that took place during three days. The Danish Board of Technology appointed a panel of fourteen citizens who were asked to consider genetically modified foods. Before the actual consensus conference, the citizen panel met twice and discussed GM foods based on some introductory information. At the conference, thirteen experts were invited to make a presentation of their knowledge and opinion considering GM foods. During the two first days of the consensus conference the experts answered questions from and discussed with the citizen panel. Conclusively, the citizen panel created a final document containing the evaluations and recommendations considering GM foods on which the panel could all agree.

Through the consensus conference ten questions considering genetically modified foods were addressed both by the experts and the citizens. In the final document, each question is evaluated by the citizen panel and followed by some recommendations. The main topics that characterized the ten questions concerned amongst others: environmental impacts, human health, market conditions, national and international regulation, information, and ethics.

MAJOR OUTCOMES OF THE PROJECT

The consensus conference concluded that the production of genetically modified foods undoubtedly affects nature's cycle. However, the experts strongly disagree about the seriousness of the effect and whether or not the effect is hazardous. Argu-

ments for and against GM foods were discussed among the citizen panel and resulted in some recommendations. These recommendations emphasize some of the challenges that the further development of GM foods involves.

The panel emphasized the importance of preserving the biodiversity of plants and animals and to protect the natural eco-systems. Thus, the citizen panel agreed that it should be possible to hold manufacturers of GM foods responsible for adverse effects on human health and the environment.

The laymen panel believed that authorisations for tests and production of genetically modified organisms should be subjected to severe regulations for risk evaluation and requirements of efficient control. Further, public regulation was recommended as a means to offset monopolistic companies from controlling the market for GMO's. It was also suggested that companies should lose their right of use for unapplied patents. The panel also supported the idea of a convention guaranteeing developing countries free access to utilising gene technology patents. Because biotechnological research to a wide extent is concentrated in the private sector, the panel recommended that public funding for research in the field should be increased.

The panel highlighted the importance of ensuring consumers still to be guaranteed a choice between genetically modified and non-genetically modified foods. It was further emphasized that dissemination of information is crucial and that comprehensible and informative declarations of contents are necessary.

The panel further recommended that ethical aspects should be given the same priority as purely technical aspects in relation to applications for testing, production and marketing of GM foods. Thus, the panel recommended that a committee charged with ensuring an ethical evaluation of the authorisation process should be established.

IMPACTS AND FOLLOW UP OF THE PROJECT

The consensus conference kick-started a more widespread debate on genetically modified food in the public. The Danish Board of Technology found that the political interest in the field increased in the wake of the conference. Both national and EU-politicians showed interest in the project and were curious to know what the citizens worried about.

CHALLENGES IDENTIFIED IN THE PROJECT

Different challenges considering genetically modified foods and how to handle them appeared throughout the project. First of all it became clear that there is a conflict between experts when it comes to assessing the risks and benefits of GM foods. Hence, the project showed that experts disagree whether GM foods are predominantly beneficial or if they pose a threat to the environment and/or human health. These disagreements pose a challenge to the further discussions considering GM foods. Another challenge that was identified considered the question of monopoly

highlighting that knowledge about GM foods is only available to very few people. The question of responsibility was further a challenge that appeared during the consensus conference; who can be held responsible if something goes wrong with GM foods? The challenge is to take such matters into consideration. The project further emphasized the importance of ethical considerations when dealing with genetically modified foods. Thus, the question is whether the utility value of GM foods matches up with the ethical issues.

LITERATURE

The Danish Board of Technology, (1999): Gensplejsede fødevarer. http://www.tekno.dk/pdf/projekter/p99_genspl.pdf; English summary: Genetically modified foods. http://www.tekno.dk/pdf/rtt_125_uk.pdf

AUTHOR OF THE REVIEW

Søren Gram

GENETICALLY MODIFIED CROPS IN DEVELOPING COUNTRIES – CHALLENGES FOR THE DEVELOPMENT AID (2003) 2.2

BACKGROUND OF THE PROJECT

The DBT project *"Genetically modified crops in developing countries"* were initiated based on the conclusions of the UNDP's Human Development report 2001, which focused on the role of ICT and biotechnology in the reduction of world poverty. The report stated quite a clear position in favour of biotechnology by emphasizing an opposition to put restrictions on technological developments. Instead, the report called on an examination of what it takes to control and exploit new technology in everybody's interest. The UNDP report gave rise to immediate counter-reactions emphasizing that the problems of hunger and poverty in the third world countries are a matter of distribution because we already produce enough food to feed the whole world. Based on these counter-reactions the DBT set out to assess the pros and cons of using genetically modified crops to fight poverty and hunger in the third world.

BASIC DATA ABOUT THE PROJECT

The project ran from 2002 to 2003 and involved an interdisciplinary task force appointed by the Danish Board of Technology. The task force consisted of six experts all with specialist knowledge within the field of biotechnology and development aid respectively. The objective of the task force was to consider if, and how, dealing with GM crops should be an integrated part of the official, Danish development policy.

The task force arranged three workshops where leading experts within selected areas presented and discussed experiences and the latest knowledge. The first workshop assessed the technical and environmental possibilities and risks regarding already existing biotechnologies. The second workshop assessed social, environmental, ethical and cultural issues. It aimed to assess the implications and desirability of using biotechnology in third world farming structures. The final workshop discussed the compatibility of GM food with the overall aims of Danish development policy in relation to using participatory methods, fighting poverty, the precautionary principle etc. During all three workshops the task force invited other leading experts to contribute with comments, ideas and their expertise on the matter.

Through the project, the task force was asked to answer a two-pronged question, which constituted the starting point of the DBT project; *Can Danish development aid be used positively to 1) incorporate genetically modified crops into the work of improving the living conditions of the poorest population groups in developing countries – and 2) can this be done without conflicting with existing Danish development policy strategies?* The task force approached the questions in view of the fact that the dissemination of GM crops is already taking place – just not considering Danish development aid. The first part of the question was considered to be too complex and

diverse to be answered by a simple yes or no, which is why the task force decided to take a diversified, more pragmatic and action-oriented approach. Thus, the DBT report does not contain arguments for or against GM crops as such but rather provides a basis for the assessment of benefits and drawbacks of the possible use of GM crops in specific contexts. Considering the second part of the question, the task force assessed that the use of GM crops in developing countries would not necessarily conflict with Danish development aid policy.

The result of the project was communicated through a report targeted at institutions and organisations engaged in agricultural development in the poor countries of the world, and further at politicians, researchers, corporate staff or others who, directly or indirectly, influence or are involved in agricultural development, legislation, commerce etc. in the third world.

MAJOR OUTCOMES OF THE PROJECT

The project was concluded by several conclusions and recommendations, which were further supported by a list of premises to constitute a framework for aid organisations when and if a developing country needs assistance in dealing with GM crops. The premises were:

- Each GM crop must be assessed individually.
- The same yardstick cannot be applied to all developing countries.
- Existing GM crops are primarily adapted to the needs of farmers in the rich part of the world.
- Development of GM crops is slow, i.e. there are relatively few GM crops on the market and relatively few on the way in.
- Safety approval of GM crops is expensive since the control procedures are extremely comprehensive.
- Many developing countries do not have the capacity required to undertake needs assessment and control and would find it difficult to make their own assessment of whether they would benefit from the crops, and whether they could comply with the control and safety regulations.
- Patents influence development, and this may cause developing countries major legal and economic problems when it comes to the use and development of GM crops.
- GM crops may have an adverse effect on developing countries' competitiveness and access to western markets.
- The consequences of introducing GM crops are uncertain. No-one knows for sure what their impact will be on the environment, nutrition and biodiversity.

The task force's main message was that GM crops represent one among many technologies that may contribute to solving food supply problems in developing countries, but this form of agriculture is no miracle solution – at least not in the short or medium term. The task force assessed that Danish development aid should continue to focus on a broad range of technological and institutional solutions in the agricultural area with focus on responding to the needs of the poor farmer. Thus, the task

force considered GM crops only to play a relatively limited role in the immediate future. The task force further emphasized that the question of how best to assist countries must be assessed specifically from case to case and from country to country. Besides these more general recommendations, the task force offered more specific recommendations within four focus areas: technology, political policy, institutions and society.

IMPACTS AND FOLLOW UP OF THE PROJECT

In the wake of the project, the Ministry of Foreign Affairs of Denmark, which is in charge of the Danish development policy, invited the Danish Board of Technology to give a presentation of the project. The Ministry does not usually consult external organisations, which is why the interest in the DBT report must be considered quite an acknowledgement of the project.

CHALLENGES IDENTIFIED IN THE PROJECT

Conclusively, the task force emphasized that developing aid organisations will be failing in their responsibility if they fall short to adopt a position with regard to GM crops and their use in developing countries while it is necessary to examine whether certain GM crops might assist developing countries in ensuring sustainable agricultural production and food supply in the future. Thus, the question is not whether Danish development aid should decide on the use of GM crops in developing countries. Instead, the challenge for the Danish development aid organisations is to help the developing countries prepare for the coming of the GM plants. The challenge is to frame some conditions that enable developing countries to deal with and decide on the use of GM plants. It is crucial that developing countries are assisted with the organizing so the given countries are prepared administratively for the GM crops and possess sufficient scientific knowledge on the matter. Further, it is important that the developing countries have developed the necessary control to handle GM crops. Such issues are exactly what development aid should focus on in relation to GM plants.

LITERATURE

The Danish Board of Technology (2003): Genmodificerede afgrøder i udviklingslande - udfordringer for udviklingshjælpen. http://www.tekno.dk/pdf/projekter/p03_genmodificerede_afgroeder.pdf; English summary: Genetically modified crops in developing countries - challenges for the development aid. http://www.tekno.dk/pdf/projekter/p03_gen_mod_crops_summary.pdf

AUTHOR OF THE REVIEW

Søren Gram

CO-EXISTENCE BETWEEN GM CROPS AND NON-GM CROPS (2004) 2.3

BACKGROUND OF THE PROJECT

During the summer 2003, the European Parliament and the Council decided on a regulation concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms. With this regulation the EU reopened for approvals on the growth of GM crops. Based on this regulation, the European Commission recommended some guidelines for the development of national strategies and best practices to ensure the co-existence of GM crops with conventional and organic farming. Thus, the Danish government introduced a bill on co-existence. The bill on co-existence was framed with references to a report from 2003 by the Danish Institute of Agricultural Sciences concluding that co-existence is possible in Denmark considering some crops, but that there are also some exceptions were co-existence seems to be problematic.

To discuss the bill on co-existence, the Danish Parliament (Folketing) committee of Food, Agriculture and Fisheries and the committee of Environment decided to make a hearing to clarify the experiences with the growth of genetically modified crops.

BASIC DATA ABOUT THE PROJECT

The Danish Board of Technology arranged the hearing on the experiences of co-existence between GM crops and non-GM crops (within the framework of BIOSAM, a collaborative forum addressing ethical questions considering biotechnology). The hearing was open to everybody and took place May 11th 2004. Around 90 people (mostly experts and stakeholders) attended the hearing.

The hearing was split up into five sessions with each their theme. The first session of the hearing addressed the risk of GM crops spreading by a presentation of available knowledge on the subject. The next session moved on to discuss how to handle the spreading by either preventing or minimizing the spread of GM crops to fields with either conventional or organic crops. The third session of the day focused on the positive and negative consequences facing the market in connection with a growing of GM crops in Danish fields. The fourth session of the hearing discussed the issue of compensation in cases of spreading. The last session of the hearing invited different stakeholders to present their view on the bill on co-existence. Each session consisted of three short presentations by different experts. After the presentations in each session there were time for questions and discussions from the panel of politicians (committee members). Also a few questions from the audience were allowed.

MAJOR OUTCOMES OF THE PROJECT

The aim of the hearing was to initiate discussions, generate knowledge, and collect experiences on the co-existence between GM crops and non-Gm crops. The hearing was recorded and later transcribed and published in a report. Due to the method of this project the report does not contain any overall conclusions but emphasizes, through the different viewpoints, the challenges that the growing of GM crops causes.

Since Denmark has no actual experiences with the growing of GM crops, several international experts were asked to speak at the hearing to share their experiences with the co-existence between GM crops and non-GM crops. In Austria, the agricultural structure (small farms and narrow fields) makes co-existence problematic. Further, Austria has passed a law that prohibits growing of GM crops in the northern part of the country - GM-free zones. In Spain they have more experience with GM crops and Bt-maize have been grown since 1998. The GM crops have been grown without any kind of precautions, without any control considering the agricultural results and the environmental impacts, and without information and transparency. According to Friends of the Earth, there are several examples of spreading and thus contamination of conventional and organic crops in Spain. Experiences from Canada further show that the growing of GM crops will have a negative impact on organic farming.

Economic potentials and costs of growing GM crops in Denmark were further discussed with reference to international experiences. So far, the growing of GM crops seems to bring both extra costs and savings. GM crops will no doubt become a factor of competitiveness, and in order for Denmark not to loose its competitive advantages it was broad forward that it is necessary that Denmark launch GM crops now. In the end, it all comes down to the individual farmer whether there are economic incentives to grow GM crops. Besides the potential economic benefits that GM crops will bring about, other possible advantages considering GM crops were discussed. The effects of shifting to GM crops vary from crop to crop. Some of the advantages that have been identified include increased yield and productivity, a reduction in the use of pesticides, a more efficient weed control, less erosion and leaching, and a better economy for the individual farmer. If the experiences from the US are transferred to Europe there is thought to be great benefits for the farmer as well as the environment, the consumer and society.

These claims was however dismissed by other experts who emphasized that we should not expect too much from the GM crops since they have not really shown any great potentials yet. Furthermore, some experts questioned the potential environmental advantages that are often highlighted in discussion on GM crops. Thus, the hearing showed that there are quite contradictory opinions considering the potential benefits and detriments of growing GM crops.

The Government’s suggestion for a bill on co-existence includes a system of compensation that guarantees farmers whose crops are polluted by GMO’s to receive compensation. During the hearing both governmental systems of compensation and

private insurance covers were discussed in this context. It was further discussed whether such a system of compensation would cover all losses in a case of spreading from GM fields to conventional and organic fields.

The hearing pointed to a passing of the bill on co-existence in Denmark. Throughout the hearing it further became clear that the provisional proposal for the co-existence were in need of some adjustments before the final decision to pass the bill.

IMPACTS AND FOLLOW UP OF THE PROJECT

Based on the discussions and experiences derived from the hearing, the original bill of co-existence was faced with some proposed amendments. Thus, after the hearing, the bill of co-existence went through two additional readings before the final bill on co-existence was passed in the beginning of June 2004. There were several amendments employed in the final bill on co-existence and the more prominent ones included changes considering the system of compensation in favour of organic farmers and the protection of their interests, and a system of publication that would make information (position, size and type of crop) about GM fields available to the public. The final bill on co-existence further enabled the minister to revoke approvals in cases where there is a danger that an approval might be misused.

CHALLENGES IDENTIFIED IN THE PROJECT

The greatest challenge considering the co-existence between GM crops and non-GM crops is that of spreading. To avoid the spreading of pollen it is necessary to keep a distance (dependent on the biology of the crop and the threshold value) between fields with the same kind of crops, and other cultivated plants that the crop might cross with. Intervals of growing are assessed as one of the most effective methods to avoid the spreading of seeds. However, it is impossible to secure a complete non-spreading. In order to minimize spreading it is necessary to take some overall principles into account. First of all, the methods used to prevent spreading should depend on the crop being grown hereby considering the different characteristics that the different GM crops have. Secondly, the given system of agriculture, whereto the rules of co-existence should be applied, needs to be considered; e.g. geography and landscape. Ultimately, it is necessary to consider the scope of GM crops. Thus, co-existence is assessed to be possible if the necessary precautions are taken.

Conclusively, the hearing emphasized that the ultimate challenge is to make a better and extended system of compensation and that the rules on co-existence are addressed at a EU-level that secures that all member states have common rules considering co-existence and compensation. Considering the widespread scepticism towards GM products that can be identified within the Danish population, it is crucial that consumers are given a genuine choice between GM products and non-GM products. This can be ensured through labelling of products that are genetically modified and through a securing of GM-free production; e.g. that organic alternatives are available.

LITERATURE

The Danish Board of Technology, (2004): Erfaringer med sameksistens: Høring om erfaringer med sameksistens mellem genetisk modificerede afgrøder og konventionelle og økologiske afgrøder. http://www.tekno.dk/pdf/projekter/p04_Erfaringer_med_sameksistens.pdf

AUTHOR OF THE REVIEW

Søren Gram

NEW GM CROPS – NEW DEBATE (2005) 2.4

BACKGROUND OF THE PROJECT

The DBT-project *"New GM crops – new debate"* was initiated with the purpose to investigate how the Danish citizens assess the use of new GM crops involving plants producing medicine and industrial chemicals and new ornamental plants. The project was suggested by the Danish Forest and Nature Agency (part of the Ministry of the Environment). Previous projects and debates had shown a public scepticism towards GM food and feed crops due to the fact that the benefits of this technology are not obvious or directly related to the public. Thus, it became interesting to investigate the public's attitude towards the use of GM plants with completely different purposes than those usually discussed.

Many of these new applications of GM plants appear to bring potential benefits to both human health and the environment. GM plants producing medicine are expected to be able to reduce the production costs of certain expensive medicines, and in other cases to create new possibilities for treatment. For industrial use, plants are genetically modified to be little biofactories that produce raw materials and thus contribute to a minimization of the use of chemicals. Finally, GM ornamental plants would create inventions such as blue roses or durable harebells. Still, these GM plants are grown under the same conditions as GM food and feed crops.

Based on this, the project set out to examine how Danish citizens assess the potential advantages and disadvantages of the new GM plants. The aim of the project was to present arguments for and against: how are the plants' potential benefits and detriments considering health and environment assessed, and what are the economic possibilities and consequences – considering both the societal and the consumer level.

BASIC DATA ABOUT THE PROJECT

The project was addressed through the use of a citizens' jury. 2000 Danish citizens were invited via the Civil Registration Number register to apply for participation in the citizens' jury. On the basis of the applications received, 16 citizens were selected. The aim was to assemble a citizens' jury that was relatively representative regarding gender, area of residence, age, education and job.

The sixteen laymen took part in the citizens' jury that was assembled from the 28th of April to the 2nd of May 2005. A planning group assisted the Danish Board of Technology in planning the project and formulating the questions that the citizens' jury was presented with. During the five days of the citizens' jury, the laymen met with experts and stakeholders and discussed advantages and disadvantages of the new crops. Based on this dialogue, the citizens' jury formulated arguments for and against the new GM plants and conditions for the possible growing of GM plants in Danish fields and general recommendations in connection with this.

Ultimately, the citizens' jury was concluded by a vote upon the arguments, conditions and recommendations that expressed their attitude the best. Thus, citizens were not required to reach a consensus, but asked to prioritise the arguments elaborated by them-selves and then vote for those that they considered most important.

The citizens were asked to consider the new uses of GM plants at three different levels: what are the arguments for and against GM plants within the category in question (medicine, industry or ornamentation); on which conditions can GM plants for medicine, industry or ornamentation respectively be grown in Danish markets; and which general recommendations are there for the future handling of new GM plants. These questions were addressed through 7 votes on which the recommendations and conclusions of the report are based.

MAJOR OUTCOMES OF THE PROJECT

Interpreting the voting results, the main conclusions of the report seem to be that the citizens' jury assessed the new uses of GM plants to be predominantly beneficial. Still, the citizens' jury had reservations considering some specific applications of the technology. Thus, the citizens' jury proclaimed a conditional yes to the new GM plants.

The main arguments *for* the GM plants included improvements with regard to the environment and public health, financial advantages (both for society in general and the individual consumer) and business opportunities. The citizens' jury assessed that Denmark should tap its potential for developing GM plants due to the fact that Denmark has significant knowledge and experience, not to mention effective legislation. The most important argument *against* GM plants referred to the risk of unintentional spreading of foreign or undesirable characteristics. But the majority of the citizens' jury assessed that existing regulations – including the act on co-existence – and approval procedures considers these problematic issues.

Considering the usage of GM plants for **medicine** the voting results showed that the arguments for received more votes than the arguments against them. However, if the production of medicine includes the use of human or animal genes, it was a high priority for the citizens that there are strict requirements for approval of new products, and that the production takes place in closed environments.

The citizens' jury received developments of **industrial** GM plants as positively as plants producing medicine. It was especially applauded that industrial plants have the potential for replacing present production methods with more environmentally sustainable ones.

The attitude towards GM **ornamental** plants was less optimistic than the two other usages. The vote showed that there was slightly more arguments against than for the growing of GM ornamental plants in Danish fields. The citizen's jury further emphasized that the main condition for the growing of GM ornamental plants is that herbicide-tolerant grasses are not going to be approved due to the significant risk of spread to cultivated areas as well as to other vegetation.

An important condition for allowing the new plants that was emphasized was, that the environmental consequences of irresponsible practices should be assessed. Further, the growth of the new plants should not pollute more than existing modes of production - particularly concerning fertilizer or pesticide usage. Thus, any negative impact on ground water and soil should be part of the risk assessment. However, the citizens' jury did not see any reason for alarm while the present legislation and administration is considered adequate to limit the risks. Instead, there should be more focus on public education and information about the new GM plants. In fact, the clearest message from the citizens' jury was not about advantages, disadvantages and conditions with regard to GM plants, but about the necessity of informing the population about these matters as part of an open and nuanced debate.

Conclusively, it appears that the public's estimation of use clearly differs depending on the use of GM plants. The debates on GM plants for food and feed showed that the public questioned these usages by asking: why? The purposes and benefits are not obvious to the public. On the contrary, this project on the use of new GM plants poses the question; why not? In general, the citizen's jury did not see any reasons to impede the further development of GM plants - at least for medical and industrial use - as long as this does not involve environmental or health hazards, that exceed existing or alternative modes of production.

IMPACTS AND FOLLOW UP OF THE PROJECT

The citizens' jury presented their results the 2nd of May 2005 at a conference at the Danish Parliament with the attendance of politicians, experts and various stakeholders. After the citizens' jury's presentation of the results, politicians representing different parties and different stakeholders commented on the assessments and discussed them with the jury. The results of the conference were subsequently mentioned in the media.

In November 2005 the Ministry of the Environment held a conference on the use of GMO's. Whether this conference was a direct follow-up of the DBT-project is difficult to say, but the themes discussed at the conference were, in particular, concerned around new uses of GM plants.

The results of the citizens' jury were furthermore mentioned in a report on a biotechnology strategy considering non-food and feed published by the Directorate for Food, Fisheries and Agri Business in February 2006.

In September 2005 the Danish moratorium (since 1999) on the growing and the marketing of GM crops were finally revoked. The reasons for this action were grounded in the implementation of rules considering labelling, traceability and co-existence. The results of the citizens' jury *might* have had an impact on these decisions, but it would be wrong to link the two incidents directly.

CHALLENGES IDENTIFIED IN THE PROJECT

The citizens' jury identified several challenges considering the use of GM plants for other purposes. One challenge is the retention of a free consumer choice in a way that genetically modified products are labelled. Another challenge is to strengthen public research to form a contrast to private research and development, as public research seems necessary to maintain sufficient control of the new GM plants. The far most obvious challenge considering these new GM plants is that usages do not pollute more than the corresponding traditional modes of production or better alternatives.

LITERATURE

The Danish Board of Technology, (2005): Nye GM-planter - ny debat. http://www.tekno.dk/pdf/projekter/p05_GM-planter_rapport.pdf; English summary: Contitional yes to new GM plants. http://www.tekno.dk/pdf/projekter/p05_gmp_rtt.pdf

AUTHOR OF THE REVIEW

Søren Gram

FINLAND 3.

DEBATE BETWEEN PUBLIC ADMINISTRATION, RESEARCHERS AND GENERAL PUBLIC CONCERNING THE PLANT GENE TECHNOLOGY

During last five years, the Finnish debate between public administration, researchers and general public concerning the plant gene technology can be divided in four types of activity:

- General and plant gene technology focused public hearings
- Public administrative information of field tests and product approval processes
- Special administrative processes which have taken into account the public opinion
- Scenarios concerning possible implications of plant gene technology

PUBLIC HEARINGS

In order to discuss the ethical dimensions of genetics, Ministry of social affairs and health arranged a seminar "Genes and values" in Hanasaari, Espoo in 2002. The audience consisted of over 100 invited participants, and the program consisted of presentations by experts and a panel guided by a media professional.

A booklet introducing in the subject had been composed in advance, and it was delivered for the participants. The booklet served mostly prejudices and popular beliefs concerning plant biology and agriculture circulated by GM critical political movements. The beliefs were discussed by philosophers specialized in ethical problems of gene technology. No scientific experts of plant breeding research were consulted in the booklet.

The popular beliefs were the foci of the meeting, too. The sole discussant representing the science of plant biology - an associate professor in plant breeding - was offered a very short time (5 minutes) to tell about new GM varieties. The media professional chairman had customarily little knowledge of science.

The leaders of the Finnish anti-GM society were invited. Their full handful of members trespassed in the seminar with video cameras and recorded the discussions. Such behaviour did not promote the free atmosphere of the discussions. As their response to the scientific presentations, the "activists" nailed up the ultimatum that the scientist lecturing on plant breeding shall be discharged.

It was no surprise that the seminar resulted in messages putting science under suspicion. But as a trade-off it also brought important science reporters in place. The presentation on plant breeding, albeit minuscule, gave many a first contact with the sub-

ject and its true possibilities. Hence, certain media columns were opened later on for the first time also for scientific facts regarding modern plant breeding.

Special contribution was made by philosophers. They analyzed also in the final report of the conference the quality of typical arguments given for and against gene technology. Logical analysis of superficial statements made by emotional opponents is a good way to promote rationality in the field. Besides that it is highly important that with careful scientific (and not only logical) analysis prejudices and real threats will be separated.

Other ministries have also arranged general seminars in the area. E.g. ministry of agriculture and forestry (MAF) have arranged many seminars as a part of the hearing process of their strategies or laws in preparation. Such seminars have been arranged concerning Gene Technology Strategy[2] (2003, wwwb.mmm.fi/julkaisut/tyoryhmamuistiot/2003/trm2003_18_en.pdf) and Co-existence[3] (2005, wwwb.mmm.fi/julkaisut/tyoryhmamuistiot/2005/Trm2005_9a.pdf). The bulk of the invited participants have been professionals from the field of activities of the ministry, but invitations also cover public interest groups such as societies and other NGOs.

In addition, seminars explaining the biological basics and topical situation regarding GM products in agriculture have been arranged by MAF for media people a few times, with fair success. Presentations are always given by top experts of science, legislation or administration in the field. Experiences of such focused seminars connected with preparatory work of administration and authorities are in general positive in Finland

PUBLIC ADMINISTRATIVE INFORMATION OF FIELD TESTS AND PRODUCT APPROVAL PROCESSES

Applications for GM product approvals are decided at Community level in EU, and all member states participate in the process. When the information concerning a product application arrives in Finland, a short Finnish summary and links to official documents dealing with the application are made publicly available. They are in the Internet pages of Finnish Food Safety Authority EVIRA, the authority ordered to take responsibility of the information delivery in these cases. In the pages, advice is also given how people can give their opinion of the application to EU authorities using Finnish language. In addition, a press release is given in a broad delivery in order to activate the media.

2 Gene Technology Strategy and Action Plan of the Ministry of Agriculture and Forestry 2003-2007. Working Group Memorandum 2003:18, Ministry of Agriculture and Forestry, Helsinki, Finland, 2003.

3 Enabling the coexistence of genetically modified crops and conventional and organic farming in Finland. Mid-term report. Expert Work Group on Coexistence, Ministry of Agriculture and Forestry, Finland, 2005

Finnish Gene Technology Act provides for the applications of GMO field tests to be communicated with public efficiently enough. The act implements Directive 2001/18/EC. Regarding a field test with GM white birch seedlings, public informative meeting was selected as the way of action.

The meeting was thoroughly advertised in local media, starting well beforehand. In spite of that, only two persons representing general public did arrive, the other of these was probably a local farmer. All other audience, a few scores of people, consisted of (mainly local) university scientists, many of whom participated in the GM research program (ESGEMO), and members of the Board for Gene Technology; plus the handful of activists (always the same few ones) from the specialised "GM-free" society.

For public discussion, far more important was the destruction of GM white birch seedlings made by plant GM opponents. As the result of extensive discussions in newspapers, the public opinion turned strongly against destructors. It was realized that there was no point in this destructive act because these non-flowering birches have no real way to diffuse their genetic material to non-GM birches or other plants. Instead, GM birches would have a real positive impact on town environments because of less allergic reactions. Actually based on their safety and positive impacts on health, an environmental organization (Ekosäätiö, Eco Foundation) gave its price to the developers of GM birches. Based on the destructive act, the public opinion is now much more favourable for the limited public information concerning the cultivation places GM plants. The irrationality of the GM opponents became much more evident for the general public.

SPECIAL ADMINISTRATIVE PROCESSES WHICH HAVE TAKEN IN ACCOUNT THE PUBLIC OPINION

We consider that it is highly important for a rational approach concerning the plant gene technology that the administration does not follow prejudices of the public opinion. This is especially important because of the feedback to the public opinion. Critics of gene technology with little science expertise can use the choices of the administration as an evidence for their opinions.

In Finland, the above problem was met related to restaurant criteria proposed for the Nordic Swan ecolabel. The aim of the ecocertificate is declared to be helping people "to choose the most environmentally-friendly products" and to avoid the use of the most environmentally burdening products (www.svanen.nu/Eng/default.asp).

Criteria for Nordic restaurants to fulfil in order to receive the ecolabel were proposed (June 2006). Without any statement of reason based on facts or science, all use of genetically modified constituents was categorically forbidden in the restaurants with ecolabels. That proposition excited Finnish life scientists to express their objections to the misuse of such populist prejudices which only damage true efforts on environmental protection. Among others, the traditional and most prestigious life science society in Finland (Societas Biochemica, Biophysica et Microbiologica Fenniae)

strongly criticized such anti-science attacks detrimental to environment in its statement. Applications of modern biological research, including gene technology and genetic modification, are fundamentally required for environmental ameliorating, and their impacts shall be properly assessed case-by-case.

Notable environmental benefits have already been obtained by producing the so-called traditional GM varieties for 10 years (Sanvido et al. 2006[4], Brookes et Barfoot 2006[5]). Yet essentially greater remedies could be anticipated from "second generation" GM varieties specifically designed for environmental enhancements. Such innovations include resistant plant varieties with better tolerance to drought, cold, flooding, salt as well as pests and diseases.

For example, blight-resistant potato was bred with gene technology by obtaining the resistance gene from a wild potato species. The healthy variety is in field tests for the third year in EU. Cultivating blight-resistant potatoes would save EU each year from 860 million kg of yield being wasted, and 7.5 million kg of fungicides to be sprayed (expressed as active ingredient). Of course that also means great reductions in oil use and greenhouse gas emissions in agriculture (Phipps et Park 2002[6], Gianessi et al 2003[7]). Organic producers could also benefit from the use of blight resistant varieties, because the risk of spreading the disease from other plantations to the fields used for organic production would be smaller.

---

4 Olivier Sanvido, Michèle Stark, Jörg Romeis and Franz Bigler (2006). Ecological impacts of genetically modified crops. Experiences from ten years of experimental field research and commercial cultivation. *ART-Schriftenreihe 1*. Fed. Dep. Econ. Aff. DEA, Switzerland, 108 p.

5 Graham Brookes and Peter Barfoot (2006). Global Impact of Biotech Crops: Socio-Economic and Environmental
Effects in the First Ten Years of Commercial Use. *Agbioforum* 9: 139-151.
Abstract: Genetically modified (GM) crops have now been grown commercially on a substantial scale for ten years. This paper assesses the impact this technology is having on global agriculture from both economic and environmental perspectives. It examines specific global economic impacts on farm income and environmental impacts of the technology with respect to pesticide usage and greenhouse gas emissions for each of the countries where GM crops have been grown since 1996. The analysis shows that there have been substantial net economic benefits at the farm level amounting to $5 billion in 2005 and $27 billion for the ten year period. The technology has reduced pesticide spraying by 224 million kg (equivalent to about 40% of the annual volume of pesticide active ingredient applied to arable crops in the European Union) and as a result, decreased the environmental impact associated with pesticide use by more than 15%. GM technology has also significantly reduced the release of greenhouse gas emissions from agriculture, which, in 2005, was equivalent to removing 4 million cars from the roads.

6 Phipps & Park (2002). *J Animal Feed Sci.*11**:** 1–18.

7 Leonard Gianessi, Sujatha Sankula and Nathan Reigner (2003). Plant biotechnology: Potential impact for improving pest management in European agriculture. Potato case study. NCFAP

The objections of the scientific community were accepted by the administration responsible for the Nordic Swan ecolabel. It was decided in autumn 2006 that genetically modified constituents are allowed in Nordic Swan ecolabeled restaurants.

SCENARIOS CONCERNING POSSIBLE IMPLICATIONS OF (PLANT) GENE TECHNOLOGY

Based on assessment project concerning social impacts of the human genome and stem cell research by the Committee for the Future, a scenario book was made. The aim of the book was to inform the general public about most important results of the assessment project. Beside that it illustrated possible future impacts of gene technology with three scenarios. The scenario book (Kuusi 2004)[8] got considerable publicity in media.

The names of the scenarios characterize their content:

- Safety first of all
- Wealth and employment from gene technology
- Gene information belongs to everybody

All scenarios were discussed as reasonable choices making different assumptions concerning future developments. After the presentation of the scenario story its probability was discussed. For example, in the first scenario the blight-resistant potato resulted in a lagged serious health problem. In the discussion part, the probability of that problem was discussed. It was considered that even taking into account the risk it is reasonable to accept the blight-resistant potato. The conclusion was the same as in the third scenario: Also in order to solve possible problems related to gene technology, the best choice is to make it commonplace.

Like the information technology, gene technology should belong to everybody. It requires an internet based "Gene Information Centre" providing its services to everybody. In a safe environment (compare banking services), it makes sense to integrate this type of personal gene information with one's personal electronic patient records.

AUTHORS OF THE REVIEW

DSc(Agr&For) Jussi Tammisola

PhD Osmo Kuusi

8 Osmo Kuusi (2004) Geenitieto kuuluu kaikille (Gene information belongs to everybody), Edita, Helsinki

FLANDERS 4.

PUBLIC FORUM »NEW IMPULSES FOR THE DEBATE ON GENETICALLY MODIFIED FOOD« (2003) 4.1

BACKGROUND OF THE PROJECT

On September 25th 2001 a hearing was held in the Flemish Parliament to discuss the advices published by five Flemish advisory bodies[9], by request of the Flemish Parliament[10], on the topic of genetically modified organisms(GM organisms). A recurring element in the five reports was the importance of organizing a public debate on this topic.

The Flemish Institute for Science and Technology Assessment, viWTA, established by Decree on 17/07/2000 provided the opportunity to respond to this advice. The Board of the viWTA decided in December 2001 to organise a pilot project on this topic. In Spring 2002 this topic was narrowed down to 'genetically modified food'. The project was officially launched in May 2002 with a pre-study. The goal of this study was to map the existing debate on genetically modified food in Flanders (actors, positions, legal situation,…). The report of this study was published in November 2002, in December 2002 the Public Forum was launched. On the 26th of May 2003, the 15 members of the citizens panel submitted their final report to Mr. Norbert de Batselier, President of the Flemish parliament.

MAJOR OUTCOMES OF THE PROJECT

The report of the Flemish lay panel contained 28 recommendations, centred around six major themes:

- Legislation, control and consultation
- Information
- Ethics
- Health issues
- Global and economic issues
- Environmental consequences

Most important of these recommendations, also in the light of European legislation, are:

9 De Sociaal Economische Raad van Vlaanderen (SERV), de Milieu en Natuurraad van Vlaanderen (Mina-raad), de Vlaamse Raad voor wetenschapsbeleid (VRWB), de Vlaamse Land- en Tuinbouwraad (VLTR) en de Vlaamse Gezondheidsraad.

10 Adviesvraag van 11/02/2001 van Trees Merckx-Van Goey houdende raadpleging van diverse adviesorganen over de problematiek van genetisch gemodificeerde organismen.

Legislation, control and consultation:

- Even after the discussion it is still not clear who is liable in case of problem (product liability as well as environmental liability). The reference persons did not know the answer. This leaves the initiative to politicians. The liability has to be regulated so as to be legally binding. It has to be unambiguous, leaving little room for interpretation and for dodging responsibilities.
- It is hard to choose between genetically modified foodstuffs or food without GM organisms: you cannot choose for something that is not available yet. But when genetically modified food arrives, there is a real danger that non-genetically modified food will be under pressure. The choice has wider implications than mere labels. If you want to sell both (labelled) genetically modified food and non-modified food, you need two completely separate circuits. Freedom of choice has to be guaranteed. This is a complex issue. Both those who want to purchase genetically modified food as those who do not, need to be able to make a choice. If nothing changes, the situation will not improve.
- The introduction of genetically modified food on the market might lead to increasing production costs for non-GM food, a.o. because of extra checks. The sector of genetically modified food will be able to compensate this extra cost because of cheaper production techniques.
- The European rules for permits are not bad; they are the result of hard work. The E.U has a procedure for quickly recalling GM products in case of problems. But the rules are not watertight: the evaluation of permits is left to scientists and politicians. The evaluation of permits ought not to be restricted to scientists, but extended to other areas of expertise (economists, sociologists, philosophers).

Information:

- The new EU legislation allows for public consultations, but the form in which this will happen is still vague (active or passive approach?) A large majority of the Flemish laypanel believes the government ought to provide clear and neutral information. A majority thinks the existing website of the Belgian Biosafety Server (http://biosafety.ihe.be) can fulfil this role, but is must be translated from English. The site can be expanded into a portal site.
- Labels must be uniform throughout Europe (using clear icons)
- Citizens prefer an active consultation of the public under EU legislation. This allows the citizen to voice his opinion. Participation can only be useful after an awareness-raising campaign.

Ethics:

- There is no universally accepted ethical position, but there are nevertheless clear ethical limits. The different scope of arguments (based on risks vs. based on duties) makes an ethical debate difficult. However, ethical considerations must play a role in allowing genetically modified foodstuffs.

Health issues:

- The health risk of genetically modified foodstuffs that are introduced in the market are negligible. Strict and reliable checks have convinced the lay panel that the health risks of regulated genetically modified food are negligible. Consumers can regain their confidence if they are informed in a reliable way about the health issues related to genetically modified food. But permanent checks and controls stay necessary for genetically modified food. Because of the complexity of the issues, this debate must be conducted in public.

Global and economic issues:

- The authorities have to provide a framework and the means for the transfer of knowledge and technology between North and South, and for establishing local research facilities in the South.
- The authorities should continue to support fundamental research and the technological development of genetically modified organisms. But the subsidies have to be made dependent on promises to share the relevant knowledge with the Third World.
- Research into traditional and biological agriculture must not be neglected, but should continue to exist as a full area of research.

Environmental consequences:

- Evaluation of the environmental hazards is extremely important. Each case has to be thoroughly investigated.
- Biotechnology must make a responsible choice, respecting biodiversity, the biotope of the crop and the ecosystem. These elements must be taken into account during risk analysis.
- Once genetically modified food is brought to market, environmental risks still need to be monitored. The present post-marketing plan does not provide for adequate control. The costs for more systematic controls have to be borne by the biotech industry.

CHALLENGES IDENTIFIED IN THE PROJECT

Potentially problematic issues, that could be further explored in the questionnaire, seem very generally:

- Ways to engage the public in decision making processes on GMO's: active/passive?
- Importance of understandable, down to earth communication about GMO's
- Freedom of choice/possibility of creating complete separate circuits
- Effect on introduction GM-food on production costs for non GM food (extra checks and quality control systems)
- Multi-disciplinary evaluation of risks
- Challenges to labelling
- How to involve ethical considerations in future approvel procedures?

› How can the south benefit from European research?

AUTHOR OF THE REVIEW

Els van den Cruyce and Stef Steyaart

FUNCTIONAL FOODS. STATE OF THE ART (2006) 4.2

BACKGROUND OF THE PROJECT

Functional foods represent one of the most intensively investigated and promoted area in the food and nutrition sciences today. Functional foods are fortified or enriched foods that provide health benefits beyond the provision of essential nutrients, when they are consumed at efficacious levels as part of a varied diet on a regular basis. Linking the consumption of functional foods with health claims should be based on scientific evidence. However, not all foods on the market today that are claimed to be functional foods are supported by enough solid data to merit such claims. What are the benefits and what are the risks?

In this comprehensive study, the consortium Food2Know (University of Ghent) and Flanders' FOOD (knowledge centre for the Flemish Food Industry) made an overview of different functional food products on the market in Flanders. Using a questionnaire, the societal issues were elaborated by 30 experts in this field (diet and nutrition experts, retailers, consumer and patient organisations, regulatory bodies, academic researchers and stakeholders from the Flemish food industry). Information was gathered on issues such as the scientific evidence linked to the health claims, the regulation in Flanders and Europe and the role of functional foods in the Flemish health policy.

The results were summarized in a report (only available in Dutch) and were presented during a debate with experts and policymakers in the Flemish Parliament. The project had no further impact on policy making.

MAJOR OUTCOMES OF THE PROJECT

The study focused on the following issues:

Scientific evidence for health claims:

There is a need for stricter control of the scientific basis of health claims on functional food products. Today, health claims are not reliable enough. More precise understanding of the mechanisms of actions of functional food and more scientific evidence is required.

Functional foods and health policy:

A frequently asked question is if functional food can be a part of the disease risk-reduction public health program? This study concluded that government policy and action must keep focussing on healthy lifestyle, balanced food intake and sport. Functional food cannot solve what has been damaged by ignoring these points.

Safety:

The products that are on the market today, are considered to be safe. Nevertheless, enrichment of food products with specific nutrients can imply much higher doses of intake by consumers. The experts in this study supported the idea of mentioning a maximum dose on the label of each functional food product. Another important risk is that functional food can give a false feeling of safety. Functional food could become an excuse to give less attention to sport and food habits.

Price of functional foods:

Functional food products are quite expensive. Experts recommend actions to make the possible advantages of functional food available for everybody.

Information overload:

News articles are often contradictory. It is very difficult for consumers to select the relevant and scientific based information.

Food and medicine:

Experts see a clear trend towards the use of food for medical purposes.

CHALLENGES IDENTIFIED IN THE PROJECT

Potentially problematic aspects of functional food, that could be useful to the subject of GMO's, seem very generally:

- Scientific evidence for benefits of these type of food products
- Safety of the products
- Price of the products: Who can benefit? Who will pay for GM food?
- Challenges to labelling: information overload for consumer
- Consumers attitude towards GM food: experience of food, food culture.

AUTHOR OF THE REVIEW

Els van den Cruyce and Stef Steyaart

INDUSTRIAL BIOTECHNOLOGY IN FLANDERS: STATE OF THE ART (2006) 4.3

BACKGROUND OF THE PROJECT

Industrial or white biotechnology is the application of biotechnology for the processing and production of chemicals, materials and energy. White biotechnology uses enzymes and micro-organisms, such as yeast and bacteria, to make products in chemistry, food, paper and pulp, textiles and energy. White biotechnology uses biomass as an alternative to fossil resources for the production of biochemicals such as biofuels and biopolymers. In the future, genetically modified crops could be developed, as a renewable source for non-food applications.

In this comprehensive study, the Laboratory for Industrial Microbiology and Biocatalysis (University of Ghent) made an overview of the applications and fields of expertise in Flanders. Using a questionnaire, the societal issues were elaborated by 30 experts in the field of industrial biotechnology. Information was gathered on issues such as Flanders' chances to evolve to a bio-based economy, the opportunities for a more sustainable production, the implications for the economy in Flanders, and more specific for the agricultural sector.

The results were summarized in a report (only available in Dutch) and were presented during a debate with experts and policymakers in the Flemish Parliament. The project had no further impact on policy making.

MAJOR OUTCOMES OF THE PROJECT

The study focused on the following issues:

- *Sustainability*:
  Industrial biotechnology offers opportunities for a more sustainable production. Enzymes can drive chemical reactions towards the desired end product in a very effective and efficient way, under circumstances of normal temperature and pressure. Less energy is consumed and waste production is reduced. However, only a complete life cycle analysis can asses whether the use of industrial biotechnology is more eco-efficient.
  Secondly, instead of fossil fuels, agricultural raw materials, such as cereals and coleseed are used. This reduces the emission of greenhouse gasses. Some experts expect that production of crops will be more geographically spread, in contrast to the concentration of power within the limited amount of petroleum producing countries.
  Thirdly, the agricultural raw material must be produced in a sustainable way, avoiding deforesting, erosion and soil impoverishment.
- *Safety of the use of micro-organisms for industrial applications*:
  The (genetically modified) micro-organisms are bred in a closed reactor. After

use, the micro-organisms are separated from the product and killed. This is called "contained use".

- *Perception of the public*:
  Recent Eurobarometer results show that more than half of the interviewees believe that biotechnology can improve the life standard. Especially the medical applications receive a lot of support. However, the European citizen is still very critical towards the modification of agricultural crops or green biotechnology. Experts fear that this negative attitude will also involve genetic modification of crops for non-food applications.
- *Implications for the agricultural sector*:
  The agricultural sector of the future will not only produce food, but will more and more become a producer of chemicals, industrial raw materials and biofuels. Because the area of land in Flanders used for the agricultural production is limited, some experts fear that this competition will threaten the production of food. Proponents argue that the Belgian and European agriculture suffer from overproduction and that the European agriculture requires a high proportion of the overall EU budget to subsidise it. Another argument is that a lot of area is available in the member states that integrated the EU in 2004.
  In the future green biotechnology could make a substantial contribution in the production of agricultural production such as cereals for non-food uses.
- *Can Flanders evolve to a biobased economy*:
  In a biobased economy, an increasing number of chemicals and materials will be produced in biorefineries using renewable resources. Biomass derived energy is expected to cover an increasing amount of the energy consumption.
  The agricultural sector in Flanders will be unable to meet the demand for biomass. Import from neighbouring countries, Eastern Europe, America and even Africa will be necessary. Because of its central location and extensive transport infrastructure, Flanders is well placed for import and transport of these raw materials.
- *Financial investment in research and development of industrial biotechnology*:
  The biotechnological research in Flanders is mainly focused on green and red biotechnology. Therefore the experts from the questionnaire propose to invest more in the research and development of industrial biotechnology in Flanders.

CHALLENGES IDENTIFIED IN THE PROJECT

Potentially problematic issues, that could be further explored in the questionnaire, seem very generally:

- Sustainability of GM crops for non-food issues
- Perception of the public towards GM crops for non-food issues
- Implications for the European agricultural sector
- Europe and the biobased economy

AUTHOR OF THE REVIEW

Els van den Cruyce and Stef Steyaart

FRANCE 5.

INRA PROJECT »CO-CONSTRUCTION OF A RESEARCH PROGRAMME« (2002)

BACKGROUND OF THE PROJECT

The French National Institute for agronomic research (INRA) has been working for many years on the elaboration of a transgenic rootstock potentially resistant to Grapevine Fanleaf Virus (GFLV), together with a private partner. In 1999, the private partner decided to stop its participation to this research, because of the hatred public discussion on GM grapevine. INRA decided to continue its research and passed on all material to its laboratory in Colmar.

However, in 2001, and because the public debate on transgenic was still going on, INRA decided to suspend the ongoing experiments and to initiate a discussion on their pursuit within a working group integrating researchers, professionals and consumers, using a participatory process.

The initial question the working group had to answer was about the opportunity to realise field trials of rootstock potentially resistant to Grapevine Fanleaf Virus (GFLV). However, the working group reformulated the demand in the following direction:

- Which are the philosophical, social, economical and technical aspects at stake in this field trial? Knowing that there are many research needs related to grapevine diseases, how to define priorities et how to choose the types of arbitration.
- Should INRA continue to research on GM-grapevine and, if yes, which conditions have to be met in order to pass to the stage of field trials?

BASIC DATA ABOUT THE PROJECT

The selected method was based on the so-called “Technology assessment through interaction”[11]. It consists in putting together various worldviews, so that deliberations are nourished from a variety of arguments and standpoints.

The number of participants was limited to 14, so as to allow deliberation on complex problems and heterogeneous questions. Whereas some participants had no special expertise in the topic (so-called “laypersons”’), the group also comprised researchers and wine-professionals. The selection process was based on the results of a sociological study, which displayed a social cartography of worldviews around the topics of grapevine, wine and GMOs. The conceptions of science have also been considered

11 See Grin, J., van de Graaf, H., Hoppe, R., (1997). Technology assessment through interaction. A guide. Den Hag, Rathenau Institute (available at http://www.rathenau.nl).

in the selection process, as well as attitudes towards research on a transgenic rootsock for grapevine. Based on this analysis, the organisers invited:

- Four researchers working on research on grapevine diseases, but who hold different worldviews.
- Six grapevine and wine professionals, stemming from different geographical regions and holding different worldviews.
- Four citizens, also invited for the variety of their worldviews.

The working group met 7 times, from April to September 2002.

Various instances were part of the experiment:

- The General Direction of INRA, which initiated the project.
- 2 project managers.
- One research assistant.
- A steering group (comité de pilotage), composed of the project managers and the INRA Direction.
- An evaluation committee, composed of personalities external to INRA, specialized in the analysis of controversies and of participation.
- A moderator for the working group sessions.

MAJOR OUTCOMES OF THE PROJECT

The working group came to the following conclusions:

- Wine has a strong symbolic dimension. As a consequence, a genetic modification done on grapevine dedicated to the fabrication of "wine-food" could have a negative impact on "wine-pleasure" and on high quality wines.
- There is a strong attachment to a system production based on biological, technical and cultural variety. With respect to the threats related to grapevine diseases, various fighting methods should be developed, so as to contribute to the various production modes of vinegrape.
- Considering research activities, there is a lack of integrated and transversal approaches. There is a necessity for a better understanding of the interaction between the plant and its environment.
- INRA should continue to do research on genetically modified vinegrape in laboratory and green house. Field trials should also be implemented. But, on this last point, all group members did not agree on the opportunity to have field trials (2 persons against). Opponents to the field trials considered that even the solution may be technically satisfactory, it is not socially acceptable. In this respect, it could prejudice the status and image of French wine. The other 12 members considered as acceptable field trials with transgenic grapevine. But their positive opinion is limited to a given experiment and no opinion has been formulated on a possible commercialisation.

IMPACTS AND FOLLOW UP OF THE PROJECT

The report of the working group has been passed on to the INRA Direction in September 2002. In January 2003, INRA decided to ask for an authorization for the implantation of field trials in Colmar, to set up a local follow-up committe and to create a mix commission in charge of defining the major orientations of wine and vinegrape research.

CHALLENGES IDENTIFIED IN THE PROJECT

- role of public research.
- transgenic wine and vinegrape
- dialogue and interaction
- The issue of trust
- Ability of public resarch institutions to set a boundary between research and its applications

LITERATURE

Co-construction d'un programme de recherche : une expérience pilote sur les vignes transgéniques. Rapport final du groupe de travail et réponse de la direction de l'INRA.2003. INRA: Paris. http://www.inra.fr/genomique/rapport-final-ogm-vigne.html

AUTHOR OF THE REVIEW

Danielle Bütschi

GERMANY 6.

GENETIC ENGINEERING, BREEDING AND BIODIVERSITY (1998) 6.1

BACKGROUND OF THE PROJECT

The TAB-project "Genetic engineering and breeding from the viewpoint of biodiversity in agriculture" (short title: “Genetic engineering, breeding and biodiversity”) was based on a recommendation by the Committee on Food, Agriculture and Forestry and was approved in Autumn 1996 by the Committee for Education, Science, Research, Technology and Technology Assessment of the German Parliament.

Background for the project was the 4. International Technical Conference on Plant Genetic Resources of the FAO at Leipzig in June 1996, which approved the Global Action Plan and the Leipzig Declaration for the “Conservation and Sustainable Utilization of Plant Genetic Resources for Food and Agriculture”. Further, the Convention on Biological Diversity – ratified by Germany in 1993 – had defined objectives for the protection and use of the global biodiversity. These international commitments, to be implemented on national level, were one starting point. The other starting point was the questions, which impacts on biodiversity results from modern biotechnology.

The goal of the TA-project was to investigate what negative influences the use of genetic engineering in plant breeding can have on biodiversity, what contributions breeding and genetic engineering can make to conserving biodiversity and finally, what potentials can be derived for policy-making. A restricted, technology-centred perspective was not adequate for this theme. Particularly for the issue of potentials for conserving plant genetic resources and biodiversity in general, the approach was expanded in order to cover the significance of genetic engineering and breeding in the overall context.

BASIC DATA ABOUT THE PROJECT

The TA-project was executed in one and a half year, and finished in 1998. Four scientific studies were awarded in the project. The draft final report of TAB was based mainly on these studies and was evaluated by a number of experts from science, government and stakeholders.

The investigation area was limited to the field of plant breeding and - as far as possible - was restricted to the agricultural sector in Germany, taking into account European framework conditions. The topics of the project were:

- biodiversity and plant genetic resources – status and development,
- plant breeding – its goals, economic development and legal regulation,

- direct and indirect impacts of new (conventional and genetically engineered) varieties on biodiversity – systematic analysis of impact chains,
- biodiversity conservation measures – ex-situ, in-situ and on farm measures,
- international agreements and implementation of international obligations,
- options for action in the areas of research, agricultural, environmental and development politics.

MAJOR OUTCOMES OF THE PROJECT

The results of the project showed that modern agriculture has made a considerable contribution to reducing the biodiversity of many crops and wild plants in Germany through intensification, rationalisation, specialisation and concentration of production. Impacts on biodiversity have in particular been generated by changes in fertilisation, plant protection, rotation and land reallocation and consolidation. Plant breeding and modern plant varieties are all part of the changed agricultural production system and their impact on biodiversity is more of an indirect one. The central conclusion of the project was that in Germany and Central Europe the use of genetic engineering procedures in plant breeding will not have a specific, significantly negative influence on biodiversity compared to conventional breeding practices in the short to medium term. On the other hand, however, genetic engineering in plant breeding will not make any significant contribution to conserving or extending plant genetic resources.

To achieve the goal of "conserving biodiversity", there was seen a particular need for action on direct conservation measures. To this end the ex-situ, in-situ and on-farm conservation measures must be improved and developed. As Germany did not have a coordinated procedure on the conservation of plant genetic resources which incorporates all conservation measures, it was recommended to develop a combined conservation strategy. This would simultaneously be a major contribution to conserving biodiversity in Germany. In order to implement international agreements at national level and to develop and apply a national strategy to conserve biodiversity (including plant genetic resources (PGR)), close coordination and cooperation was regarded as necessary between the various policy fields and levels affected. Interested and affected societal groups should be incorporated into the national strategy development and implementation process.

A matter of central importance for the sustainable conservation of biodiversity was seen in a full-coverage change towards sustainable agriculture, in which the promotion of agricultural diversity and the protection of wild flora and fauna is a major component. The principles of organic farming which, in contrast to the still predominant conventional farming, involve more extensive and diversified farming practices, could therefore provide significant guides. It was pointed out that changes in basic framework conditions for agricultural and environmental policy do not make specific conservation measures (as discussed in the project) become superfluous, but their scope and urgency would take on a relative basis.

A broad spectrum of options for action in the different areas of the project was identified and discussed. As future issues were identified:

- monitoring of the impacts of patenting on plant breeding and variety protection;
- research on the impacts of the introduction of new varieties (conventional and transgenic plant varieties) on biodiversity of agro eco-systems and adjacent eco-systems, with special attention to the issues of changes in cropping systems, resistance development and resistance management;
- long-term ecological impacts require comprehensive post-marketing monitoring, coordinated and combined with fundamental research activities on biodiversity and plant genetic resources.

IMPACTS AND FOLLOW UP OF THE PROJECT

The report was published as parliamentary document (Bundestagsdrucksache 13/11253). In the following electoral term, the report was deliberated in the leading Committee for Nutrition, Agriculture and Forestry and two consulting committees. The result of the deliberation in the committees was a recommendation and report for the plenary (Bundestagsdrucksache 14/1716), with a detailed catalogue of actions based on the options for action in the TAB-report. This recommendation was approved in the plenary meeting of the German Bundestag on 16th December 1999, by the governmental majority and the PDS.

In the federal agricultural report 2000 (Bundestagsdrucksache 14/2672), the Federal Government had pointed out that measures for the national programme on plant genetic resources and a research programme on biodiversity has been prepared, in order to implement the above mentioned decision of the German Bundestag.

CHALLENGES IDENTIFIED IN THE PROJECT

In the project identified (future) challenges which are still valid (conclusions of the reviewer):

- preservation of plant genetic resources
- impacts of patenting on plant breeding and variety protection
- uncertain future of small and medium seed producers
- impacts of the introduction of new varieties (conventional and gm varieties) on biodiversity of agro eco-systems and adjacent eco-systems

LITERATURE

Meyer, R.; Revermann, C.; Sauter, A. (1998): Biologische Vielfalt in Gefahr? Gentechnik in der Pflanzenzüchtung. Studien des Büros für Technikfolgen-Abschätzung beim Deutschen Bundestag Band 6. Edition sigma: Berlin

English summary: http://www.tab.fzk.de/en/projekt/zusammenfassung/ab55.htm

AUTHOR OF THE REVIEW

Rolf Meyer

RISK ASSESSMENT AND POST-MARKETING MONITORING OF TRANSGENIC PLANTS (2000) 6.2

BACKGROUND OF THE PROJECT

The TAB-project "Risk assessment and post-marketing monitoring of transgenic plants" was demanded by the Committee on Food, Agriculture and Forestry of the German Parliament.

Background for the project was the ongoing debate in the EU on the authorisation of transgenic varieties and the amendment of the Deliberate Release Directive 90/220/EEC. The development culminated in the summer of 1999 in a de facto moratorium on approval of transgenic plants for marketing by the Council of Environmental Ministers, combined with the demand that the reforms in progress be completed before any new approvals are issued.

During the project execution, the German marketing approval for the maize variety Bt176/ "Windsor" (about to receive variety approval from the "Bundessortenamt" – German Federal Plant Variety Agency) was suspended in February 2000 under Article 16 of the Release Directive, which constitutes a safeguard clause. This event has sparked off forceful political and scientific controversy in Germany, which has also involved the German Bundestag and its committees on a number of occasions. In June 2000 the German Chancellor announced an initiative seeking to agree a three-year transitional phase with the companies involved during which commercial cultivation of transgenic plants would be possible only on a limited scale and in combination with increased research into safety aspects, and particularly an intensive monitoring programme. This was not implemented due to the emerging of the BSE crisis in Germany.

The goal of the TA-project was to give a focused overview of the status of the scientific and political debate. It was not the purpose of the project to provide novel answers to the outstanding questions on biosafety or develop separate proposals for the post-marketing monitoring.

BASIC DATA ABOUT THE PROJECT

The TA-project was executed in fifteen months (July 1999 – November 2000). Five scientific studies were awarded in the project. The draft final report of TAB was based mainly on these studies and was evaluated by a number of experts from science and government.

The investigation was limited to a status report on risk assessment and post-marketing monitoring of transgenic agricultural crop plants. The main topics of the project were:

- the status in safety research (inc. post-marketing monitoring) and the debate on risks,

- the state of regulation and treatment of authorisation procedures in the EU for the release, marketing and variety licensing of gm agricultural crop plants,
- the state of implementation of the Novel Food Directive (licensing and labelling).

MAJOR OUTCOMES OF THE PROJECT

For the **scientific debate on risks**, it was worked out that controversies regarding both general and specific impacts relate primarily to three different levels:

- first, the fundamental likeliness of occurrence (e.g. of outcrossing or development of resistance by insect pests),
- second, the degree of possible damage (e.g. reducing biological diversity or adversely affecting organic farming), and
- third, the possible or necessary measures to avert risk (e.g. size of the protective zones around fields with transgenic plants or design of resistance management).

Generally, the state of data appeared deficient in many respects, as while there had been over 1,300 release experiments in Europe alone, fewer than 1 % of release experiments worldwide have been linked with accompanying ecological research (although in Germany the figure was 15 %). Another reason why there was virtually no "real knowledge about risk" is the safety requirements needed for the accompanying ecological research. Critical voices pointed out that the lack of evidence of adverse ecological impacts suggests more that the wrong questions are being asked (with a resulting lack of corresponding studies) than the absence of any risk. Conversely, it is true that conventionally bred plants (i.e. not using genetic engineering) have never been subjected to biological safety testing, so that the impacts of transgenic varieties are always more thoroughly researched than those of conventional varieties. Many scientists also stressed that the new characteristics of transgenic plants are in principle much more clearly defined – and hence more easily documented and researched – than the results of conventional breeding.

However, a whole series of questions will in any event be impossible to answer in research projects with a limited life. First, the results of scientific research always generate not only answers but also new questions, and second because long-term indirect effects can generally only be observed in the course of longer-term cultivation of transgenic plants on a significant scale. This realisation had led to virtual unanimity among all involved on the development and implementation of long-term monitoring of transgenic plants under cultivation.

For the **risk assessment in the approval procedures**, the report looked in detail at how far the status of the scientific risk debate, and specifically the ecological aspects, were taken into account in the opinions in the framework of the approval procedures for marketing under Directive 90/220/EEC of both the EU scientific committees and national agencies (in Germany, Austria, the UK and – in part – Sweden), and how differences identified in the opinions can be explained. The result was that

- scientific contributions and arguments have been very much selectively used and variously interpreted,

- diverging conclusions have been drawn from gaps and areas of uncertainty in our knowledge, and
- above all, the possible consequences have been very differently evaluated in terms of the scale of damage and resulting implications.

Even after the amendment, there is still no definition of damaging impacts, so that there will still be considerable scope for different assessments. Not least, the question will be which agricultural paradigm the impacts of transgenetic agricultural plants are measured against. It will not be possible to derive a normative framework for this paradigm simply from the debate about GE applications: instead, this will require a serious definition and specification of the term "sustainable agriculture" as a stated goal of European agricultural policy.

For the **post-marketing monitoring** was pointed out that three dimensions or distinctions have special relevance:

- monitoring based on cause-and-effect hypotheses (even if partly unexplained or uncertain) versus unexpected or rare events,
- surveys of the agricultural ecosystem (and adjoining marginal structures) versus surveys of the environment generally,
- monitoring for limited periods versus long-term or unlimited monitoring.

The **overall main conclusions** of the report were:

No excessive expectations should be raised for the amended Deliberate Release Directive 90/220/EEC and the introduction of post-marketing monitoring. Their potential for resolving problems will inevitably remain limited until such time as fundamental agreement is reached on definitions of damage and desirable agricultural practice.

Both the amended Deliberate Release Directive and the Novel Food Regulation require operationalisation and specific guidelines for implementing the safety assessment and approval procedures. This is the only way to reduce discussions about the scope, coverage, methodology and interpretation of the safety assessments. This should build on the current state of the scientific risk debate. To this extent it will be an ongoing task, rather than a one-time exercise.

New instruments – such as post-marketing monitoring or revised labelling regulations – should only be introduced when their integration into existing statutory provisions and their implications have been carefully considered and widely discussed. To avoid new areas of conflict and controversy, e.g. in post-marketing monitoring a distinction should be made as early as possible between this and pre-marketing safety research and risk assessment and the criteria for incorporating information from monitoring in the approval procedure should be clarified.

Finally, new areas of conflict should be identified at the earliest possible state and investigated in advance. Attention is drawn particularly to the announced second-generation transgenic plants, which are e.g. supposed to have a health-promoting effect as "functional food". These will probably result in a shift in the debate from possible ecological impacts towards potential health impacts and also pose entirely

new and possibly even greater problems in safety assessment than the current transgenic plants.

IMPACTS AND FOLLOW UP OF THE PROJECT

The report was published as a parliamentary document (Bundestagsdrucksache 14/5492). The report was deliberated in the leading Committee on Consumer Protection, Food and Agriculture and two consulting committees. Thereby, the report was discussed controversial. The governmental majority presented a motion which included the whole spectrum of the report issues, proposed a further development of the concept sustainable agriculture and demanded a consequent application of the precautionary principle. In contrast, the motion of the opposition (CDU/CSU) concentrated on the rapid implementation of the new Deliberate Release Directive 2001/18/EC and was demanding a strengthened research and use of transgenic crop plants.

The result of the deliberation in the committees was a recommendation (of the governmental majority of SPD and the Greens) and report for the plenary which was approved in the plenary meeting of the German Bundestag on 14th June 2002. The TAB report was once again unanimously noticed by the plenary.

The part on post-marketing monitoring of the report was used in a documentation of the Federal Environmental Agency (UBA 2001) which summarise the state of debate at that time.

The report had pointed out that TA should be started on the new generations of transgenic plants at the earliest state as possible because these will probably result in a shift in the debate from possible ecological impacts towards potential health impacts and also pose entirely new and possibly even greater problems in safety assessment than the current transgenic plants. Following this recommendation, TAB was commissioned with a project on transgenic plants of the second and third generation in 2003.

CHALLENGES IDENTIFIED IN THE PROJECT

In the project identified (future) challenges which are still valid (conclusions of the reviewer):

- need for more accompanying ecological research to assess possible risks of gm plants
- missing definition of damaging impacts, so that there is still a considerable scope for different assessments
- missing normative framework for desirable agricultural practice or sustainable agriculture, against which impacts of gm plants can be measured
- insufficient implementation of post-marketing monitoring
- need for clear distinction between post-marketing monitoring and pre-marketing safety research

- development of criteria for the feed-back of information from the post-marketing monitoring to the authorisation agencies and for impacts on running approvals or re-approvals
- importance of the second and third generation of gm plants (in particular plant-made-pharmaceuticals, plant-made-industrials, functional food) with potentially a shift in the debate from ecological impacts towards health impacts and new problems in risk assessment

LITERATURE

Sauter, A.; Meyer, R. (2000): Sachstandsbericht Risikoabschätzung und Nachzulassungs-Monitoring transgener Pflanzen. TAB-Arbeitsbericht Nr. 68. Berlin http://www.tab.fzk.de/de/projekt/zusammenfassung/ab68.pdf

English Summary: http://www.tab.fzk.de/en/projekt/zusammenfassung/ab68.htm

UBA (2001): Stand der Entwicklung des Monitoring von gentechnisch veränderten Organismen (GVO) – Materialsammlung. UBA-Texte 60/01

AUTHOR OF THE REVIEW

Rolf Meyer

DISKURS GRÜNE GENTECHNIK (GREEN BIOTECHNOLOGY DISCOURSE) (2002) 6.3

BACKGROUND OF THE PROJECT

The so-called "Diskurs Grüne Gentechnik" ("Green Biotechnology Discourse" was initiated by the federal Ministry of Consumer Protection, Nutrition and Agriculture (Bundesministerium für Verbraucherschutz, Ernährung und Landwirtschaft, BMVEL) in 2001.

The situation in the starting year was characterised by the worldwide growing commercialisation of gm crops, the amendment of the EU regulation on genetic engineering, the abandonment of the three-year transitional trial phase of introducing gm crops in agriculture due to the BSE crisis (see review on the TAB project 2000), and the new direction of the German agricultural policy (so-called "Agrarwende").

The goal was to "establish a forum for clarification of facts and for debate among all relevant societal groups" (BMVEL 2003, p. 5).

BASIC DATA ABOUT THE PROJECT

The "Green Biotechnology Discourse" was started in December 2001 and finalised in September 2002. 30 stakeholder groups – industry, agricultural organisations, environmental and consumer groups, churches, trade unions – took part in the discourse. Further, representatives of different other ministries were present. The steering committee of the discourse consisted of representatives of the stakeholder groups and was chaired by a representative of the BMVEL.

The discourse was split in two phases, the starting phase (with a kick-of meeting, the selection of the moderator, the constitution of the steering committee and a hearing) und the phase of so called "discourse rounds". The stakeholder and representatives of the ministry met in five "discourse rounds" of two days duration und in a conference. At these meetings opinions of 53 experts were heard and discussed by the participants. Care was taken to have an equal proportion of "pro-GM" and "anti-GM" experts. The moderator had prepared in the starting phase a "basic reader" which gave an overview on scientific, economic, ethic, social and legal issues.

The steering committee agreed on the main topics to be discussed in the five "discourse rounds":

- preservation of biodiversity,
- innovation potential and future chances of green biotechnology,
- benefits and risks for consumer and producer,
- preconditions, chances and consequences of an abandonment of green biotechnology,
- information, participation of the public and freedom of choice.

The results were published in a final report written by the steering committee (BMVEL 2002). The BMVEL published in addition a booklet in which the results are resumed as seen by the ministry (BMVEL 2003).

MAJOR OUTCOMES OF THE PROJECT

For major points, a consensus was not achieved. The final report lists for the different topics the points of consensus and dissent, and open questions. Some major outcomes are (BMVEL 2002):

- Biodiversity: Consensus on the importance of preservation the biodiversity, but dissent on what is a negative impact on biodiversity (e.g. out-crossing); important open questions are seen in the definition of ecological damage and in the responsibility for damages on biodiversity;
- Risk assessment: Fundamental disagreement on the deliberate release and use of gm plants; as most important open question was identified the understanding of the precautionary principle;
- Benefits of GM plants: Consensus about the importance of plant breeding, the potentials of conventional breeding and the need of molecular-genetic and ecosystem research for successful plant breeding, but dissent on specific benefits from GM plants; important open questions are seen in the clarification of potential fundamental differences between conventional breeding and genetic engineering and in the regulation of intellectual property rights;
- Benefits of GM foods: Consensus on the high standards of food security and quality in the industrial countries, but disagreement on the consumer benefits from product innovation in the past and from gm food; as prior open questions are regarded the definition of improved foods and the possibilities of healthier nutrition through gm food;
- Freedom of choice and coexistence: Consensus on the freedom of choice for producer and consumer, the labelling of gm foods and that with zero tolerance coexistence is not possible, but dissent on thresholds, measurements and accountability; to the identified open questions belong feasibility of coexistence, coexistence rules and liability;
- Labelling: Clear and practicable regulation for labelling is demanded; a consensus for seed thresholds was not achieved.

IMPACTS AND FOLLOW UP OF THE DISCOURSE

All important stakeholders in the field of green biotechnology have participated in the discourse. But no changes in the German discussion on gm plants and foods resulted from this exercise – there was no successful mediation across the GM divide. The discourse is extensively documented on the "transgen" website (www.transgen.de). This official website declares: "In the end the discourse had little effect. The various views continue to stand opposed to each other. A number of questions that were discussed at the time have meanwhile been settled politically, but this has hardly calmed down the controversies." (Transgen 2007) For the in 2002 re-

elected red-green coalition government, freedom of choice and coexistence remained the leading policy goals for the area of biotechnology and food. Following the new EU regulation, an amendment of the German regulation on genetic engineering took place in 2004 [?]. Pro-GM participants regarded this new regulation as blocking the use of gm plants.

It has been suggested that the discourse had a built-in design to cement rather than to mitigate the controversy. A fundamental divide between two sides appeared due to the requirement of the pro/contra proportionality in the selection of experts. This arrangement offered organisations with more outspoken views greater leverage on the kind of expertise that would be presented. Any substantive debate between different experts was frustrated. Experts were used as strategic resources by the participating organisations. One effect of the discourse was apparently that cooperation and coordination within each side of the GM controversy was strengthened (Paula/van den Belt 2006, p. 32).

CHALLENGES IDENTIFIED IN THE DISCOURSE

In the discourse identified (future) challenges which are still valid (conclusions of the reviewer):

- definition of ecological damage
- definition and operationalisation of the precautionary principle
- regulation and impacts of intellectual property rights and patenting
- consumer benefits from gm foods as improved food products and healthier nutrition
- feasibility of coexistence, coexistence rules and liability
- working labelling regime for gm food
- thresholds for labelling of seeds

LITERATURE

BMVEL (Bundesministerium für Verbraucherschutz, Ernährung und Landwirtschaft) (2002): Diskurs Grüne Gentechnik. Ergebnisbericht, durch den Lenkungsausschuss am 27. August 2002 verabschiedet

BMVEL (Bundesministerium für Verbraucherschutz, Ernährung und Landwirtschaft) (2003): Diskurs Grüne Gentechnik. Hintergründe, Standpunkte und Erwartungen zum Einsatz der Gentechnik in der Land- und Ernährungswirtschaft

Heine, N.; Heyer, M.; Pickardt, T. (2002): Basisreader der Moderation zum Diskurs Grüne Gentechnik des Bundesministeriums für Verbraucherschutz, Ernährung und Landwirtschaft – BMVEL. Osnabrück, April 2002

Paula, L.; van den Belt, H. (2006): INES – The Institutionalisation of Ethics in Science Policy: practices and impact. Work Package 5: Ethics in Food Technologies. Final report

Transgen (2007): Diskurs Grüne Gentechnik: Wissen, Informationen, Meinungen. http://www.transgen.de/wissen/diskurs/ (27.02.2007)

AUTHOR OF THE REVIEW

Rolf Meyer

GENETIC ENGINEERING AND ORGANIC FARMING (2003) 6.4

BACKGROUND OF THE PROJECT

In December 2000, the German Federal Environmental Agency (Umweltbundesamt – UBA) held a professional conference on the subject of "Green genetic engineering and organic farming". During this conference, possible approaches for protecting organic production sites as the use of genetically modified plants increase in conventional agriculture were discussed with persons representing organic farming from the research, production and administration sector.

The experts participating in the conference agreed that the only way to minimise contamination due to introgression from genetically modified plants is to use suitable prescribed distances between organic farming areas and fields containing genetically modified plants. Additionally, the establishment of zones that are free of GMOs should be considered within protected areas.

At the starting time of the project, there was no basic legal stipulations in Germany or in Europe with regard to these calls for minimum prescribed distances and GMO-free protected areas.

The objective of the "Green genetic engineering and organic farming" project was thus to present different legal scenarios for establishing regulations on minimum prescribed distances between organic farming areas and fields containing genetically modified plants within the German und European legal systems.

BASIC DATA ABOUT THE PROJECT

The specialist report entitled "Green genetic engineering and organic farming" (Barth et al. 2003) was prepared on behalf of the German Federal Environmental Agency by the Forschungsinstitut für biologischen Landbau Berlin e.V. and the Öko-Institut e.V. in the time between June 2001 and August 2002. The report includes the results of two workshops held on 29 October 2001 and 16 January 2002 in Berlin during which the initial results were discussed with various experts.

MAJOR OUTCOMES OF THE PROJECT

There is a world wide consensus among organic farmers not to use genetically engineered organism (GMO). Initially implemented through the guidelines of organic farming associations, this rule now gained accession to consumer protection legislation in the USA, Japan and the European Union.

EU LAW PERMITS PROTECTIVE MEASURES FOR ORGANIC FARMING

At the European level neither the EU regulation on organic agriculture nor the seeds directives prescribe mandatory measures for the protection of organic crops against

pollination by GMO pollen. An evaluation of EU Directive 2001/18/EC on the Deliberate Release of GMO shows, however, that the permission to market GMO may include an order to take measures to avoid property damage through pollination as one of the "specific conditions of use and handling" of the GMO. This results from a systematic and parallel interpretation of the EU Directive on the release of GMO and the EU regulation on organic agriculture. Only inasmuch as the interpretation of the Directive on the release of GMO takes into account the legislative targets of the EU regulation on organic agriculture will a balance of interests between organic agriculture and the cultivation of GMO be accomplished.

PROPOSALS FOR ISOLATION DISTANCES

Currently the most widely discussed option for affording protection against property damages is to provide isolation distances between cultures with GMO plants and organically managed cultures; another is to demarcate GMO-free regions.

Isolation distances have for a long time been used in seed production to maintain purity of breed. The goal is to keep impurity to a minimum. Statutory minimum isolation distances are based on past experience with seed production and they do not completely rule out hybridisation. Nevertheless, the imposition of safety distances does offer itself as one possible way of protecting organic agriculture.

An analysis of empirical data with a view of defining isolation distances revealed many gaps and hence an urgent need for further research. Despite this shortcoming, and for pragmatic purposes, the present survey was based on what data were available to derive first recommendations for isolation distances.

Measures for protection against property damages through GMO pollination in organic agriculture, such as the declaration of isolation distances on commercial packaging of GMO seeds, could be imposed by way of commercialisation permits. Implemented through commercialisation permits such measures could even today have an effect on civil-law relationships between organic farmers and GMO farmers, under certain conditions entitling organic farmers to claims for damages caused by genetic introgression.

PATHS TOWARD CONCILIATION BETWEEN NEIGHBOURS

In Germany the private legal rights and spheres of interest of organic farmers and users of transgenic varieties are defined and delimited by civil law. The borderline is drawn by a system of legal claims governing neighbourly relationships. § 906 of the German Civil Code is the central norm of private environmental law. Under this paragraph users of transgenic plants can be required to avoid or minimise genetic modifications in neighbouring cultures. When an organic farmer suffers market losses due to the pollination of organic cultures by GMO pollen, the owner of the neighbouring transgenic cultures can be ordered to pay damages. At present it is difficult to assess the level of enforceable claims. The complex intercalating system of claims to desist or to compensate will have an inhibitory impact on the use of transgenic seeds, and the economic burden of having to avoid GMO pollination of

neighbouring cultures or pay compensation, will not be calculable in advance. However, organic farmers are so burdened with having to secure cogent proofs of causality that many will see this as an intolerable manacle. Under these conditions there will be little hope of arriving at a state of peaceful coexistence.

The idea of a self-organised mediation system for temporal and spatial isolation in connection with a compensation scheme financed by GMO producers and users is introduced.

PUBLIC REGISTER OF PRODUCTION SITES

All member states of the European Union are required by the Directive 2001/18/EC to establish public registers documenting GMO cultivation sites and the identity of cultivated GMO varieties for the purpose of monitoring environmental effects. This register could at the same time serve as a production register for GMO. The directive leaves it up to the member states to determine the details of register management. The directive contains no impediment to requiring farmers to provide precise information on the location of their GMO cultures for the register. Information concerning the precise design of the GMO and the analytic measures to detect it could be included along the lines of the draft of the EU regulation concerning traceability and labelling. However, this draft only requires that the codes of GMO sequences be published. Since organic farmers must be in a position to reliably detect GMO sequences, the cultivation register would need to contain precise information on their identity.

INTRODUCTION OF GOOD PRODUCTION PRACTICE IN GMO CULTIVATION

Protective measures to avoid GMO pollination could be imposed on users of GMO seeds through the introduction of a code of "Good Production Practice in GMO cultivation" (GPP). Such measures could include, for example, defensive cultivation planning and the maintenance of specific distances between transgenic and susceptible organic cultures. For the implementation of the GPP code the administration must be empowered to impose specific single protective measures. Non-observance of such an order must be penalised as a regulatory offence. GPP could be introduced by an amendment to the Gentechnikgesetz (German act on genetic engineering) or the Saatgutverkehrsgesetz (German act on the marketing of seed). Alternatively, it could be introduced through an amendment to a specific (organic) agriculture statute.

DAMAGE FUND FOR GMO POLLINATION

For pollination by GMO from non-determinable sources a system for compensating organic farmers for market losses is necessary and indeed feasible. Compensation could be provided by a governmental compensation system or a fund model based on a statutory regulation or a voluntary self-commitment of producers and users of GMO.

PROTECTION OF ORGANIC SEED PRODUCTION

The protection of organic seed production necessitates closed regional production areas. This requires the development of an appropriate legal basis.

IMPACTS AND FOLLOW UP OF THE PROJECT

Some points are incorporated in the amended German legislation on genetic engineering, but many other points are still discussed controversial.

CHALLENGES IDENTIFIED IN THE DISCOURSE

In the project identified (future) challenges which are still valid (conclusions of the reviewer):

- definition of isolation distances and Good Production Practice
- liability and compensation fund
- protection of organic seed production
- coexistence which does justice to consumers' right to freedom of choice is not easily to be arrived

LITERATURE

Barth, R., Brauner, R., Hermann, A., Hermanowski, R., Nowack, K., Schmidt, H., Tappeser, B., Meier, J. (2003): Genetic Engineering and Organic Farming. UBA-Texte 02/03, Berlin

AUTHOR OF THE REVIEW

Rolf Meyer

GREEN GENETIC ENGINEERING – TRANSGENIC PLANTS OF THE SECOND AND THIRD GENERATION (2005) 6.5

BACKGROUND OF THE PROJECT

The TAB-project “transgenic plants of the second and third generation” was demanded by the Committee for Education, Research and Technology Assessment. The term "second generation" was used to describe those genetically modified plants (GMP) which are in the pipeline (i.e. in industrial development and shortly before licensing), while “third generation” is applied to those in research or a very early stage of development.

The origin of this project can be clearly traced back to the previous TAB project "Risk assessment and post-marketing monitoring of transgenic plants", where the investigation of this topic was brought up as an important recommendation concerning future TA need (see review 6.2).

A second motivation was the (as well since a long time especially in the political debate repeated) assumption, that a shift in the European consumers' hostile attitude towards GMP can't be expected as long as no products from GMP with a convincing benefit are on the market. The TAB project to study the potential and risks of future transgenic plants was limited to the subset of GMP with modified use properties for the consumer (so-called “output traits”). The TA project aimed to answer the following questions:

- how the targeted additional benefits of these GMP are defined,
- how they are supposed to be achieved,
- what economic potential can be expected,
- what new (types of) risks should be assumed,
- what new questions of safety assessment result from these,
- whether existing safety measures appear adequate, or whether they need to be modified, expanded or supplemented,
- what regulatory challenges result, and also
- what effects on consumer acceptance are to be expected.

BASIC DATA ABOUT THE PROJECT

The TA-project was executed in 21 months (November 2003 – July 2005), subdivided into two phases. Eight scientific studies (expert opinions) were commissioned during the project. In the first phase (until August 2004), based on three of the expert opinions, an overview of research and development as well as concerning the economic potentials and the international debate on risk evaluation and assessment was worked out. The second phase of the project was devoted to an in-depth analysis of "molecular farming" which means the use of GMP for the production of industrial materials (so-called PMI or plant made industrials) and especially as a source of

pharmaceutical substances for human and animal medicine (so-called PMP, or plant made pharmaceuticals). The draft final report of TAB was based mainly on the commissioned scientific studies and was evaluated by a number of experts from science and government.

The main topics of the final report were:

- a detailed description of GMP for functional foods, for PMI and PMP[12]
- including an in-depth discussion of their economic potentials and
- their possible ecological and health risks;
- the possible performance of biological and physical confinement measures;
- the regulation of molecular farming (in the EU, compared to the U.S. and Canada):
- areas for action (with regard to the German national and the EU level).

MAJOR OUTCOMES OF THE PROJECT

OVERVIEW OF RESEARCH AND DEVELOPMENT – LICENSING AND RELEASE

GMP with output traits were divided into six groups:

1. improved contents in plants which are a source of food (functional foods - FF);
2. improved contents in plants which are a source of animal feed;
3. optimised or modified plants for production of industrial materials (PMI) or
4. for production of pharmaceutical substances (PMP);
5. GMP for phytoremediation (plants for the treatment of contaminated soils);
6. modified properties of decorative flowers (colour) or plants (e.g. lawn).

GMP with output traits play no role in global cultivation, which is still completely dominated by herbicide and insect resistance. Until 2005 eleven GMP with modified output traits have been licensed in various countries (2006: plus one), nine of them without relevance for the TAB report (tomatoes with longer shelf life, modified decorative flowers, tobacco with reduced nicotine content). The two remaining varieties, a rapeseed with high lauric acid content and a soy bean with increased oleic acid content, have been unsuccessful on the US market, and are accordingly not grown to any effective extent. In the *EU*, only the three modified carnations have been licensed (since 1997/98). The licensing pipeline contains (since 1997) 21 applications, including one PMI GMP, the "famous" potato with modified starch composition.

Among the releases in the U.S. (1988-2003), GMP with modified output traits account for c. 20% of the c. 10,000 applications, equivalent to 150-230 a year since 1994. In the EU, GMP with modified output traits account for c. 15% of all releases in 1988-2003 (over 270 of 1,850 applications). In line with the trend for GMP gener-

12GMP for animal feedstuff were not dealt with in depth, as their uses are more comparable with agronomically modified GMP, and hence do not open up new prospects for use in the same way as the other three groups, and because they play only a minor role in Europe, quantitatively speaking.

ally, there has been a very definite decrease in release applications since 1996/97. A breakdown by individual groups shows a much smaller significance of the feedstuff sector than in the USA.

GMP FOR THE PRODUCTION OF FUNCTIONAL FOODS OR THEIR INGREDIENTS

The range of functional ingredients produced or (to be) modified in plants by genetic engineering is still very manageable. The GMP developed so far are predominantly prototypes to demonstrate fundamental feasibility, which need further development for commercial use and must be tested not only in the field but also on humans in nutrition studies.

For most functional ingredients, the current genetic engineering approaches – overexpressing or reducing the activity of individual genes directly involved in the relevant metabolic pathways – are not sufficient to achieve commercially attractive content of the functional ingredients in the GMP. Hopes involve conceptual and methodological further developments in metabolic engineering, which seeks to affect entire metabolic pathways and regulatory networks in a coordinated way. Whether FF GMP can be established in the medium term as a source of functional food raw materials and ingredients depends crucially on whether the assumed cheaper production of functional ingredients in GMP can be actually achieved. This is not easy, as there are established production platforms already in existence (e.g. chemical synthesis, microbial production, isolation from natural sources) for most of the ingredients currently being researched in GMP, which FF GMP will have to compete with. The resource-intensive and comparatively long development period for new GMP varieties and the functional foods or ingredients produced from them represent a comparative disadvantage, as the regulatory requirements mean tying up resources in the long term in a dynamic market which actually requires a rapid and flexible response. In addition, GMP approaches generally have to be supplemented by other food technology options, as functional GMP for direct consumption can only meet a small segment of the possible entire supply of and demand for functional foods, for reasons of shelf life, seasonal availability, convenience and bioavailability.

PLANT MADE PHARMACEUTICALS

GMPs have been discussed for many years as a highly promising new production platform for drug production. The hope is particularly for low-cost production in large quantities. Products produced using genetic engineering methods account for the overwhelming part of pharmaceutically effective proteins and peptides, which are also called “biopharmaceuticals”. Significantly less important (and also in very early stages of development) are genetic approaches to influencing pharmaceutically effective so-called secondary metabolites, which were not discussed in the report.

To date, no PMP GMP has been licensed for placing on the market anywhere in the world. There are intensive research and release activities in the USA and Canada, while the activities in the EU come predominantly from two French firms (Meristem Therapeutics and Biocem). The plant species used are predominantly maize and tobacco, followed by rapeseed and soy bean. No PMP has yet been given “real” ap-

proval as a drug. Several proteins which also have pharmaceutical uses are already on the market, although so far they can only be sold as research or diagnostic reagents. They come from experimental releases (in the USA).

Of those PMP in development, so far only two have been recognised as having so-called orphan drug status (for treating rare diseases). In the EU orphan drug status (for use with mucoviscidosis sufferers) was granted in 2003 to a so-called gastric lipase (from maize). To date the protein comes from experimental releases in France, and could be the first PMP for application for approval as a drug in the EU. In the USA a so-called galacosidase was granted orphan drug status in the same year. 15 PMP were identified in various phases of clinical testing. In addition to gastric lipase, an antibody for caries prophylaxis and patient-specific antibodies for treating non-Hodgkin lymphomas are in an advanced stage of testing. Several PMP are currently being developed for veterinary use, with the option of extending these to human indications later if successful. Besides these concrete examples, there is a vast number of PMP in preclinical R&D stages. A key area is developing antibodies, presumably because possible specific advantages of production in GMP seem most within reach.

To assess the future potential of PMP GMP, comparison with competing production platforms is needed. To date, biopharmaceuticals have almost entirely been produced microbially or in animal cell cultures, and transgenic animals are rather more advanced than PMP approaches (although here again no drug has yet been approved). The various production platforms are briefly presented and described in the report.

Possible specific advantages of PMP GMP were considered in terms of freedom from human-pathogenic agents, correct glycosylation and of investment and production costs including scalability. These were found to be predominantly dependent on the product. For example, it is clear that glycosylation closer to mammalian cells (modification of the protein in the cell) from PMP has an advantage over microbial systems for many drugs, although this may also prove a pharmacological disadvantage for others. It is fairly certain that general cost advantages cannot be assumed for production from PMP – these are only plausible on the unrealistic assumption of only slightly regulated open cultivation (plus ideal yields). An in-depth investigation of the foreseeable potential of possible oral vaccines showed that oral vaccines do not seem very important for vaccine development, and particularly that the idea of ingestion in the form of unprocessed fruits (still frequently cited) is entirely unrealistic.

An overall assessment of the currently foreseeable economic potential concluded that in view of the major and growing importance of biopharmaceuticals generally, there is probably also growing potential for production in PMP, without the general cost advantages generally assumed. Their competitiveness is decisively determined by advances in competing production systems and development of specific regulations for cultivation and corresponding risk management measures.

PLANT MADE INDUSTRIALS

Use of PMI GMP seems comparatively further away. This is a little surprising, given the intensive work on relevant GMP concepts over many years, and the fact that the

first two such GMP were approved and commercialised years ago. The only currently foreseeable example here in the EU is the starch potato, which has been in the approval pipeline for years.

For all other approaches (whether in "designer oils" or "designer starches", production of industrial enzymes, biopolymers or other special ingredients) it is virtually impossible to assess how far the work has come in concrete terms. In some cases, this is in-house work, in other cases the development work – e.g. on bioplastics from GMP – seems to be taking significantly longer than hoped. The reasons for this differ, depending on the development goal and plant species, but the examples presented suggest possible general assessments (which also apply e.g. to development of FF GMP).

- In several cases, expectations particularly of attainable product yields have been not been satisfied even after many years of development. In the course of maximising content, apparently undesired side effects have emerged (are emerging) in many cases which then result in lower yields. While this does not make the concept (economically) unusable, it does affect the range of substances which can be produced on a commercially competitive basis.
- In several cases, the transition from the highly promising model plants to specifically usable ones did not proceed as hoped, as the genes failed to "function" accordingly.
- In other products, the alternative production systems (cell-based systems, transgenic animals) developed faster or more efficiently.

An assessment of the prospects for PMI concepts is accordingly (even) more difficult than for PMP. Production of bulk products seems unlikely in the foreseeable future, the production of renewable raw materials is more likely to be optimised through breeding of non-genetically-modified plants. Industry sees realistic prospects for high-price special applications, if these can only be produced in GMP and not in conventional varieties or the cultured varieties otherwise used. Dual use (e.g. bioplastic and feedstuff) depends on relevant approval, which is only conceivable for selected approaches. Transgenic trees for plantation farming could become more significant worldwide, but cultivation in the EU is unlikely for a long time.

POSSIBLE ECOLOGICAL AND HEALTH RISKS

Given the early stage of GMP modified for output traits, no risk discussion has developed for most sub-aspects, so that no presentation in detail was possible. This applied particularly to the possible ecological risks of FF GMP and the possible health risks of PMI GMP. The risk discussion for FF GMP is focusing on the basic question of safety evaluation of innovative and primarily functional foods, while for PMP GMP the emphasis is on possible release into the environment and food and preventing this. Therefore the risk debate on molecular farming (of PMP and PMI) generally has so far concentrated almost entirely on the question of reliable sequestration and containment of GMP.

Basically, GMP modified for output traits fundamentally change the situation for risk regulation (i.e. risk assessment, risk evaluation and risk management), because at least PMP GMP as well as some PMI GMP have an inherent risk because of the medical and physiological impact of their ingredients.

The current goal of risk regulation is to approve only GMP which are risk free as compared to "conventionally" bred plants. This concept must be at least modified by developing comprehensive and rigorous safety requirements for cultivation and processing e.g. for PMP GMP with their potential environmental and health risks (as is the case in Canada and the USA). It will probably be necessary to impose group-specific measures which imply moving away from the pure case-by-case principle, or at least supplementing it.

At the same time, the discussion of benefits is taking on new priority compared with the 1st generation of GMP, including risk evaluation and regulation. So far, it has been possible to ignore doubts about the benefits of the genetically introduced properties from the regulatory point of view (because no concrete risks to health and the environment were established as a prerequisite for approval), and to leave evaluation to market forces. In future, the desired benefit (e.g. production of life-saving drugs) is likely to play a greater role – at least in some cases – in risk evaluation, including in the approval decision.

BIOLOGICAL AND PHYSICAL CONFINEMENT MEASURES

In considering possible risk management measures for GMP modified for output traits, it is necessary to distinguish between two groups of GMP which pose very different requirements for regulation, namely those which can be regarded as just as safe as the approved 1st generation GMP, and all others.

The first group could include several of the conceivable PMI applications, e.g. if these involve modified food plants which are currently being used for industrial purposes in their conventional form. At least if the relevant GMP has explicit approval for food and feed, large scale cultivation is conceivable subject to the prevailing variety-specific coexistence regulations, and would not differ substantially in quality from the food sector. The second group presumably includes most PMP, together with a range of conceivable PMI plants for which special containment/confinement will be required. In the event of open cultivation, and possibly greenhouse cultivation, particularly strict biological and physical confinement measures must apply, as the current regulations in Canada and the U.S. require.

The report discusses in detail the question how reliable the various methods in preventing undesired dissemination of GMP are. The overall conclusion was that the present state of science and technology is unable to offer any system for confinement of transgenic nonfood plants which permits coexistence in open cultivation of GMO and non-GMO species completely free of any influence. But it was emphatically stressed that the extent to which such influence can be tolerated and under what conditions are matters for society to decide.

Only few biological confinement methods have reached a state of development where substantial studies on integrity and leak tightness can be carried out. An (almost) complete prevention of the escape of a transgene is up to now only possible in closed systems.

REGULATION ISSUES IN MOLECULAR FARMING

Consideration of the state of regulation of genetic engineering showed that the present regulations and procedures for molecular farming are not entirely appropriate or adequate. For molecular farming of "high price" products or ingredients on comparatively small areas, approval for release under Part B of European Directive 2001/18/EC is inadequate in many cases (because the relevant products may not be placed on the market), although approval for placing on the market under Part C would actually not be required, because free trade and unlimited cultivation are not goals of GMP development. At least in the medium term, there will accordingly be a need for change, particularly in the regulation of genetic engineering. By contrast, there is currently hardly any need for change apparent in drug and chemical regulation.

Activities and discussions in the EU (until summer 2005) showed that very little attention had been paid to the issue of molecular farming so far, particularly in comparison with Canada and the U.S. *[this has changed a little bit since then, as EFSA and IPTS have started several activities, both of them taking notice of the TAB report; see below]*. This implies a need at EU and national level for more intensive consideration of the opportunities and potential risks of GMP modified for output traits.

AREA FOR ACTION: OPERATIONALISATION OF VISIONS AND SCENARIOS

Although molecular farming has been described as a future option for many years in the debate on genetic engineering, it has mostly been presented in very vague terms, either as largely unsupported assumptions about possible benefits (and/or risks) or as visions of the future. The relevant documents typically focus on scenarios for the use of possible products from GMP modified for output traits, describing scenarios for production and cultivation which have little contact with reality, and completely ignore regulatory aspects and realistic coexistence scenarios. Such operationalisation accompanied by greater social opening seems very important for the coming debates on possible future use of transgenic plants. These tasks should be addressed with a view to the coming Framework Programme 7, together with more substantial links to the relevant policy areas, strategies and goals (including more extensive use of renewable raw materials, development of rural areas, sustainability of agriculture, healthier nutrition).

AREA FOR ACTION: GERMAN RESEARCH POLICY

Facing the new and complex questions regarding the benefit as well as novel risks and their management, for German research policy the development of interministerial promotional R&D measures for research into molecular farming was assessed

as being adequate. A viable and societally acceptable approach would require not only bringing together the ministries' technical points of view but also including various interest groups in developing such promotional programmes and projects.

No assessment was performed for R&D approaches in detail, e.g. deserving promotion or safety issues requiring particularly urgent investigation. However, a specific proposal was made for a “Progress report by the Federal Government on the status of publicly funded activities in connection with research, approval, cultivation and marketing of GMP”, which should in detail review the aims and outcomes of the last 10 to 15 years and draw conclusions for the future promotion and funding of R&D devoted to biotechnology and plant sciences (a proposal, which seems to be suited for every other country as well as the EU level). Such a report could possibly offer a basis or at least a point of reference for more constructive and sustainable further development of research policy on green genetic engineering and alternative strategies.

AREA FOR ACTION: MODIFICATION OF REGULATION AT EU LEVEL

The need for action concerning modification of regulation was clearly located at EU level. The regulation has to come under review if it is suited for the production of PMP and PMI (which seems not so; see results above). With regard to national regulations, it was concluded that they have to be revised in a second step according to the EU regulation.

IMPACTS AND FOLLOW UP OF THE PROJECT

Parliamentary debate and/or decision:

The proposal of the "Progress Report" was picked up several times in parliamentary debates (on GMOs, but not directly connected with the TAB report) and has been integrated in the official statement of the (together with the christian democrats governing) social democrats concerning the current amendment of the gene technology law.

Public perception:

Compared to other TAB projects, a relatively broad press coverage in print and web-based media began directly after the acceptance by the Committee for Education, Research and Technology Assessment and publication of the report in February 2006. In June 2006, TAB together with the Committee for Education, Research and Technology Assessment organized a public workshop in the German Parliament and invited stakeholders from industry, regulatory authorities and academia to answer to and to discuss the report's view. The workshop was very well attended, by all kinds of stakeholders. The usual heavily polarized debate was astonishingly moderate, in our view the outcomes of the report were completely validated, although "the industry" tried to proof a too negative judgement concerning the economic potentials (but failed to show any other perspective than was discussed by TAB).

Scientific recognition:

The performance of the report was appreciated a lot (there is up to now no publication of comparable comprehensiveness in Germany, maybe in Europe?), accompanied by heavy criticism from scientists who refuse to concede that the results of molecular farming up to now are in many respects of a poor nature (and probably are opposing the proposal of the reviewing "Progress Report"). The websites on GMOs and biosafety of the German research ministry refer to the report (especially concerning the risk regulation of PMP) and integrated links to TAB. IPTS invited TAB to a workshop on molecular farming which was then attended by Armin Spök from IFZ (Graz, Austria) who was responsible for two of the expert opinions on risk regulation, and who has published its results recently in TRENDs in Biotechnology.

CHALLENGES IDENTIFIED IN THE PROJECT

Due to the up to now very limited presence of the topic "molecular farming" in the debate on GMOs (at least in a detailed manner), an overall need at EU and national level for more intensive consideration of the opportunities and potential risks of GMP modified for output traits is obvious.

- Technical dimension: The possible performance of future GMP could be assessed in a more realistic way (via an in-depth "Progress Report"); with respect to the cultivation of PMP and PMI GMP, the development and assessment of biological and physical confinement measures are of special and fundamental importance;
- Social dimension: The possible acceptance of PMI and PMP GMP will (in my opinion, A. Sauter) depend on an early and transparent participation already in the R&D phase, beyond promotional communication activities like "Plants for the Future" (see "operationalisation of visions and scenarios");
- Political / regulatory dimension: The whole EU regulation has to be checked for appropriateness for molecular farming (EFSA has started a self tasking activity, IPTS is also working by order of the Commission).

LITERATURE

Sauter, A., Hüsing, B. (2005): Grüne Gentechnik - Transgene Pflanzen der 2. und 3. Generation. TAB-Arbeitsbericht Nr. 104, Büro für Technikfolgen-Abschätzung beim Deutschen Bundestag, Berlin http://www.tab.fzk.de/de/projekt/zusammenfassung/ab104.pdf

English summary: http://www.tab.fzk.de/en/projekt/zusammenfassung/ab104.htm

Spök, A. (2006): Molecular farming on the rise – GMO regulators still walking a tightrope. In: TRENDS in Biotechnology 25(2), pp.74-82

AUTHOR OF THE REVIEW

Arnold Sauter

GENTECHNOLOGIEBERICHT (GENE TECHNOLOGY REPORT) (2007) 6.6

BACKGROUND OF THE PROJECT

The “Gentechnologiebericht” (Gene Technology Report) of the Berlin-Brandenburg Academy of Sciences and Humanities is a monitoring project that focuses not only on GM plants or GM foods but includes also medical applications. The report assesses the entire field of gene technology, because unlike other technologies this particular field is affecting the basic principles of life, human existence and that of all other living beings.

The report surveys carefully all present facts and the latest developments in the field of gene technology and presents a critical study from an impartial viewpoint.

BASIC DATA ABOUT THE PROJECT

The report is edited by an interdisciplinary study group consisting of several members of the Berlin-Brandenburg Academy of Sciences and Humanities. The participating authors are impartial. They are experts on different disciplines of the subject, and they observe the subject beyond their own specific discipline as well. Acknowledged external experts are involved additionally for further detailed questions.

The report was published for the first time in 2005 (Hucho et al.). It consisted of four main chapters representing different case studies, which were chosen following public controversies at that time. One of these case studies is on gene technology applied to plant breeding, farming and foods (green gene technology). A separate supplement published in March 2007 updates the data and adds news topics (Müller-Röber et al., 2007).

MAJOR OUTCOMES OF THE PROJECT

The monitoring of the report consists of three parts: The first part is a documentation of today's state of technological development including scientific progress and the recent range of applications. The second part is a detailed overview of economic, ecological, social, political, legal, and ethical aspects. The third part is a system of indicators that are suitable to unravel and describe the topics connected with the application of gene technology to plant breeding, farming and foods.

The first part of the monitoring report, the documentation of technological developments, gives a detailed view on recent research and describes the aims of this research as well as the applied techniques. Cisgenic plants and smart breeding are examples for two newly invented techniques that were presented in the media as alternatives to transgenic plants, which is the “classic” way of modifying plants. The report draws the conclusion that both techniques could be useful extensions of the scientific methods. But they will not be able to replace the methods of genetic engineer-

ing transferring foreign DNA from other species since the available genes are restricted to closely related species.

Further topics are the DNA sequencing of plant genome, the use of genetic engineering in research on biodiversity and ecosystems, enabling technologies in modern plant breeding, new methods of selection and both the creation and phenotyping of genetic diversity. On top of giving an overview over current scientific progress, the monitoring report includes an overview of the input and output traits that are worked on in the field of GM plants. Several examples are being examined, including insect resistant maize, the cultivation of which has been started in Germany recently, “golden rice” that could arouse a great deal of interest especially for poorer people in developing countries, and “energy plants” which gain high yield of biomass and are being discussed in public as an alternative form of energy production.

The second part of the monitoring report examines different topics concerning GM plants and GM foods, which are debated controversially in the general public. Public opinion on GM plants and GM foods is a major factor and has to be taken into account, not only in Germany but in the whole European Union. The scepticism about these particular applications of gene technology is much higher in Europe than in the US, Canada or Argentina, where GM plants have been cultivated for almost ten years now. The report investigates the background to this poor acceptance. On the one hand, GM plants meet with criticism because of possible unforeseen negative ecological side effects, on the other hand GM foods are criticized because of the risk of unpredictable health effects. The report examines both argumentations. GM plants that are resistant against herbicides or insects are used as two examples to document the recent scientific findings on ecological and health effects. Furthermore, the report focuses on economic aspects being of particular interest to political debates. An overview over several studies on the economic potential of GM plants is being presented. The topics being discussed are the development of the areas cultivated with GM plants, the question who will profit from GM plants, the preconditions for benefiting of today's GM plants, the potential benefits of GM plants for the future, and the number of jobs being connected with the use of GM plants in agriculture and food production. Furthermore, a portrayal of the current situation of European and German laws on GM plants and GM foods is presented, which includes the topics coexistence and liability. Despite the fact that ethical questions might be less important for the agricultural use of gene technology than for medical use, the report even examines ethical problems that could be associated with the use of gene technology during the process of plant breeding.

The third part presents indicators that allow to describe the different current developments in the field of green gene technology clearly and easily to understand. A single indicator stands for a “measuring device” which allows to depict complex issues that cannot be measured directly and to assess these issues representatively. An indicator reduces complexity through which developments at long and at short intervals are less difficult to spot. A set of indicators makes it possible to back up subjective perceptions of developments or to falsify them. Proven developments can be analysed and interpreted with the help of further data. A misleading concentration on certain details frequently produces wrong results or misleading interpretations. The

report tries to prevent this serious risk by relating the indicators to one of the specifically defined problems that are connected strongly or weakly with the subject. All these defined problems seen as a whole should describe the issue of green gene technology entirely. This methodological step prevents observation loopholes if no suitable indicator could be found. In detail, the several defined problems take up again the different economic, ecological, social, political, legal, and ethical questions and also latest scientific research and current applications, which are presented in the second part of the report. In addition, connections between these aspects are pointed out and even problems connected to GM plants and GM foods less obviously are part of the overall picture. The definition of the problems is an important task of its own. The definition of what is seen as a problem is based on the public point of view on chances and risks, which might be diametrically opposed to an experts viewpoint. Nevertheless, this guarantees that the report does not deal with an experts debate only.

The following indicators represent some examples: The number of traits, the number of field trials and the number of traits in these field trials are used to examine the potential that green gene technology has developed currently. The sales and profits being made with genetically modified seeds, the worldwide area under cultivation with GM plants and several cultivation data for Germany are some of the indicators being used to determine the current economic relevance of GM plants and GM foods. The amount of money being spent on research on GM plants and the number of applied patents are two of the indicators that try to measure the scientific and economic importance of green gene technology. Ecological effects are observed for example by the number of proven cases, when a GM plant interbreeds with another plant outside the field, and the use of pesticides on GM plants compared to the amount used on non-GM plants. The dissemination of GM foods can be described for example by the number of GM plants being approved for food use in the EU and by the market share of these products. The consumers' and the farmers' acceptance of GM plants and GM foods are two indicators being used to measure the intensity of conflicts that the introduction of these products might cause. Generally, the indicators are used to describe the situation in Germany. The data is updated yearly. The report makes use of appropriate and valid sources like scientific studies or official databases of the government. The particular scientific work of the monitoring report is the selection of the indicators that has to base on intelligible criteria and that should cover all different aspects of green gene technology. Single results are linked with each other to achieve a more precise assessment and a balanced interpretation. Finally, the report publishes recommendations based on this work.

IMPACTS AND FOLLOW UP OF THE PROJECT

The monitoring report is not only addressed to the policy makers in parties, government, administration, non-profit organisations, scientific societies etc. but also to the general public interested in this particular issue. The report would like to make a good case for public discussions without taking a position for one side or the other. Thus the report wants to achieve a more objective public debate.

The next report is going to be published in 2008. Therein the issue of genetically modified animals will be dealt with additionally. Further and current information can be found at www.gentechnologiebericht.de.

CHALLENGES IDENTIFIED IN THE PROJECT

The annual update of the indicators does not only include the presentation and the interpretation of the recent data. It includes also a discussion if the indictors themselves. The main stress within the complex topics could have changed during the time and new additional data could be necessary for a conclusive interpretation. New topics have to be recognized as well, for example the debate about the consequences of the recent discoveries in the field of epigenomics.

LITERATURE

F. Hucho, K. Brockhoff, W. van den Daele, K. Köchy, J. Reich, H.-J. Rheinberger, B. Müller-Röber, K. Sperling, A. M. Wobus, M. Boysen, M. Kölsch (2005): Gentechnologiebericht - Analyse einer Hochtechnologie in Deutschland. Forschungsberichte der Interdisziplinären Arbeitsgruppen. Berlin-Brandenburgische Akademie der Wissenschaften, Berlin

Bernd Müller-Röber, Ferdinand Hucho, Wolfgang van den Daele, Kristian Köchy, Jens Reich, Hans-Jörg Rheinberger, Karl Sperling, Anna M. Wobus, Mathias Boysen und Meike Kölsch (2007): Grüne Gentechnologie - aktuelle Entwicklungen in Wissenschaft und Wirtschaft, Supplement zum Gentechnologiebericht (mit Beiträgen von Volker Beckmann und Christian Schleyer). Berlin-Brandenburgische Akademie der Wissenschaften, Berlin

AUTHOR OF THE REVIEW

Mathias Boysen

NORWAY 7.

RECONVENING THE LAY PEOPLES PANEL ON GM FOOD 4 YEARS AFTER (2000) 7.1

BACKGROUND OF THE PROJECT

The lay people's panel was commissioned in 1996, by the Norwegian Biotechnology Advisory Board (NBAB) and The National Committees for Research Ethics (NCRE), based on government grants. It consisted of 15 persons randomly chosen among 400 applicants. None of these had particular affiliations concerning the question of genetically modified food.

After several meetings to develop internal reflection on the issue of GM-food, the panel teamed up with a panel of experts to discuss central challenges regarding GM-food. After the conference, the lay people's panel delivered a consensus report with advice for action.

In 2000, the panel reconvened to discuss the issue with a new panel of experts, under the auspices of NBAB, NCRE and the Norwegian Board of Technology (NBT). In the meanwhile, some members of the panel had continued their involvement in the issue, thus establishing themselves as experts on the issue. Again, the lay people's panel delivered a consensus report.

The conference had the following aims:

- give a summary of central developments on research and use of GM food since the conference in 1996
- present a consensus report with advice on whether a moratorium on importing and marketing GM-food should be imposed and eventually on other relevant topics
- to strengthen the emphasis on lay people's insights in technology assessment and management

BASIC DATA ABOUT THE PROJECT

The project was a consensus conference based on a hearing of experts. The conference was undertaken on 15th-16th of November 2000. Participants included 15 lay people, 18 experts took part in the hearing. In addition there were a number of facilitators.

The hearing focused on the following topics:

- Status of knowledge about effects on health and environment
- Status of regulations and control: Are present regulations comprehensive and efficient?

- Is a moratorium feasible and legitimate?
- What are the interests of consumers, retailers, processors and producers?

MAJOR OUTCOMES OF THE PROJECT

The panel gave the following conclusions:

A moratorium should be imposed, prohibiting cultivation of GM food and feed with the exception for test purposes. Imports and marketing of GM food and feed should also be prohibited. The moratorium should only be lifted when certain criteria are met:

- - Knowledge of the long-range consequences of the technology should be improved
- - Laws and regulations should be coordinated internationally
- - Monitoring, control and traceability should be strengthened

A group representing broad interests should be convened to elaborate these criteria and evaluate when these are met.

Within health, no evidence of harm is given, but this cannot be excluded. Further, the technology has not contributed within promising fields of increased nutrition or lower allergenic effects.

There is no evidence that use of pesticides or herbicides have been reduced as a result of GM-cultivation. On the other hand, GM-agriculture has accentuated the use of monocultures and industrial approaches, which is harmful. There are indications that GMOs can disturb ecosystems, thus causing irreversible harm. There is an urgent need for better knowledge about effects on the environment.

Although the GM-plants marketed so far are not useful for Norway, they could prove advantageous in other regions of the world. However, despite promises that GM would especially benefit the poor, such applications have not been delivered. On the other hand, the development towards monocultures cannot be seen as serving the poor.

There is a mismatch between regulations on living matter and regulations on food and feed. While, according to the Norwegian Gene Technology Act, living matter is evaluated on criteria such as societal benefit, ethics and sustainability, these criteria are not considered in the Food Act which regulates food. Thus, food imports are not evaluated on the same criteria as domestic products.

The panel expressed disappointment that some members of the expert panel presented their own judgment of the consensus report, and that they were not able to distinguish between normative and factual topics/discussions.

Insights from experts:

There is no evidence of adverse health effects of GM food, but knowledge is insufficient. On environmental effects, knowledge is almost non-existent. Views on the

appropriateness of a moratorium vary, the strongest arguments against a moratorium is that it would challenge WTO rules. Further, the risk for GM contamination is limited to imports, and controlling this is dependent on systems for screening and tracing, rather than legal restrictions.

Acceptance of GMOs can be seen as a combination of risk, benefit and moral acceptance. While risk and benefit are quantitative factors, moral acceptance is a qualitative factor, constituting a veto. Opposition to GMOs up to 2000 can be based on perceptions of low benefits, rather than perceptions of high risk.

The Norwegian agricultural sector, including farmer unions and cooperatives, are sceptical towards GMOs, and practice a self-imposed restriction. This is based both on internal attitudes, but also on the lack of confidence among consumers. Although certain producers may be tempted to consider GM products, experiences with growth hormones and foreign cattle breeds indicate that producers are generally sceptical to growth-enhancing technologies.

Norwegians became more sceptical towards bio- and gene technology from 1996 to 2000, and are relatively more sceptical than the average European. As long as the consumers are sceptical, both retailers and food processing businesses try to avoid such products – also from imports. Thus, GM production is disadvantageous to Norwegian interests. Regulations that can be trusted by all parties will be advantageous.

To control products, methodology to reveal GM contamination is necessary. It is also necessary to establish a system of traceability to control products based on GM but where there are no trace of transgenes in the end-product. However, who shall pay for a system of traceability? If the businesses shall cover such expenses, can this be something that only the major actors can afford?

IMPACT AND FOLLOW UP OF THE PROJECT

The project got overall good coverage by the press and mass media and was looked upon as a valuable contribution in the further public debate. The project was described in detail in the Norwegian biotechnology journal “Genialt”, published by the Norwegian Biotechnology Advisory Board. Furthermore the facilitators were invited to present the major conclusions and recommendations from the project in the Norwegian Parliament on January 18th 2001.

In recent years, several of the challenges identified during the project (see underneath) have been met by the Norwegian Government. At present, routines for analysing imported food and feed for GM content are in place and running, legislation for traceability and labelling are established and there is a high degree of legislative harmonization.

CHALLENGES IDENTIFIED IN THE PROJECT

(The panel identified a number of challenges. The reviewer is not in a position to judge to what extent these challenges have been met through recent developments.)

- Systems for screening GMOs for adverse effects must be developed
- Systems for controlling GM-contamination must be developed. Existing schemes often only indicate GM-contamination, they cannot prove such contamination.
- Systems for labelling and traceability must be developed.
- Laws and regulations must be coordinated at the international level.

While health effects can be expected to be the same across regions, environmental effects may vary. Therefore, there is a higher need for independent Norwegian studies on environmental effects.

LITERATURE

Bioteknologinemnda, Forskningsetiske komiteer and Teknologirådet (2000): Oppfølgingskonferansen om Genmodifisert mat. Genialt nr. 4/2000. Web: http://www.teknologiradet.no/dm_documents/genialt42000_O6pbG.pdf

AUTHOR OF THE REVIEW

Jon Magnar Haugen

PUBLIC MEETING ON COEXISTENCE (2004) 7.2

BACKGROUND OF THE PROJECT

The Norwegian Biotechnology Advisory Board (NBAB) arranges a number of meetings and seminars to strengthen public reflection and debate on GMOs and to prepare hearings and statements on policies.

BASIC DATA ABOUT THE PROJECT

The meeting was held on 29th of April 2004. There were 94 participants, including a mixture of stakeholders, government officials and experts, with only a few lay people. The project did not intend to build consensus. Thus, outcomes presented underneath do not represent common understandings.

The debate covered the following topics:

- Case-study on gene flow between GM crops and their relatives – the case of canola
- Potential for gene flow in important crops for Norwegian agriculture
- Possible practical measures to reduce gene flow
- Possible political measures to minimize gene flow
- Specific co-existence challenges for organic agriculture
- Co-existence: strategies in a feed company
- How to ensure GM-free feed imports
- How to ensure GM-free seed

The presentations and key comments are documented in a report based partly on documents submitted by participants, and partly on transcripts from recordings.

MAJOR OUTCOMES OF THE PROJECT

Closing remarks:

- New regulatory frameworks for co-existence should not be used as a political instrument to introduce GM crops, but also to secure GM-free production.
- Co-existence is not only about biology, but also a question of commercial interests and economic compensation. Central stakeholders believe that the "polluter pays-principle" should apply and that the burden of proof should be placed on the producer.

Comments from participants (given without consensus):

- EU-regulation on co-existence is tailored to give consumers a choice. However, believing that GM may allow for choice may prove naïve. Separation measures either in cultivation or in transport and processing may be prohibitively expensive,

thus one type of farming will be harmed if the other is allowed. Which side to loose is a political question – and this should be what regulation is all about.

- Producers, feed industries etc. want to follow a restrictive line, but these sectors are dependent on imports of seed and feed. Imports from countries outside EEA raises particular challenges: Which can guarantee GM-free products? Can there be conflicts b/w objective of avoiding GM and other objectives such as contributing to income generation in developing countries?
- Norwegian producers, including fish farmers, avoid using GM feed because of consumer demand. However, this is not displayed on the final products. Wouldn't it be to farmers own interest to establish systems of labelling?

Perspectives on gene flow

The challenge of separation is not entirely new as organic products are already handled separately from conventional. However, the challenge of handling gene flow between crops/crop rotations is new.

There are a number of criteria on which the likelihood of gene flow can be evaluated. Gene flow through pollen is related to degree of out-crossing. The likelihood of gene transfer vary, dependent, inter alia, on the occurrence of related crops nearby. It also depends on whether the traits give a fitness advantage (for instance pest tolerance). Further, pollen flow is of highest concern when the seeds are the harvest of interest. For many vegetables, grasses etc., pollen flow is less relevant. Mitochondrial and chloroplastic DNA is not transferred with pollen, so transgenes within will be less susceptible to gene flow.

Particular challenges to particular sectors, some are also particular to Norway:

- For aquaculture, there is a challenge that soy meal and oils is gaining importance but GM-free soy is limited. On the other hand, the combination of fatty acids of today's soy is not entirely suitable for aquaculture – a challenge that could be solved by GM. Aquaculture therefore faces particular challenges in relation to GM feed, first by securing GM-free soy, and second by being tempted to adopt GM feed.
- In conventional agriculture, the strong position of agricultural cooperatives, alongside a high degree of regulation, favour a standard approach shared by neighbouring farms.
- Organic agriculture may have a higher diversity – both intentional and unintentional (weeds). This may allow them to be sinks of GM-volunteers – especially for Bt-crops and other GM-crops that may have a fitness advantage.

IMPACTS AND FOLLOW UP OF THE PROJECT

Insights from the meeting have been communicated in relation both to the development of general regulation, and in relation to specific submissions for deliberate release. The meeting marked the opening of the debate on co-existence in Norway. After the meeting, researchers and experts have been mandated to draft a bill for co-

existence, addressing crucial issues such as the risk for gene flow in different crop species, systems for compensation, and the right to information about GM fields.

CHALLENGES IDENTIFIED IN THE PROJECT

(Remaining challenges, based on judgments by the reviewer)

- What are the defining differences between GMOs and non-GMOs? The technology that is applied, or the traits that the organisms carry? While it is the (potentially harmful) traits that one wants to control, the regulations are defined by the techniques employed.
- Which properties/practical measures can reduce risk for gene flow? Can for instance mitochondrial/chloroplastic transgenes pose lower risk, thus be treated differently from regular transgenes?
- Systems for accountability, liability and compensation.
- The issue of organic farming becoming a sink of transgenes must be examined, including legal and economic aspects.
- Imports of meat, and of feed from 3rd party countries, increase likelihood of meat based on GM feed. This could create an urge for a labeling system for such products. However, should this be a mandatory labeling of meat based on GM feed, or should it be voluntary labeling of non-GM meat?

LITERATURE

Linnestad, Casper (ed) (2005): Co-existence. Report, The Norwegian Biotechnology Advisory Board. ISBN 82-91683-34-4.
http://www.bion.no/publikasjoner/20050905_Sameksisten_web.pdf

AUTHOR OF THE REVIEW

Jon Magnar Haugen

EVALUATING THE CRITERIA OF SUSTAINABILITY AND SOCIETAL IMPACTS IN RELATION TO GM FOOD – THE WORK OF THE NORWEGIAN BIOTECHNOLOGY ADVISORY BOARD 7.3

BACKGROUND AND BASIC DATA

GM food on the market today is partly consisting of living entities, for instance intact corn grains or entire fruits or vegetables (containing viable seed). In Norway, such commodities must be evaluated not only in the food legislation context, but also in relation to the act relating to the production and use of genetically modified organisms. This act strongly emphasizes that the deliberate release of genetically modified organisms (GMOs) should have no detrimental effects on either health or the environment (at the same taking into account that we are not living in a risk-free society). This emphasis is fully in line with the legislation of other nations concerning the regulation of GMOs. Distinct from the regulations of most other nations, however, the Norwegian Gene Technology Act also stresses that the deliberate release of such organisms should represent a "benefit to the community" and enable "sustainable development". In general, the GM applications under directive 2001/18/EC or regulation 1829/2003 do not contain information that makes such a comprehensive GMO evaluation process possible.

It is not self-evident how "sustainability" and "benefit to the community" should be considered in terms of the practical application of the Act. The Norwegian Biotechnology Advisory Board is appointed by the Norwegian government with a mandate to give advice on these additional requirements.

The Norwegian Biotechnology Advisory Board

The Norwegian Biotechnology Advisory Board (NBAB) is an independent body established in 1991. The Board is founded in the Act relating to the application of biotechnology in medicine and the Act relating to the production and use of genetically modified organisms. The Board consists of 21 members, including 13 persons mandated by the government, and 8 persons mandated by different organisations. Representatives of six ministries have observer status. The Board's secretariat has seven to eight employees.

The main tasks of the NBAB are to identify and examine the ethical questions raised by applications of modern biotechnology on humans, animals, plants and microorganisms and to provide advice that can assist policy-making and stimulate public debates on the issues. The Board gives recommendations both concerning the development of general regulation, and in relation to specific submissions for deliberate release.

The work of NBAB can be described as a form of technology assessment done by a standing expert committee, with a specific emphasis on sustainability and societal

impacts. The activities involve meetings, dissemination, statements etc. Statements and advice are generally not based on consensus, but on majority votes.

This document explores how the NBAB interprets and addresses the issues of sustainability and societal impacts. The text is based primarily on conclusions from activities that were dedicated to discuss these issues broadly. However, insights from statements and advice in specific cases are also included.

MAJOR OUTCOMES OF THE PROJECT

The Norwegian Biotechnology Advisory Board finds that it is not clear whether the provisions relating to "benefit to the community" and "sustainable development" are to be considered as additional requirements or as a softening-up of the requirement for non-detrimental effects on either health or the environment. "Sustainable development" and "benefit to the community" can be understood as either:

- additional requirements to the absence of detrimental effects on health and the environment; or
- a softening-up of the requirement of non-detrimental effects; or
- an additional requirement that alone could be sufficient grounds for refusing approval or for a softening-up of the requirement of non-detriment.

According to the first alternative, the requirement would be that, in addition to having no detrimental effects on health and the environment, the "deliberate release represents a benefit to the community and a contribution to sustainable development". If the deliberate release fails to fulfil this requirement, the recommendation would be to reject an application for approval. Under this alternative, any softening-up of the requirement of non-detriment would be impossible.

The second alternative does allow for the approval of deliberate releases even when the possibility of detrimental effects on health and the environment have been established, if it can be demonstrated or argued that the "deliberate release represents a benefit to the community and a contribution to sustainable development". Consequently, the requirements of "sustainable development" and "benefit to the community" are being used as an opportunity for softening up or counterbalancing the requirement of non-detriment, but may not be applied as an additional requirement that alone could be sufficient grounds for rejecting an application for approval.

In the third alternative, the requirement of "benefit to the community" and/or "sustainable development" could constitute independent grounds for rejecting an application for approval. Furthermore, "sustainable development" and "benefit to the community" can be used to soften up the requirement of non-detriment. This could be considered as a combination of the first two alternatives and is the alternative the NBAB judges to be the best interpretation of the Act.

In the opinion of the NBAB, the Norwegian Gene Technology Act should be interpreted to mean that the requirements of "sustainable development", "benefit to the community" and other "ethical and social considerations" represent prerequisites that

alone could carry decisive weight against granting an application, but that should also be considered in relation to, and weighed against the risk of detrimental effects, when such risk is low.

Hence, an assessment of an individual GM application (also GM food, se above) will have the following structure:

1) Danger of detrimental effects on health and the environment:

   - what are the possible negative consequences?
   - what is the likelihood of such consequences occurring?

2) The precautionary principle:

   - is the risk assessment associated with justified uncertainty?
   - is there a possibility of substantial or irreversible harm?

3) Is it:

   - in compliance with the principle of "sustainable development"?
   - of "benefit to the community"?
   - "ethically and socially justifiable"?

Sustainable development

"Sustainable development" could be said to build on a series of ideas, including the following:

- the idea of the global effects of human activities;
- the idea of ecological limits and that these limits have been exceeded in several areas;
- the idea of meeting basic human needs;
- the idea of just distribution between generations;
- the idea of just distribution between wealthy and poor nations;
- the idea of a new form of economic growth.

This final point indicates that it is not a matter of just any form of economic growth. On the contrary, two types of qualification are required. Firstly, it should be economic growth involving an absolute – and not only a relative – efficiency improvement in the use of energy and other natural resources. Secondly, this economic growth must entail a more balanced distribution between poor and wealthy nations.

The six points listed above can serve as a structure for assessing whether the deliberate release of a genetically modified organism is in compliance with the requirements of "sustainable development". The same type of checklist questions could be asked for each of these points as those considered when assessing health and environmental risks and the precautionary principle. The responses to and the discussion of all the questions would, in this case, provide an overall picture of the extent to which there is compliance or non-compliance with the requirements set.

Furthermore, a clarification of the relationship between biodiversity (i.e. diversity of genes, species and ecosystems) and ecological sustainability is needed. Effects on

biodiversity would be assessed in relation to detrimental effects on health and the environment and the precautionary principle, thus be included in standard assessments also within the EU. However, relating biodiversity to the question of "sustainable development" implies a shift of focus in time and space. Assessments of the possible detrimental effects on health and the environment refer primarily to local, regional and national contexts. Assessments of the issue of "sustainable development" apply globally and also, to a longer time span (generations). When diversity is reduced, humankind's opportunities of promoting "sustainable development" are reduced accordingly. Preserving biodiversity represents a form of long-term life insurance – for the existence of species, ecosystems and humankind. Another aspect worth underlining is the type of ethical assessments associated with the notion of intrinsic value. The concept of "sustainable development" encompasses two different types of intrinsic value. The first is nature's own intrinsic value; the second applies to certain forms of humankind's absolute intrinsic value. In the opinion of the NBAB, assessments of this kind might be more usefully made in relation to the issue of "other ethical and social considerations" and not in relation to the issue of "sustainable development".

Global effects

- Is biodiversity affected on a global scale?
- Is the functional capacity of ecosystems affected?
- Do these effects differ between production and use?

Ecological limits

- Is the efficiency of energy use affected?
- Is the efficiency of other natural resource use affected?
- Is the distribution between the use of renewable and non-renewable natural resources affected?
- Are discharges of pollutants with a global/transboundary range affected?
- Are emissions of greenhouse gases especially affected?
- Do these effects differ between production and use?

Basic human needs

- Is the fulfilment of basic human needs affected?
- Do these effects differ between production and use?

Distribution between generations

- Is the distribution of benefits between generations affected?
- Is the distribution of burdens between generations affected?
- Do these effects differ between production and use?

Distribution between rich and poor

- Is the distribution of benefits between rich and poor countries affected?
- Is the distribution of burdens between rich and poor countries affected?
- Do these effects differ between production and use?

Economic growth

- Is economic growth's demands on energy and other natural resources affected?
- Are economic growth's global/transboundary environmental impacts affected?
- Is economic growth's distribution between rich and poor countries affected?
- Do these effects differ between production and use?

Comment

Compliance with the requirements of "sustainable development" will have to be based on an overall assessment and discussion of all these questions. However, not all the questions above may be relevant in all cases.

Benefit to the community

As mentioned above, the concept of "benefit to the community" appears in the Gene Technology Act as one of several criteria for granting an application. It is, in any case, a complex concept, for which neither the Act itself nor its legislative history provides any clear guidance as to how it should be understood. In the current context, the NBAB has opted for a relatively pragmatic approach, and try to ask some "check-list questions" that may be relevant:

Product characteristics

- Is it reasonable to say that there is a need for the product in terms of demand or otherwise?
- Is it reasonable to say that the product will solve or possibly contribute to solving a societal problem?
- Is it reasonable to say that the product is significantly better than equivalent products already on the market?
- Is it reasonable to say that there are alternatives that are better than the product in terms of solving or possibly contributing to solving the societal problem in question?

Production and use of the product

Among the relevant aspects to be considered are:

- Does the product contribute to creating new employment opportunities in general and in rural areas in particular?
- Does the product contribute to creating new employment opportunities in other
- countries?
- Does the product create problems for existing production whose existence should otherwise be preserved?
- Does the product create problems for existing production in other countries?

(This list of questions is not meant to be exhaustive, but is meant primarily to serve as an indication of the type of questions that should be considered).

Comment

Any assessment of benefit to the community must be based on a discussion of the responses as a whole. However, it should be emphasized that every question may not be equally relevant in all instances.

IMPACTS AND FOLLOW UP OF THE PROJECT

The statements made by the NBAB are generally regarded as high impact contributions by the competent authorities. Such statements are publicly available and quite often they spark a public debate. The statements are communicated to the decision-makers both through letters and by regular meetings, as the decision-makers have status as observers during the relevant NBAB discussions. NBAB is planning a conference on sustainability and GMOs late in 2007.

CHALLENGES IDENTIFIED IN THE PROJECT

Operationalizing the criteria of sustainability and societal benefit in relation, for instance, to specific submissions for deliberate release, remains challenging. Even more challenging than defining the "checklists", is to access relevant information regarding the products. As Norway appears to be unique in using these criteria, submissions within the EU do not generally include relevant data. And so far, applicants do not seem to find it worthwhile to provide such data just for Norway. Without relevant documentation, Norway cannot fully undertake the relevant assessments, and thus, based on this lack of information, Norwegian authorities may end up not authorising a given product. However, the EU might not consider such terms legitimate to reject an authorisation, which could be necessary under Norway's commitment as member of the EEA. Thus, a number of questions regarding the harmonization of regulation within the EU/EEA remain.

As described above, there also remains a question of whether criteria of sustainability and societal impacts should be interpreted as additional requirements to the absence of detrimental effects on health and the environment; or as a softening-up of the requirement of non-detrimental effects.

LITERATURE:

Linnestad, Casper (ed) (2003): Sustainability, benefit to the community and ethics in the assessment of genetically modified organisms. Discussion Paper, The Norwegian Biotechnology Advisory Board. ISBN 82-91683-21-2. Web: http://www.bion.no/publikasjoner/sustainability.pdf

The Norwegian Biotechnology Advisory Board: http://www.bion.no

The Norwegian Gene Technology Act: http://www.regjeringen.no/en/doc/Laws/Acts/Gene-Technology-Act.html?id=173031

AUTHOR OF THE REVIEW

Casper Linnestad

SWITZERLAND 8.

PUBLIFORUM »GENETIC TECHNOLOGY AND NUTRITION« (1999) 8.1

BACKGROUND OF THE PROJECT

The *PubliForum on Genetic Technology and Nutrition* took place in 1999, under the lead of the Swiss Centre for Technology Assessment, referred to below as TA-SWISS. This centre has been set up in 1992 by the Swiss Parliament and is attached to the Swiss Council for Science and Technology. Its mission is to support the political decision-making process, firstly by carrying out expert analyses, and secondly by canvassing the opinions of the citizens themselves through participatory projects. The *PubliForum on Genetic Technology and Nutrition* was the second participatory project ever organised by TA-SWISS[13].

The aim of the *PubliForum on Genetic Technology and Nutrition* was to set up an encounter between the people actively involved in the development of genetic technology (i.e. scientists, but also industry, public authorities and NGOs) and the public. Genetically modified organisms (GMOs) had already been extensively discussed about a year before, as Swiss citizens had to vote on an initiative demanding a halt to genetic engineering in Switzerland (the "initiative for genetic protection"). During the political campaign preceding the vote, all of the interested parties involved debated the issue at great length, but the fact that the rules of the game did not allow for a win-win situation (voters had to answer "yes" or "no") meant that it was difficult to get a real dialogue going. For the PubliForum on genetic technology in nutrition, the rules of the game were changed, to allow for win-win situations. The inclusion of ordinary citizens in the process would then provide greater awareness of their wishes, alternative solutions and needs. It would also provide an opportunity to learn about their argumentation patterns: how did they perceive and understand the implications of genetic technology in nutrition, what were their hopes and fears, and on which basic values and standards did they judge the issue?

Discussing these questions was considered as crucial, as the debate on GMOs was, at that time, far from being closed. As a matter of fact, when the Initiative for Genetic Protection had been first discussed by Parliament in 1996 and 1997, the Federal Assembly charged the government to fill all juridical gaps regarding genetic engineering in the non-human domain (Motion GENLEX). At the time of the PubliForum, government was working on this adaptation of the legislation[14].

13 TA-SWISS has been undertaking participatory projects since 1998.

14 The Swiss government presented its conclusions regarding the GENLEX motion in 2000, in form of a modification of the Law on environmental protection. This govern-

BASIC DATA ABOUT THE PROJECT

The *PubliForum on Genetic Technology and Nutrition* is a participatory project, using the "consensus conference" model developed by the Danish Board of Technology. This model has been adapted for the multilingual reality of Switzerland: instead of 15 citizens being invited to discuss the effects of new technologies, about 30 citizens from all parts of the country were invited to discuss and an interpretation service has been offered so that each participant could use their own language. All in all, the citizens met three times:

- In a first preparatory week-end, participants could meet and get to know each other, familiarize with the working method and inform themselves about the subject implications of genetic technology in food and plants. They also selected those aspects which they wanted to investigate more closely during the PubliForum.
- At the second preparatory weekend, the panel members defined their questions more clearly and chose the information persons who were to reply to these questions during the main PubliForum session. Their questions were related to research, environment, health, ethics and economics.
- The actual PubliForum lasted three days. During the first two days, which was open to the public, the information persons answered the questions of the citizen panel. Then the panel went behind closed doors and had 24 hours to draw up a report.

In order to create an as neutral as possible framework for the PubliForum, an accompanying group had been formed consisting of representatives from industry, research, administration, media, politics and various non-governmental organisations (NGOs). This accompanying group had the task of putting the content of the PubliForum into concrete terms and to make sure that the preparation and realisation of the event took place in an as balanced as possible way. The accompanying group was also responsible for the preparation of information sheets meant to help the Citizen Panel familiarise themselves with the subject. Another assignment was that of helping find reference persons to answer the questions and, finally, influence could be made on the composition of the Citizen Panel.

MAJOR OUTCOMES OF THE PROJECT

In its report, the Citizens' Panel acknowledged that today's level of scientific knowledge does not permit the existence of specific risks resulting from genetically modified organisms to be ruled out. And, as one cannot quantify these risks, the Panel was not in a position to make any judgement on their acceptability. Half of the Panel,

mental proposal addressed many issues, such as biodiversity preservation, civil responsibility regarding GM crops, authorization procedures and the introduction of a declaration for GM products. But the Parliament, after having examined this proposal, decided to write a specific law on genetic engineering. It took more than two years of political debate for the Parliament to come to a final text.

however, was of the opinion that genetic technology is an encroachment on life-processes, whereas the other half saw no difference between genetic technology and traditional production methods. This gap could be seen in the notion of imposing a moratorium on the production and marketing of genetically modified organisms[15], which was endorsed only by a slender majority of the Panel. Despite these differences of opinion, the Citizens' Panel agreed that freedom of choice for consumers should be maintained and that GMOs should thus be clearly labelled. It also demanded more research on risks and monitoring studies and showed some concern about the financial independence of public research.

IMPACTS AND FOLLOW UP OF THE PROJECT

The *PubliForum on genetic engineering in nutrition* caught a great deal of attention of the media and political groups, mainly for its proposal of a moratorium made by the Citizens' Panel. TA-SWISS could also present the PubliForum's results in the Parliamentary commission for science, education and culture. Many articles also were published in specialized magazines and journals.

Interestingly, what was a minority position at the time of the publication of the results of the PubliForum (the idea of a moratorium was in fact only defended by ecologists groups) became, with time and the support of farmers' representatives (who became conscious, through the PubliForum and other surveys, that consumers didn't want to consume GMO crops), a potentially majority position. Indeed, during the discussions on the new law on genetic engineering by the relevant Parliamentary Commission, a slender majority amended the law with a moratorium of 5 years (excluding field trials for scientific purposes). This proposal was ultimately rejected in the final vote in Parliament, where the Commission's slender majority was unable to gain enough support for its proposal. Interestingly, groups in favour of a moratorium tried a second time to anchor a 5-year moratorium on GMOs in Swiss legislation. This time, they tried to integrate it in the agriculture law, which was revised in 2003. And for a second time, they just failed[16]. Parallel to all these parliamentary debates, environmental groups, consumer associations and farmers group have launched an Initiative demanding a five-year moratorium on the farming GM crops for use in food (the use of GM crops for research purposes would be authorized under strict conditions). The group collected over 120'000 signatures in only seven months[17].

This initiative was contested by the government and Parliament (whereas a minority of the representatives had been supporting it), as well as by research and industry

15 Clearly defined field trials (specifically by public institutions) should, however, be permitted and supervised in order to obtain extended knowledge on any risks.

16 The proposal was in fact accepted by the lower chamber of the Parliament (National Council), but rejected by the upper chamber (State Council). In an ultimate vote, the lower chamber decided to align its position to that of the State Council in order not to bring down the whole revision.

17 To be valid, an initiative must be supported by 100'000 citizens and have to be found in a period of 18 monthes.

representatives. In November 2005, 55.7% of the Swiss citizens accepted the initiative demanding the five-year moratorium[18].

CHALLENGES IDENTIFIED IN THE PROJECT

In its report, the Citizen's Panel gave its opinion on several topics and formulated several recommendations. From these, we can consider that the challenges for GM plants and food, seen from a citizen perspective, are the following:

- The freedom of public research must be guaranteed and public funding should remain assured.
- The current supervisory mechanisms are sufficient, but citizens call for an intensified dialog between the general public and research.
- GMO-specific risks cannot be ruled out. Therefore, monitoring is absolutely necessary, in order to be able to estimate risk potential in a better way.
- Switzerland needs to have trained personnel, able to carry out monitoring research into GMOs.
- Backing out of genetic technology in the sense of a unilateral Swiss policy doesn't seem to be an option any more, since this would lead to important economic disadvantages, primarily in the Swiss research area and secondarily because of the dependence of Switzerland on imported raw materials, which could in the future contain GMO-components. Nevertheless, the question on how far a need for the use of genetically modified organisms exists in Switzerland must be answered.
- The existence of traditional, genetic-technology-free agriculture as well as organic farming must be guaranteed, in order to provide consumers with a free choice, both today and in the future. Moreover, instead of GMO production, organic farming could be a chance for Switzerland, as at the moment of the PubliForum no contamination is to be feared.
- The smaller seed producers may disappear in the long term because they will not be able to compete with large multi-national industry, which would mean that dependence could develop.
- The patenting of living organisms is for many of the members of the panel not acceptable. On the other hand, patenting creates more transparency, as the applicant has to publish his research results before the patent is granted. It is also understandable that the high costs of research have to be made to pay for themselves somehow.
- The unequivocal tracing of damage back to a GMO is very difficult. If such evidence exists, it must in all cases be possible to prosecute those responsible (e.g. the producer).

18 A survey conducted just after the vote showed that among those who voted against the initiative, 13% were actually convinced to vote against gene technology. In other words, these persons didn't correctly understand that the question they had to answer ("do you agree or not with the initiative and, eventually, the initiative should have been accepted by about 68% of the voters – an extremely high score for a popular initiative (Hirter and Linder 2006).

LITERATURE

PubliForum «Genetic Technology and Nutrition». Citizen Panel Report, Centre for Technology Assessment, TA-P1/1999e, Bern, 1999 (http://www.ta-swiss.ch/a/erna_gent/1999_TAP1_gentech_e.pdf)

AUTHOR OF THE REVIEW

Danielle Bütschi

RIBIOS FORUM »THE FUTURE OF PLANT BIOTECHNOLOGY IN SWITZERLAND« (2003) 8.2

Excerpts from the report: "The Future of Plant Biotechnology in Switzerland", Les Cahiers du RIBios, No7

BACKGROUND OF THE PROJECT

The Forum entitled « The future of plant biotechnology in Switzerland » took place at the University of Lausanne on November 3rd, 2003. It was jointly organised by the RIBios (Biosafety Interdisciplinary Network, based at the Graduate Institute for Development Studies of the University of Geneva) and by the Interface sciences-société of the University of Lausanne.

The aim of this Forum was to bring together stakeholders involved in the decisions about experimental field releases of transgenic plants in Switzerland.

BASIC DATA ABOUT THE PROJECT

The participants of the Forum were representatives of three main groups of stakeholders: public scientists involved in plant biotechnology research, the governmental bodies involved in the decision-making process, and other institutions directly involved in science policy at the national level. All the participants had been invited personally, in order to make clear that they should speak in their own name rather than in their institution's name. This sensitive issue was dealt with by agreeing with the participants that no material would be published on the content of the debates without their prior review of the documents.

Before the forum, the participants received a position paper written by the organisers. This paper was divided into six sections corresponding to important topics that would be discussed during the forum. It was aimed at giving some factual information, but also some analytical overview to stimulate the debate.

The forum lasted one day. The debates were organised by topics. In the morning, three questions were discussed: «Risk negotiation», «Coordination at the level of assessment and decision» and «Coherence between research and environment policies». In the afternoon the debates focused on «"Socially robust" research policies», «Biotechnological research in Switzerland» and «Decision-making under uncertainty: the controversial implementation of precaution».

The organisers decided to adopt a non-directive strategy for the debate regulation. Three persons were assigned to that task. One was in charge of handing over to the participants and to keep the schedule. The two other persons acted as facilitators by introducing factual or analytical elements pertinent to the debate, and by redirecting the discussion when it was clearly out of the topic of this forum.

MAJOR OUTCOMES OF THE PROJECT

Following the forum, a document restituting the main discussed points have been published in the "Les Cahiers du Ribios". The core of the text is made of participants' quotations, which are introduced by a short summary.

CHALLENGES IDENTIFIED IN THE PROJECT

The richness and diversity of the discussions during the forum show that many open questions are remaining with respect to research on GMOs. The lecture of the report shows that there is a certain frustration from the side of researchers, or at least a difficulty to cope with the social and political dimension of the issue.

CHALLENGES IDENTIFIED WITH RESPECT TO PUBLIC RESEARCH:

- To regain the public's confidence, it is necessary to define research priorities that correspond to agronomical problems which have been clearly identified and which benefit from political support.
- The distinction between fundamental and applied research must be taken into consideration. There is a sharp difference between commercialisation and experimental releases. The frontier between these two facets of research is nevertheless difficult to draw. This distinction is however important as soon as risk assessment is concerned. The standards and procedures used in the assessment do indeed depend on the nature of the trials, experimental or commercial.
- The position of Switzerland on the international scene in terms of knowledge and competitiveness in plant biotechnology is an issue to consider. There is a risk to see the competitiveness of Switzerland in the field of plant biotechnology decrease, as a result of industrial delocalisations and disinterest on behalf of students. While Switzerland has still a good knowledge base in the field of plant biotechnology, research is locked in, in part because of the difficulty to make field tests experiments.
- Research is facing important economical, political or administrative constraints. These difficulties have prevented researchers from accumulating the knowledge needed to perform an adequate risk assessment of the plants under development.
- The time lag between the application for an experimental release and the decision of the authority may be incompatible with the scientific rationale.

CHALLENGES IDENTIFIED WITH RESPECT TO RISKS:

- Rather than talking about the risks of doing research, one should also take into account the potential benefits, namely benefits that will derive from this research in the future but are still not known. In other words, the risks of doing research should be balanced with the risks of not doing it.
- Risks related to a new technology such as GMOs must not be discussed in isolation but rather in comparison with the risks of the technology it is replacing.

CHALLENGES IDENTIFIED WITH RESPECT TO PUBLIC DEBATE:

- The perception of risk by the public may sometimes be irrational. Risks related to GM food are typically over-estimated in comparison to other risks.
- Some participants pointed out the fact that communication policies have not been able until now to reverse this trend, and thus generate a positive picture of plant biotechnology in the public.
- It is more difficult to find support in the public for innovation, than to exploit the fears of the public related to these innovations.
- There is clearly a lack of communication in the field of plant biotechnology. The scientific community should do more grassroot work. However, the social acceptability of GMOs does not onlydepend on the level of information. In other words, more information does not necessarily end up with more people accepting the technology:
- There is a need to find new forms of public debate. Moreover, people and groups concerned by new technologies shoudl be included upstream (i.e.when a technology is still at the stage of research), so as to make research policies "socially more robust".

CHALLENGES IDENTIFIED WITH RESPECT TO DECISION-MAKING PROCESSES:

- There is a risk that scientific arguments are "instrumentalised" by political authorities in the decision-making process.
- Science should be more able to recognize the limits of its knowledge. This would surely be a way to improve society's confidence in science.
- Any decision in the field of risk mangement is somehow political, since a zero risk level is not achievable. Political decisions consist therefore in determining an acceptable level of risk:

LITERATURE

The Future of Plant Biotechnology in Switzerland", Les Cahiers du RIBios, No7, RIBios and IUED, Geneva, 2005.
(http://www.ribios.ch/en/documents/docs/Brochurespdf/Brochure7Forum.pdf)

AUTHOR OF THE REVIEW

Danielle Bütschi

REPORT ON THE COEXISTENCE OF DIFFERENT GM AND NON-GM AGRICULTURAL CULTIVATION SYSTEMS (AGROSCOPE RECKENHOLZ-TÄNIKON RESEARCH STATION ART, 2005) 8.3

BACKGROUND OF THE PROJECT

Worldwide GM0 cultivation is increasing year by year. Even though there is little likelihood of such cultivation in Switzerland at present, cultivation of GMOs in the future cannot be excluded. According to the Gene Technology Law (GTL), when GMOs are grown, non-GMO production and consumer's freedom of choice must be safeguarded. So-called "coexistence" must be guaranteed by segregating production flows (Warenflussstrennung) during the whole productions chain (from the field to shelves of the stores), by regulations and by technical measures. In this respect, legal threshold values were defined because it is impossible to rule out mixing completely no matter how much care is taken. They specify the percentage of genetically modified material which can be included in food and animal feeds without having to label them as «genetically modified». In line with the EU, a threshold limit of 0.9% is set in Switzerland. This limit is for approved GM crops. For non-approved GM crops there is, theoretically, a zero-tolerance.

Agroscope Reckenholz-Tänikon Research Station ART was commissioned by the Federal Office for Agriculture (FOAG) to carry out a study on whether GM and non-GM agricultural systems in Swit-zerland can coexist from a scientific and technical point of view within the present legislative framework. Maize, wheat and oilseed rape were selected as model crops.

BASIC DATA ABOUT THE PROJECT

The aim of the project was to present a concept for a coexistence of GM and non-GM cropping systems in Switzerland. In a first step mechanisms were analysed which can lead to a mixture of agricultural products during cropping. Subsequently, technical and organisational measures were listed which can minimize or prevent mixing. The study was limited to the agricultural production, i.e. from planting to the delivery of the harvest to storing or processing facilities. The cost of segregation of different cropping systems varies according to the specific biological characteristics of the crops and according to the level of segregation required. Three model crops (maize, wheat and oilseed rape) have been chosen as case studies to show what specific measures are needed in order to maintain the legally binding GMO threshold for food and feed.

The study was entirely funded from the Agroscope Reckenholz-Tänikon Research Station own resources, with no third party funding that could have cast doubts upon their independence. The scientists based their statements on objective foundations.

MAJOR OUTCOMES OF THE PROJECT

The investigations on the possibilities and limits of the «coexistence of GM and non-GM cultivation systems in Switzerland» reached the conclusion that, with the requisite crop-specific distances, discussion and agreement between farmers, and careful segregation during product handling on the farm, the cultivation of GM maize, GM wheat and GM oilseed rape in Switzerland would be technically possible.

This assessment was based on the threshold limit of 0.9 % GM content and covered cultivation up to the delivery of the harvested material at the collection point. Additional time and costs related to coexistence was not examined. The measures necessary for coexistence are detailed in the "Schriftenreihe der FAL" No 55[19]. They are for example:

- Usge of certified seed
- Optimal soil preparation after the harvest and cultivation of non-GM crops before subsequent GM planting.
- The degree of out-crossing between fields with GM and fields with non-modified plants of the same species can be reduced through isolation distances and "buffer zones" between GM an non-modified crops.. Moreover, it is possible to avoid that cross-pollination happens at the same time.
- The intermingling of GM and non-modified crops in various machines can be avoided by carefully cleaning them after having used them for GM-crop fields.
- Segragation during harvest, transport, storage and processing of the crops, as well as a documentation of these processes is essential to minimize intermingling.

IMPACT AND FOLLOW UP OF THE PROJECT

In June 2005, a conference named "Coexistence of GM and non-GM crops - scientific data, practical applications and perspectives for the next decade has been organised by the authors of the study. About 120 Swiss and international experts discussed the issue of coexistence (more info on the conference on: www.coexistence.ethz.ch/). The group took part in many other conferences dedicated to the issue of coexistence, in Switzerland or at the European level. But, at the time being, it doesn't carry any project on the theme.

In June 2006, The Federal Office for Agriculture adapted the legislation on coexistence (ordinance on coexistence) and considered some elements analysed in the study. There is, however, no evidence on how far the study influenced the legislative process.

19 Study summary as pdf (http://www.reckenholz.ch/doc/en/publ/schrift/sr55vz.html): To order Study (http://www.reckenholz.ch/cgi-bin/sql/order.pl?ref=4&lang=en&sort=-feld_0).

CHALLENGES IDENTIFIED IN THE PROJECT

- How to guarantee coexistence? This implies regulatory, technical and organisational aspects.
- The probability of intermingling depends on the biological properties of the various plants. The necessity for coexistence measures must then be separately assessed, for each cultivated plant.

LITERATURE

Olivier Sanvido, Franco Widmer, Michael Winzeler, Bernhard Streit, Erich Szerencsitz, Franz Bigler, 2005, Koexistenz verschiedener landwirtschaftlicher Anbausysteme mit und ohne Gentechnik, FAL-Schriftenreihe Nr. 55, edited by: Agroscope Reckenholz-Tänikin Research Station ART, Switzerland (http://www.art.admin.ch)

AUTHOR OF THE REVIEW

Danielle Bütschi

COORDINATION MEETING OF INSTITUTIONS OFFERING BIOSAFETY-RELATED TRAINING AND EDUCATION PROGRAMS (2004) 8.4

Excerpts from the "REPORT OF THE COORDINATION MEETING OF INSTITUTIONS OFFERING BIOSAFETYRELATED TRAINING AND EDUCATION PROGRAMS",(http://www.biodiv.org/doc/meetings/bs/bscmet-01/official/bscmet-01-01-en.pdf)

BACKGROUND OF THE PROJECT

The first Coordination Meeting of institutions offering biosafety-related training and education programs was held 4-6 October 2004 in Geneva, Switzerland. It was organized by the Swiss Agency for Environment, Forests and Landscape (SAEFL) in collaboration with the CBD Secretariat, the UNEP/GEF Biosafety Unit and the Geneva Environment Network.

Thirty-seven (37) participants from 28 institutions attended the meeting, including representatives from academic and other organizations. The participants came from all over the world (Belgium, Namibia, Switzerland, Mexico, New Zealand, USA, England, Netherlands, China, Kenya, Norway, Cuba, Thailand, Canada, Austria, Chile, Italy, Japan).

The meeting was a follow-up to the offer made by the Government of Switzerland at the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP MOP). In its decision BS-I/5 on capacity-building, the COP-MOP emphasized the need for a coordinated approach towards capacity-building at all levels and accordingly established a Coordination Mechanism to promote partnerships and maximize complementarities and synergies between various capacity-building initiatives contributing to the effective implementation of the Protocol. In this regard, the Government of Switzerland offered to sponsor a coordination meeting for representatives of academic and research institutions actively involved in education, training and research programs in biotechnology and biosafety in the autumn of 2004. The Swiss Government contracted RIBios – Réseau Interdisciplinaire Biosécurité – (Biosafety Interdisciplinary Research Network), which is part of Institut Universitaire d'Études du Développement (IUED), to organize the meeting.

The primary objective of this meeting was to bring together representatives of institutions involved in biosafety training and education to share information and compare notes regarding their ongoing programs and to learn more about the about the Protocol and the capacity-building needs and priorities for its effective implementation. The specific objectives of the meeting were:

- To review the current status ("state of the art") regarding training and education programs in biosafety, including consideration of the draft compendium of existing programs;
- To review the needs and priorities of countries and discuss ways and means for enhancing training and education programs to respond to those needs and support effective implementation of the Protocol;
- To identify and discuss key components of biosafety training and education programs;
- To explore mechanisms to enhance coordination, networking and collaboration among institutions offering biosafety training and education programs.

BASIC DATA ABOUT THE PROJECT

The agenda of the meeting consisted of two parts. The first part (day one) included presentations on: overview of the Cartagena Protocol and the COP-MOP decisions; the capacity building needs of countries and the role of training institutions in addressing those needs; the experience from the UNEP-GEF projects on capacity-building in biosafety and overview of the draft compendium. These were followed by short presentations by participants on their ongoing and planned programs.

The second part of the meeting included three plenary session discussions and one session of group discussions. The deliberations focused on the compendium; ways and means to improve biosafety training and education programs to address the needs of different target audiences; possible mechanisms for future networking/ collaboration and the next steps.

MAJOR OUTCOMES OF THE PROJECT

Overall, the meeting was a big success. It provided the first opportunity for institutions offering training and education in biosafety to meet and interact and laid a good foundation for their future collaboration and active involvement in biosafety processes at international, regional and national levels.

The meeting represented an important first step in preparing education and training institutions to play an effective role in building capacity for effective implementation of the Cartagena Protocol on Biosafety and other relevant instruments. It provided them with an insight into what the key training need are from the point of view of the countries that are now in the process of establishing and implementing their national frameworks and an the opportunity to learn more about what other institutions are offering and develop ideas for improving their programs.

The main outcome of the meeting was the development of a common format (questionnaire) for the compendium of existing biosafety training and education programs. The meeting also developed a set of draft recommendations for consideration by COP-MOP, governments, education and training institutions and other stakeholders in order to enhance biosafety training and education in support of the Protocol implementation.

IMPACT AND FOLLOW UP OF THE PROJECT

No concrete action has been implemented after the coordination meeting. Nevertheless, the meeting created a dynamic, in the sense that Malaisia University decided to organise a second meeting in April 2007, in Kuala Lumpur. The RIBios network (which organised the first meeting) will be participating and hopes that it will be able to interact and create synergies with african universities, so as to establish education programmes on biosecurity.

CHALLENGES IDENTIFIED IN THE PROJECT

While the meeting had resulted in fruitful deliberations, it also raised many new important questions. For example, questions were raised regarding:

- how to effectively to involve the newly trained experts in biosafety activities of their own countries;
- how to insure the sustainability of the biosafety training and education programs,
- how to mobilize adequate funding for biosafety training programs and for scholarships to support students from developing countries;
- how to insure the availability of technical infrastructure in all countries for the effective delivery of biosafety education and training programs and
- how to fill the gaps in the existing courses. All these questions underline the arduous challenge ahead.

LITERATURE

Report of the coordination meeting of institutions offering biosafety related training and education programs, 4-6 october 2004, by the Swiss Agency for Environment, forests and landscape, the CBD secretariat, the UNEP/GEF Biosafety Unit and the Geneva Environment Network.
(http://www.biodiv.org/doc/meetings/bs/bscmet-01/official/bscmet-01-01-en.pdf)

AUTHOR OF THE REVIEW

Danielle Bütschi

UNITED KINGDOM 9.

PROJECTS SINCE 2000

BACKGROUND

The most important activities concerning GM crops and food carried out in the UK since 2000 are

- the government commissioned dialogue on GM issues (GM dialogue)
- the Farm-scale evaluations (FSEs) of GM crops

As the latter study is scientific, this review will focus on the GM dialogue. However it should be noted that the FSE's were one of the pieces of information used by the government to inform its policy on GM crops in 2004 – see section on Impact and follow-up. POSTnote 211 *GM crops in the UK* (2004) gives an overview of the GM dialogue and the FSEs and discusses the issues raised. It was published prior to the Government setting out its policy on GM in March 2004. Other POSTnotes in this area published since 2000 are POSTnote 172 *Labelling GM foods* (2002) and POSTnote 146 *GM farm trials* (2000).

GM DIALOGUE

The GM dialogue ran from May 2002 to January 2004 and consisted of three main strands:

- GM science review –an assessment of the state of current scientific knowledge on GM crops and foods;
- economics review - an evaluation of the potential costs and benefits of GM crops in the UK;
- GM Nation? - a nationwide public debate to find out what people really think about GM.

Information on each strand and its outcome is discussed below.

GM SCIENCE REVIEW[20]

The science review was led by the Government's Chief Scientific Adviser working with the Chief Scientific Adviser to the Secretary of State for the Environment, Food and Rural Affairs, and with independent advice from the Food Standards Agency. The science review was carried out by a 26-member panel comprised of leading scientists from a spectrum of disciplines and perspectives, two lay representatives, a social scientist and a leading scientist with cross membership with the Public Debate Steering Board. It considered peer-reviewed published scientific literature and was

20 http://www.gmsciencedebate.org.uk/

focused on science-based issues identified by the public and the scientific community.

In July 2003 the panel concluded that for current GM crops and GM food:

- the risk to human health is very low;
- these crops are unlikely to invade the countryside and become problematic plants;
- it is unlikely that these crops, if consumed, would be toxic to wildlife;
- there is insufficient information to predict the long-term impact of the herbicide regimes associated with herbicide-tolerant GM crops on wildlife;
- the balance of risks and benefits will vary for each GM crop, therefore case-by case regulation is appropriate.

The panel reconvened to consider comments on its July report and the results of the FSEs, reporting in January 2004 that:-

- none of the new research published since the first Report significantly altered the earlier conclusions;
- the FSEs were of high scientific calibre. The panel found that if GM herbicide tolerant (GMHT) crops are managed as in the FSEs, a significant reduction would be expected in weeds with GMHT beet and spring oilseed rape, whereas the opposite would be found with maize. These effects arise from the herbicides and are not a direct consequence of the GM process. The different findings for different GM crops reinforced the conclusion of the first Science Review that GM crops must be assessed on a case-by-case basis.

ECONOMICS[21]

An evaluation of the costs and benefits of the possible commercial cultivation of GM crops in the UK, published in July 2003, was conducted by the Prime Minister's Strategy Unit (SU). The SU performs long term strategic reviews of major areas of policy, studies of cross-cutting policy issues, strategic audits and joint work with Departments to promote strategic thinking and improve policy-making across Whitehall. It reports directly to the Prime Minister. The study focused on the GM crops that were currently available, as well as possible developments in the next 10-15 years, and developed five scenarios to explore a range of possible futures. The study was informed by experts, the public, science and the best available economic data.

The study concluded that although existing GM crops could offer some advantages to UK farmers, at least in the short-term, any economic benefit is likely to be limited by negative public attitudes and retailer policies. Over the next 10-15 years, the SU considered that there is significant potential for benefits from future developments in GM crop technology as well as potential for impacts on wider science and industry. The key conclusion of the study was that the future of GM crops will depend on the nature of the regulatory system and public attitudes.

21 www.number-10.gov.uk/su/gm/index.htm

GM NATION? THE PUBLIC DEBATE[22]

A public debate, organised by a steering board independent of government, took place in summer 2003. The aim was to promote a programme of debate on GM issues, framed by the public, against the background of the possible cultivation of GM crops in the UK.

- The debate was overseen by a Steering board which comprised of people with different perspectives on GM and people with expertise in public engagement. A number of external contractors were appointed to manage the debate programme and deliver the different strands of the programme. Foundation Discussion workshops -nine workshops of 18-20 participants from different backgrounds/age - groups held in different regional locations.
- Public events - a series of public events organized in three 'tiers' at national/regional, county and local levels. These events included different methods - round-table discussions, expert speaker Q&A, debating a motion – but were informed by stimulus material approved by the steering board. Participants were self-selecting.
- Narrow-but-deep element – series of reconvened discussion groups that involved a selected cross-section of the wider population, who would be exposed to GM issues over a period of two weeks.

Over 37,000 people provided feedback from this range of activities which including more than 600 meetings and visits to the *GM Nation?* website. Key messages emerging from the debate include:

- people are generally uneasy about GM crops;
- there is little support for early commercialisation;
- there is a widespread mistrust of government and multi-national companies;
- there is a broad desire to know more and for further research to be done;
- the debate was welcomed and valued.

IMPACT AND FOLLOW-UP

The Government considered the reports from all three strands of the GM dialogue and published both a detailed response and a Parliamentary statement in March 2004[23]. In these the Government set out its policy on GM crops and said it would:

- assess GM crops on a case-by-case basis, taking a precautionary and evidence-based approach, and making the protection of human health and the environment the top priority
- provide choice for consumers through mandatory labelling of GM food products
- consult on measures to facilitate the co-existence of GM and non-GM crops, and on options to provide compensation to non-GM farmers who suffer a financial loss through no fault of their own

22 www.gmnation.org.uk/docs/GMNation_FinalReport.pdf
23 http://www.defra.gov.uk/corporate/ministers/statements/mb040309.htm

There are currently no GM crops being grown in the UK and no commercial cultivation is expected before 2009 at the earliest. However GM crops have been grown for research and development purposes at a number of sites, for example in the FSEs.

Co-existence

When GM crops are grown commercially measures will need to be applied to ensure that they can coexist with non-GM production. The Department for Environment, Food and Rural Affairs (Defra) consulted on proposed coexistence measures for England between July and October 2006. A summary of responses to the consultation should be available by the end of this year. Defra expects to have measures in place before GM crops are grown commercially.

CHALLENGES IDENTIFIED IN THE PROJECTS

- Generally the UK public is uneasy about GM crops. How will consumer attitudes develop over the next 5-10 years? This is likely to be key to any future success of GM crops.
- Which future developments in GM technology will offer economic benefits?
- Assessment and monitoring of the long-term impact of GM crops on the environment.
- Co-existence of GM crops with non-GM crop production. Particular problems include (1) no legal threshold for the presence of GM crops in organic crops. In practice the organic sector works to the limit of detection of the presence of GM. (2) EU seed purity levels (less than 0.9%) will challenge the seed industry, who work to 1-2% seed purity, while the organic sector would like a level of less than 0.1%.
- Liability – who will pay if there is any environmental damage as a result of GM crops being grown?
- WTO – how will the EU respond to the WTO dispute panel's findings on the implementation of GM crop regulations in Europe.

AUTHOR OF THE REVIEW

Jofey Craig

EPTA
European Parliamentary Technology Assessment

10/10/2007

JOINT EPTA PROJECT
"GENETICALLY MODIFIED PLANTS AND FOODS"

QUESTIONNAIRE

– FINAL VERSION –

INTRODUCTION

Although GM crops and food can be considered an established technology and regulation is in place in many parts of the world, the issue still gives rise to controversy.

Different countries have taken different approaches to regulating GM crops and foods. In the USA, product regulation does not imply any mandatory requirement to tell consumers if a product contains GM material. In contrast, it is a central tenet of the EU approach that consumers should be made aware that a product contains, or has been produced using, GM material. This has required the EU to introduce regulations on labelling and traceability so that GM and non-GM products can be segregated through the entire production and marketing chain.

The difference in regulatory philosophy across continents has already created some tension in international trade relations. In 2003 the WTO was asked to rule on the legality of the EU's failure to process marketing applications for new GM agricultural products between 1998 and 2001.

In addition to the possibility of similar challenges in the future, a range of other factors might bring pressure to bear on the current EU regulatory approach to GM foods and crops. These include inconsistencies among EU Member States on the way that they have implemented EU regulations or have dealt with the issue of co-existence.

So far, the EU regulatory framework has not entailed that all aspects of the regulation of GMOs are dealt with uniformly throughout the EU. Member States have been left to

devise and implement their own regulations concerning the co-existence of GM and non-GM crops and approaches vary considerably across the EU.

Another key factor may be technological developments particularly if these introduce new traits with perceived benefits to consumers or if they render the traditional distinction between GM and non-GM products less clear-cut. Such factors could influence public attitudes towards GM foods and crops within the EU in an unforeseeable way.

Whatever happens, the future development of the debate on how best to regulate GM crops and foods in the EU is undetermined and the current regulatory system may face new challenges.

I. FACTORS INFLUENCING THE FUTURE OF GM PLANTS IN EUROPE

I.1 GENERAL ASSESSMENT

Question 1:

a) Many factors will influence the future of GM plants and food in Europe. Below is a list of frequently cited major factors. Please indicate for each factor whether you think it will encourage or discourage the demand for GM plants and foods.

Please feel free to add other important factors not listed.

major factors	Encour-age demand	Discour-age demand	Neither	Don't know
World food demand				
Attitudes to health				
Attitudes to the environment				
Use of bio-energy and biomass				
Global trade of food products				
Structures and power relations in the food chain (for instance increasing retailer power)				
Differentiation of food products (consider developments such as food label-ling and use of processed foods)				
International trade regulation				
Increased use of for pharmaceuticals				
Pest pressure				
Trend towards more efficient agricultural production methods				
.....				
.....				

b) Overall, would you think that the demand to introduce new GM plants in the

European agriculture will increase or decrease?
(Please select one possibility)

Increase	
Decrease	
No net effect	
Don't know	

Question 2:

Do you think that the "first generation" of GM plants (as insect resistant (IR), herbicide resistant (HR) and virus resistant (VR) plants) will be grown in Europe to a noticeable extent (say more than 5 % of the available agricultural crop land) in the next 15 years?

Time scale of introduction	in Europe	in your country
Within the next 5 years		
Within 6 – 10 years		
Within 11 - 15 years		
Not within the next 15 years		
Don't know		

I.2 NEW GM PLANTS, NEW APPLICATIONS

Question 3:

a) Currently there are several classes of new GM plants in development. Please check if you believe the following statements are valid for the different classes of crops.

Please feel free to add other classes of new gm plants not listed.

Statement: "Such crops will become available within the coming 10 years."	Valid	Not valid	Don't know
GM plants with new agricultural input traits (e.g. reduced need for fertilizer, water)			
GM plants with consumer benefits (e.g. improved nutritional value, taste, less allergens)			
GM plants for bioenergy (e.g. higher biomass yield, new plants)			
GM plants for plant made industrials (e.g. starch, fibre, plastics)			
GM trees designed for industrial/energy purposes			
GM plants for plant made pharmaceuticals (e.g. haemo-proteins, vaccines)			
GM plants for phytoremediation (e.g. plants for extracting toxics from the soil)			
New GM flowers etc. (e.g. new flower colours, grasses for lawns and golf courses)			
.....			
.....			
.....			

Statement: "Such crops will be authorised for cultivation in Europe."	Valid	Not valid	Don't know
GM plants with new agricultural input traits (e.g. reduced need for fertilizer, water)			
GM plants with consumer benefits (e.g. improved nutritional value, taste, less allergens)			
GM plants for bioenergy (e.g. higher biomass yield, new plants)			
GM plants for plant made industrials (e.g. starch, fibre, plastics)			
GM trees designed for industrial/energy purposes			
GM plants for plant made pharmaceuticals (e.g. haemo-proteins, vaccines)			
GM plants for phytoremediation (e.g. plants for extracting toxics from the soil)			
New GM flowers etc. (e.g. new flower colours, grasses for lawns and golf courses)			
.....			
.....			
.....			

Statement: "Such crops will find significant demand from farmers."	Valid	Not valid	Don't know
GM plants with new agricultural input traits (e.g. reduced need for fertilizer, water)			
GM plants with consumer benefits (e.g. improved nutritional value, taste, less allergens)			
GM plants for bioenergy (e.g. higher biomass yield, new plants)			
GM plants for plant made industrials (e.g. starch, fibre, plastics)			
GM trees designed for industrial/energy purposes			
GM plants for plant made pharmaceuticals (e.g. haemo-proteins, vaccines)			
GM plants for phytoremediation (e.g. plants for extracting toxics from the soil)			
New GM flowers etc. (e.g. new flower colours, grasses for lawns and golf courses)			
.....			
.....			
.....			

Statement: "Products from such crops will find acceptance with consumers."	Valid	Not valid	Don't know
GM plants with new agricultural input traits (e.g. reduced need for fertilizer, water)			
GM plants with consumer benefits (e.g. improved nutritional value, taste, less allergens)			
GM plants for bioenergy (e.g. higher biomass yield, new plants)			
GM plants for plant made industrials (e.g. starch, fibre, plastics)			
GM trees designed for industrial/energy purposes			
GM plants for plant made pharmaceuticals (e.g. haemo-proteins, vaccines)			
GM plants for phytoremediation (e.g. plants for extracting toxics from the soil)			
New GM flowers etc. (e.g. new flower colours, grasses for lawns and golf courses)			
.....			
.....			
.....			

Please feel free to give explanations or comments concerning your answers to these questions.

……
……
……
……
……
……

Question 4:

a) In future, technical developments such as "cisgenic" GM technology may become more important. While traditional "transgenic" plants result from gene transfers which use recombined DNA from other species, "cisgenic" plants result from gene transfers which use only recombined DNA from the same species. Please indicate if you agree or disagree with the following statements.

Statement	Agree	Disagree	Don't know
"Cisgenic" GM technology will gain high importance in the future.			
Such technologies will lead to blurring the boundaries between GM and non-GM plants in the future.			
Products derived from such technologies will be regarded as "less hazardous" by the public.			
"Cisgenic" GM technology will undermine the demand for transgenic GM technology.			
In the light of these developments, existing regulation will have to be adapted.			

b) “Smart breeding” is another new technical development. "Smart breeding" derives from traditional methods of plant breeding but includes tools on the basis of modern recombinant DNA technology such as molecular markers. Please indicate if you agree or disagree with the following statements.

Statement	Agree	Disagree	Don’t know
“Smart breeding” will gain high importance in the future.			
"Smart breeding" will have a good public image.			
"Smart breeding" will overcome the demand for currently regulated GM technologies.			
"Smart breeding" will overcome the current need to regulate GM technologies.			

Please feel free to give explanations or comments concerning your answer on these questions.

……
……
……
……
……
……

I.3 Public Attitude and Acceptance

Question 5:

Currently the consumer acceptance of gm plants and food varies across Europe. Many factors have been associated with public acceptance. Please rank the factors in the list below in their importance for consumer acceptance over the next 10 to 15 years.

Please feel free to add other factors not listed.

Factors	Not important	Little important	Important	Very important	Don't know
Risk issues related to environment					
Environmental upsides (e.g. reduced need for fertilizer, pesticides or tillage)					
Risk issues related to health					
Price benefits for consumers					
Consumer benefits related to food quality and health					
functioning risk management					
Perspectives on global food security					
Quality of information to citizens					
Getting accustomed to GM products					
Opportunity for public participation in decision making					
Efficient and transparent labelling and free consumer choice					
Global distribution of risks and benefits					
.....					
.....					

.....					

Question 6:

Will public attitudes to GM crops and food change in the next 10 to 15 years?

Issues	More negative	No change	More positive
Acceptance of GM technology in general			
Acceptance of new GM food products			
Acceptance of new GM non-food products			

Please feel free to give explanations or comments concerning your answer on this question.

……
……
……
……
……
……

II. CHALLENGES FOR EUROPEAN POLICY

II.1 CHALLENGES LINKED TO FREEDOM OF CHOICE, LABELLING AND CO-EXISTENCE

Question 7:

Co-existence measures are a central part of risk management under GM-cultivation. Co-existence is also a central prerequisite for freedom of choice. Co-existence may be a challenge, depending on type of crop and location. Do you think that co-existence will work for the "first generation" of gm plants (e.g. insect resistant, herbicide resistant and virus resistant (VR) plants) in the next 15 years?
(Please tick one possibility)

Yes, for the cultivation of GM plants on a large scale for almost every crop	
Yes, for the cultivation of GM plants on a large scale for some specific crops	
Yes, but only for the cultivation of GM plants on a small scale for almost every crop	
Yes, but only for the cultivation of GM plants on a small scale for some specific crops	
No, not at all	
Don't know	

Please feel free to give explanations or comments concerning your answer on this question.

……
……
……

……
……

Question 8:

a) For the cultivation of GM crops some experts have discussed whether there could be relevant environmental or economic risks (e.g. to farmers not applying gm crops) that would not be contained by current risk assessment and co-existence schemes. Please tick the statement that comes closest to your opinion.

Relevant risks do not exist at all	
Relevant risks exist for a few particular GM crops	
Relevant risks exist for all GM crops	
Don't know	

If you think that relevant risks do not exist at all, or if you don't know, proceed to Question 9.

b) If you think that relevant risks might exist, please tick those statements that come closest to your opinion (multiple answers possible).

In general, risks are negligible	
Environmental risks are balanced by benefits to society and acceptable	
Economic risks to other farmers can be negotiated between parties involved	
Such risks are unacceptable and need regulatory intervention	
Don't know	

c) Do you think that current regulatory provisions are sufficient to deal with such risks, today or for the foreseeable future?

Yes, in the current situation and in the foreseeable future	
Yes in the current situation, but not in the foreseeable future	
No, not at all	
Don't know	

d) If you ticked "No, not at all" or "not in the foreseeable future", how do you think these risks should be addressed? Please indicate the measure you consider most appropriate to address such risks (multiple answers possible).

New criteria for risk assessment	
More stringent litigation schemes	
Stronger liability of gm producer and user	
New regulation	
.....	
.....	
Don't know	

Question 9:

Co-existence and labelling of GM food are closely connected. There are different opinions over how well the current EU regulations would cope with the extended use and growing of gm plants in Europe. Please indicate which scenario in your opinion is most likely.
(Please tick one scenario)

Scenario	
Successful coexistence: The labelling of GM food is generally correct (including occasional mishap), non GM food is also available.	
Misapplication of labelling: All food is labelled as "may contain GM", also non GM food.	
Failure of labelling regime: GM food is on the market, but not labelled correctly.	
Failure of coexistence: More or less all food is GM or contains GM components, and is labelled as GM food.	
Blockade of GM food: Very little GM food on the market so that labelling is of little relevance.	
Don't know	

Please feel free to give explanations or comments concerning your answer on this question.

……
……
……
……
……
……

II.2 CHALLENGES LINKED TO NEW GENERATION GM CROPS

Question 10:

a) Newly developed GM plants for the non-food sector (e.g. gm plants for plant made pharmaceuticals, for industrial raw materials, and for bio-energy) are sometimes said to have new properties compared to gm plants for food and therefore pose new regulatory challenges. Do you or don't you agree with the following statement?

	Yes	No	Don't know
New GM plants for the non-food sector will pose new regulatory challenges			

If you ticked "No" or "Don't know", proceed to question 11.

b) If you ticked "Yes", please assess which regulatory challenges non-food GM plants will raise in the next 10-15 years, and whether this will be very likely, likely, unlikely or highly unlikely.

Please feel free to add other regulatory challenges not listed.

Type of regulatory challenge	Very likely	Likely	Unlikely	Highly unlikely	Don't know
New parameters for risk assessment and manage-ment					
Confinement / containment measures					
Regulation of coexistence					
Labelling					
Liability					
.....					
.....					
.....					

Please feel free to give explanations or comments concerning your answer on this question.

……
……
……
……
……
……

Question 11:

So far, the assessment procedures for GM plants and food only takes into account potential risks. Some actors have advocated that also potential benefits should be taken into consideration as applied in areas such as pharmaceuticals.
Below is a list of potential benefits that could be included in such considerations. Please assess how likely it is that in future different benefits will be considered for GM approvals.

Please feel free to add other groups not listed.

Aspect	Very likely	Likely	Unlikely	Highly unlikely	Don't know
Environmental benefit					
Economic return					
Food safety					
Food quality					
Nutritional benefit					
.....					
.....					
.....					

Please feel free to give explanations or comments concerning your answer on this question.

.....
.....
.....
.....
.....
.....

Question 12:

In order to assess risks and benefits of GM cultivation, it must be compared to established practices in agriculture. In Europe, these practices vary according to climate or soil, but also to the tasks assigned to agriculture. For example, and apart from efficiently producing crops or providing jobs, agriculture should also protect the traditional landscape and the natural environment, among others. Thus, agriculture must pursue different aims, against which the performance of GM cultivation will be measured. Please rank the aims in the list below in their importance over the next 10 to 15 years.

Aims in agriculture	Not important	Little important	Important	Very important	Don't know
Achieving high yields in crop production					
Reducing inputs in crop production					
Efficient crop production under difficult agricultural conditions (erosion, pest pressure etc.)					
Staying competitive in times of market liberalisation and reduced subsidies					
Crop production with least possible environmental impact					
Producing high quality food in great variety					
Providing jobs for the rural population					
Protecting the traditional cultivated landscape					
Promoting organic farming					

II.3 GLOBAL ASPECTS OF GM REGULATION

Question 13:

a) It is probable that more types of GM crops will be released both in export countries and in Europe. The current EU regulation, based on the precautionary principle and case-by-case risk assessment and authorisation, might be challenged by the US and other countries also in the future. Please give your judgement on how robust the EU regulatory system will turn out to be to challenges for example at the WTO in the next 10 to 15 years.
(Please tick one possibility)

Robustness of the current EU regulatory system	
The general principles and approaches of the EU regulation and the varying implementation of the EU Member States can withstand challenges through the WTO.	
The general principles and approaches of the EU regulation can be maintained. However, the most restrictive practices of individual EU Member States will have to be changed.	
The general principles and approaches of the EU regulation can be maintained, but a more substantial harmonisation among the EU Member States will be necessary.	
The EU regulatory system can not be maintained due to challenges through the WTO.	
Don't know	

b) The EU legalisation has been a model for regulations in some other countries. Will the EU regulation continue to be influential in the future?
(Please tick one possibility)

Yes	
No	
Don't know	

Please feel free to give explanations or comments concerning your answer on this question.

……
……
……
……
……
……

III. CHALLENGES FOR RESEARCH POLICY

Question 14:

In view of new developments in the research on GM plants, what will be the objectives of publicly-funded research in your country in the coming years?

Please feel free to add other objectives not listed.

Objectives of R&D	Very likely	Likely	Unlikely	Highly unlikely	Don't know
Risk assessment and management					
Development of products/solutions responding to agronomic problems not covered by private research					
Development of innovative products with the intent to improve economic competitiveness					
.....					

IV. AREAS OF ACTION

Question 15:

In order to meet challenges that have been explored in this questionnaire, it could be necessary for government institutions to take further action. Please prioritise the areas below in which you consider action needs to be taken.

Please feel free to add areas of action not listed.

Area of action	Very low priority	Low priority	High priority	Very high priority	Don't know
Research funding					
Better implementation of existing regulation					
Amendment of existing regulation					
Adaptation to international ruling (e.g. WTO)					
Reform of competent authorities/institutions					
Subsidiarity / change in the level of decision making					
Expert involvement in decision making					
Stakeholder involvement in decision making					
Public involvement in decision making					
None, let the system work as it is					
.....					
.....					

.....					

Question 16:

In order to further explore new challenges, within which areas do you consider further investigations (for example technology assessment projects) to be most relevant.
(Please give key words)

……
……
……
……
……
……

ANNEX 5: TABLES OF RESULTS

FIGURE 1: INFLUENCING FACTORS FOR THE FUTURE OF GM PLANTS AND FOOD IN EUROPE (*Question 1A; n = 71)*

Question: Many factors will influence the future of GM plants and food in Europe. Below is a list of frequently cited major factors. Please indicate for each factor whether you think it will encourage or discourage the demand for GM plants and foods. Please feel free to add other important factors not listed.

	Encourage demand	Discourage demand	Neither	Don't know	Total	
	%	%	%	%	%	n
World food demand	50.7%	8.5%	33.8%	7.0%	100.0%	71
Attitudes to health	31.0%	43.7%	15.5%	9.9%	100.0%	71
Attitudes to the environment	28.2%	54.9%	12.7%	4.2%	100.0%	71
Use of bio-energy and biomass	74.6%	1.4%	19.7%	4.2%	100.0%	71
Global trade of food products	50.7%	8.5%	29.6%	11.3%	100.0%	71
Structures and power relations in the food chain (for instance increasing retailer power)	9.9%	49.3%	23.9%	16.9%	100.0%	71
Differentiation of food products (consider developments such as food labelling and use of processed foods)	22.5%	33.8%	31.0%	12.7%	100.0%	71
International trade regulation	52.1%	8.5%	25.4%	14.1%	100.0%	71
Increased use of for pharmaceuticals	52.1%	5.6%	31.0%	11.3%	100.0%	71
Pest pressure	53.5%	11.3%	28.2%	7.0%	100.0%	71
Trend towards more efficient agricultural production methods	66.2%	8.5%	19.7%	5.6%	100.0%	71

FIGURE 2: FUTURE DEMAND FOR NEW GM PLANTS IN EUROPEAN AGRICULTURE (*Question 1B; n = 71)*

Question: Overall, would you think that the demand to introduce new GM plants in the European agriculture will increase or decrease?

ABB. 2

	Column %	Count
Increase	62.0%	44
Decrease	14.1%	10
No net effect	18.3%	13
Don't know	5.6%	4
Total	100.0%	71

FIGURE 3: FUTURE CULTIVATION OF FIRST GENERATION GM PLANTS IN EUROPE

(*Question 2; n = 71)*

Question: Do you think that the "first generation" of GM plants (as insect resistant (IR), herbicide resistant (HR) and virus resistant (VR) plants) will be grown in Europe to a noticeable extent (say more than 5 % of the available agricultural crop land) in the next 15 years)?

	Within the next 5 years	Within 6 – 10 years	Within 11 - 15 years	Not within the next 15 years	Don't know	Total	
	%	%	%	%	%	%	n
in Europe	21.1%	35.2%	15.5%	19.7%	8.5%	100.0%	71
in your country	1.4%	23.9%	21.1%	40.8%	12.7%	100.0%	71

FIGURE 4: AVAILABILITY OF NOVEL GM PLANTS

(*Question 3A; n = 71)*

Question: Currently there are several classes of new GM plants in development. Please check if you believe the statement: "Such crops will become available within the coming 10 years."

	Valid	Not valid	Don't know	Total	
	%	%	%	%	n
GM plants with new agricultural input traits (e.g. reduced need for fertiliser, water)	54,9%	22,5%	22,5%	100,0%	71
GM plants with consumer benefits (e.g. improved nutritional value, taste, less allergens)	50,7%	32,4%	16,9%	100,0%	71
GM plants for bioenergy (e.g. higher biomass yield, new plants)	60,6%	15,5%	23,9%	100,0%	71
GM plants for plant made industrials (e.g. starch, fibre, plastics)	78,9%	4,2%	16,9%	100,0%	71
GM trees designed for industrial/energy purposes	25,4%	46,5%	28,2%	100,0%	71
GM plants for plant made pharmaceuticals (e.g. haemo-proteins, vaccines)	64,8%	14,1%	21,1%	100,0%	71
GM plants for phytoremediation (e.g. plants for extracting toxins from the soil)	23,9%	39,4%	36,6%	100,0%	71
New GM flowers etc. (e.g. new flower colours, grasses for lawns and golf courses)	60,6%	14,1%	25,4%	100,0%	71

FIGURE 5: AUTHORISATION OF NOVEL GM PLANTS (*Question 3B; n = 71)*

Question: Currently there are several classes of new GM plants in development. Please check if you believe the statement: "Such crops will be authorised for cultivation in Europe."

	Valid	Not valid	Don't know	Total	
	%	%	%	%	n
GM plants with new agricultural input traits (e.g. reduced need for fertiliser, water)	57,7%	22,5%	19,7%	100,0%	71
GM plants with consumer benefits (e.g. improved nutritional value, taste, less allergens)	53,5%	26,8%	19,7%	100,0%	71
GM plants for bioenergy (e.g. higher biomass yield, new plants)	62,0%	18,3%	19,7%	100,0%	71
GM plants for plant made industrials (e.g. starch, fibre, plastics)	70,4%	14,1%	15,5%	100,0%	71
GM trees designed for industrial/energy purposes	32,4%	38,0%	29,6%	100,0%	71
GM plants for plant made pharmaceuticals (e.g. haemo-proteins, vaccines)	43,7%	29,6%	26,8%	100,0%	71
GM plants for phytoremediation (e.g. plants for extracting toxins from the soil)	32,4%	31,0%	36,6%	100,0%	71
New GM flowers etc. (e.g. new flower colours, grasses for lawns and golf courses)	50,7%	16,9%	32,4%	100,0%	71

FIGURE 6: DEMAND FROM FARMERS FOR NOVEL GM PLANTS (*Question 3C; n = 71)*

Question: Currently there are several classes of new GM plants in development. Please check if you believe the statement: "Such crops will find significant demand from farmers."

	Valid	Not valid	Don't know	Total	
	%	%	%	%	n
GM plants with new agricultural input traits (e.g. reduced need for fertiliser, water)	66,2%	19,7%	14,1%	100,0%	71
GM plants with consumer benefits (e.g. improved nutritional value, taste, less allergens)	39,4%	36,6%	23,9%	100,0%	71
GM plants for bioenergy (e.g. higher biomass yield, new plants)	64,8%	16,9%	18,3%	100,0%	71
GM plants for plant made industrials (e.g. starch, fibre, plastics)	57,7%	23,9%	18,3%	100,0%	71
GM trees designed for industrial/energy purposes	26,8%	43,7%	29,6%	100,0%	71
GM plants for plant made pharmaceuti-cals (e.g. haemo-proteins, vaccines)	22,5%	45,1%	32,4%	100,0%	71
GM plants for phytoremediation (e.g. plants for extracting toxins from the soil)	16,9%	53,5%	29,6%	100,0%	71
New GM flowers etc. (e.g. new flower colours, grasses for lawns and golf courses)	32,4%	38,0%	29,6%	100,0%	71

FIGURE 7: ACCEPTANCE WITH CONSUMERS OF NOVEL GM PLANTS (*Question 3D; n = 71)*

Question: Currently there are several classes of new GM plants in development. Please check if you believe the statement: "Products from such crops will find acceptance with consumers."

	Valid	Not valid	Don't know	Total	
	%	%	%	%	n
GM plants with new agricultural input traits (e.g. reduced need for fertiliser, water)	31,0%	43,7%	25,4%	100,0%	71
GM plants with consumer benefits (e.g. improved nutritional value, taste, less allergens)	56,3%	29,6%	14,1%	100,0%	71
GM plants for bioenergy (e.g. higher biomass yield, new plants)	50,7%	29,6%	19,7%	100,0%	71
GM plants for plant made industrials (e.g. starch, fibre, plastics)	50,7%	26,8%	22,5%	100,0%	71
GM trees designed for industrial/energy purposes	35,2%	38,0%	26,8%	100,0%	71
GM plants for plant made pharmaceuticals (e.g. haemo-proteins, vaccines)	47,9%	26,8%	25,4%	100,0%	71
GM plants for phytoremediation (e.g. plants for extracting toxins from the soil)	47,9%	25,4%	26,8%	100,0%	71
New GM flowers etc. (e.g. new flower colours, grasses for lawns and golf courses)	39,4%	28,2%	32,4%	100,0%	71

FIGURE 8: FUTURE IMPORTANCE OF "CISGENIC" GM TECHNOLOGY (*Question 4A; n = 71)*

Question: In the future, technical developments such as "cisgenic" GM technology may become more important. While traditional "transgenic" plants result from gene transfers which use recombined DNA from other species, "cisgenic" plants result from gene transfers which use only recombined DNA from the same species. Please indicate if you agree or disagree with the following statements.

	Agree	Disagree	Don't know	Total	
	%	%	%	%	n
"Cisgenic" GM technology will gain high importance in the future.	33,8%	14,1%	52,1%	100,0%	71
Such technologies will lead to blurring the boundaries between GM and non-GM plants in the future.	50,7%	31,0%	18,3%	100,0%	71
Products derived from such technologies will be regarded as "less hazardous" by the public.	35,2%	39,4%	25,4%	100,0%	71
"Cisgenic" GM technology will undermine the demand for transgenic GM technology.	16,9%	50,7%	32,4%	100,0%	71
In the light of these developments, existing regulation will have to be adapted.	57,7%	22,5%	19,7%	100,0%	71

FIGURE 9: FUTURE IMPORTANCE OF "SMART BREEDING" (*Question 4B; n = 71)*

Question: "Smart breeding" is another new technical development. "Smart breeding" derives from traditional methods of plant breeding but includes tools on the basis of modern recombinant DNA technology such as molecular markers. Please indicate if you agree or disagree with the following statements.

	Agree	Disagree	Don't know	Total	
	%	%	%	%	n
"Smart breeding" will gain high importance in the future.	69,0%	7,0%	23,9%	100,0%	71
"Smart breeding" will have a good public image.	56,3%	14,1%	29,6%	100,0%	71
"Smart breeding" will overcome the demand for currently regulated GM technologies.	15,5%	54,9%	29,6%	100,0%	71
"Smart breeding" will overcome the current need to regulate GM technolo-	9,9%	74,6%	15,5%	100,0%	71

gies.					

FIGURE 10: NEW REGULATORY CHALLENGES CAUSED BY NOVEL GM PLANTS?
(*Question 10A; n = 71)*

Question: Newly developed GM plants for the non-food sector (e.g. gm plants for plant made pharmaceuticals, for industrial raw materials, and for bio-energy) are sometimes said to have new properties compared to gm plants for food and therefore pose new regulatory challenges. Do you or don't you agree with the following statement?

		Column %	Count
New GM plants for the non-food sector will pose new regulatory challenges	Yes	62,0%	44
	No	35,2%	25
	Don't know	2,8%	2
	Total	100,0%	71

FIGURE 11: AREAS OF NEW REGULATORY CHALLENGES OF NOVEL GM PLANTS
(*Question 10B; n = 44)*

Question: If you ticked "Yes" *[in question 10B]*, please assess which regulatory challenges non-food GM plants will raise in the next 10-15 years, and whether this will be very likely, likely, unlikely or highly unlikely. Please feel free to add other regulatory challenges not listed.

Type of regulatory challenge	Very likely	Likely	Unlikely	Highly unlikely	Don't know	Total	
	%	%	%	%	%	%	n
New parameters for risk assessment and management	45,5%	45,5%	6,8%	0,0%	2,3%	100,0%	44
Confinement/containment measures	52,3%	36,4%	6,8%	0,0%	4,6%	100,0%	44
Regulation of coexistence	56,8%	36,4%	4,5%	0,0%	2,3%	100,0%	44
Labelling	25,0%	43,2%	29,5%	0,0%	2,3%	100,0%	44
Liability	34,1%	54,5%	2,3%	0,0%	9,1%	100,0%	44

FIGURE 12: **PUBLIC ATTITUDES (*Question 6; n = 71)***

Question: Will public attitudes to GM crops and food change in the next 10 to 15 years?

	More negative	No change	More positive	Total	
	%	%	%	%	n
Acceptance of GM technology in general	5,6%	36,6%	57,7%	100,0%	71
Acceptance of new GM food products	9,9%	52,1%	38,0%	100,0%	71
Acceptance of new GM non-food products	2,8%	22,5%	74,6%	100,0%	71

FIGURE 13: FACTORS INFLUENCING PUBLIC ATTITUDES (*Question 5; n = 71)*

Question: Currently the consumer acceptance of gm plants and food varies across Europe. Many factors have been associated with public acceptance. Please rank the factors in the list below in their importance for consumer acceptance over the next 10 to 15 years. Please feel free to add other factors not listed.

Factors

	Not important	Little important	Important	Very important	Don't know	Total	
	%	%	%	%	%	%	n
Risk issues related to environment	4,2%	12,7%	45,1%	35,2%	2,8%	100,0%	71
Environmental upsides (e.g. reduced need for fertiliser, pesticides or tillage)	4,2%	47,9%	28,2%	16,9%	2,8%	100,0%	71
Risk issues related to health	1,4%	5,6%	35,2%	54,9%	2,8%	100,0%	71
Price benefits for consumers	8,5%	23,9%	31,0%	35,2%	1,4%	100,0%	71
Consumer benefits related to food quality and health	2,8%	12,7%	33,8%	49,3%	1,4%	100,0%	71
Performance of risk management systems	2,8%	23,9%	43,7%	25,4%	4,2%	100,0%	71
Perspectives on global food security	16,9%	38,0%	25,4%	15,5%	4,2%	100,0%	71
Quality of information to citizens	2,8%	18,3%	42,3%	35,2%	1,4%	100,0%	71
Getting accustomed to GM products	8,5%	15,5%	42,3%	29,6%	4,2%	100,0%	71
Opportunity for public participation in decision making	8,5%	40,8%	36,6%	11,3%	2,8%	100,0%	71
Efficient and transparent labelling and free consumer choice	2,8%	9,9%	43,7%	42,3%	1,4%	100,0%	71
Global distribution of risks and benefits	8,5%	45,1%	32,4%	8,5%	5,6%	100,0%	71

FIGURE 14: WILL COEXISTENCE WORK FOR FIRST GENERATION GM PLANTS?
(*Question 7; n = 71)*

Question: Co-existence measures are a central part of risk management under GM-cultivation. Co-existence is also a central prerequisite for freedom of choice. Co-existence may be a challenge, depending on type of crop and location. Do you think that co-existence will work for the "first generation" of gm plants (e.g. insect resistant, herbicide resistant and virus resistant (VR) plants) in the next 15 years? (Please tick one possibility).

	Percentage	Count
Yes, for the cultivation of GM plants on a large scale for almost every crop	15,5%	11
Yes, for the cultivation of GM plants on a large scale for some specific crops	31,0%	22
Yes, but only for the cultivation of GM plants on a small scale for almost every crop	5,6%	4
Yes, but only for the cultivation of GM plants on a small scale for some specific crops	25,4%	18
No, not at all	15,5%	11
Don't know	7,0%	5
Total	100,0%	71

FIGURE 15: CAN CONSUMERS' CHOICE BE MAINTAINED? (*Question 9; n = 71)*

Question: Co-existence and labelling of GM food are closely connected. There are different opinions over how well the current EU regulations would cope with the extended use and growing of gm plants in Europe. Please indicate which scenario in your opinion is most likely. (Please tick one scenario)

	Percentage	Count
Successful coexistence: The labelling of GM food is generally correct (including occasional mishap), non GM food is also available.	52,1%	37
Misapplication of labelling: All food is labelled as "may contain GM", also non GM food.	5,6%	4
Failure of labelling regime: GM food is on the market, but not labelled correctly.	14,1%	10
Failure of coexistence: More or less all food is GM or contains GM components, and must be labelled as GM food.	7,0%	5
Blockade of GM food: Very little GM food on the market so that labelling is of little relevance.	16,9%	12
Don't know	4,2%	3
Total	100,0%	71

FIGURE 16: DO COEXISTENCE SCHEMES ADDRESS RISKS? (*Question 8A; n = 71)*

Question: For the cultivation of GM crops some experts have discussed whether there could be relevant environmental or economic risks (e.g. to farmers not applying gm crops) that would not be contained by current risk assessment and co-existence schemes. Please tick the statement that comes closest to your opinion.

	Percentage	Count
Relevant risks do not exist at all	15,5%	11
Relevant risks exist for a few particular GM crops	29,6%	21
Relevant risks exist for all GM crops	49,3%	35
Don't know	5,6%	4
Total	100,0%	71

FIGURE 17: HOW TO MEET RISKS? (*Question 8B; n = 56)*

Question: If you think that relevant risks might exist [*in question 8A*], please tick those statements that come closest to your opinion (multiple answers possible).

	Respondents	Responses	Percentage (n=71)
In general, risks are negligible		9	13 %
Environmental risks are balanced by benefits to society and acceptable		17	24 %
Economic risks to other farmers can be negotiated between parties involved		23	32 %
Such risks are unacceptable and need regulatory intervention		26	37 %
Don't know		2	3 %
Total	56	78	

FIGURE 18: ARE REGULATORY PROVISIONS SUFFICIENT? (*Question 8C; n = 56)*

Question: Do you think that current regulatory provisions are sufficient to deal with such risks [*see question 8B*], today or for the foreseeable future?

	Count	Percentage
Yes, in the current situation and in the foreseeable future	19	27 %
Yes in the current situation, but not in the foreseeable future	16	23 %
No, not at all	20	28 %
Don't know	1	1 %
Total	56	

FIGURE 19: **BENEFIT ASSESSMENT (*Question 11; n = 71)***

Question: So far, the assessment procedures for GM plants and food only takes into account potential risks. Some actors have advocated that also potential benefits should be taken into consideration as applied in areas such as pharmaceuticals.
Below is a list of potential benefits that could be included in such considerations. Please assess how likely it is that in future different benefits will be considered for GM approvals. Please feel free to add other groups not listed.

	Highly unlikely	Unlikely	Likely	Very likely	Don't know	Total	
	%	%	%	%	%	%	n
Environmental benefit	15,5%	25,4%	38,0%	16,9%	4,2%	100,0%	71
Economic return	29,6%	28,2%	23,9%	12,7%	5,6%	100,0%	71
Food safety	16,9%	25,4%	33,8%	18,3%	5,6%	100,0%	71
Food quality	16,9%	31,0%	31,0%	15,5%	5,6%	100,0%	71
Nutritional benefit	15,5%	31,0%	35,2%	12,7%	5,6%	100,0%	71

FIGURE 20: **AIMS IN AGRICULTURE (*Question 12; n = 71)***

Question: In order to assess risks and benefits of GM cultivation, it must be compared to established practices in agriculture. In Europe, these practices vary according to climate or soil, but also to the tasks assigned to agriculture. For example, and apart from efficiently producing crops or providing jobs, agriculture should also protect the traditional landscape and the natural environment, among others. Thus, agriculture must pursue different aims, against which the performance of GM cultivation will be measured. Please rank the aims in the list below in their importance over the next 10 to 15 years.

	Not important	Little important	Important	Very important	Don't know	Total	
	%	%	%	%	%	%	n
Achieving high yields in crop production	5,6%	19,7%	36,6%	31,0%	7,0%	100,0%	71
Reducing inputs in crop production	2,8%	5,6%	46,5%	36,6%	8,5%	100,0%	71
Efficient crop production under difficult agricultural conditions (erosion, pest pressure etc.)	2,8%	14,1%	42,3%	33,8%	7,0%	100,0%	71
Staying competitive in times of market liberalisation and reduced subsidies	1,4%	15,5%	39,4%	33,8%	9,9%	100,0%	71
Crop production with least possible environmental impact	0,0%	4,2%	39,4%	52,1%	4,2%	100,0%	71
Producing high quality food in great variety	1,4%	7,0%	35,2%	50,7%	5,6%	100,0%	71
Providing jobs for the rural population	7,0%	21,1%	45,1%	19,7%	7,0%	100,0%	71
Protecting the traditional cultivated landscape	7,0%	12,7%	40,8%	33,8%	5,6%	100,0%	71
Promoting organic farming	8,5%	32,4%	23,9%	26,8%	8,5%	100,0%	71

FIGURE 21: ROBUSTNESS OF THE EU REGULATORY SYSTEM (*Question 13A; n = 71)*

Question: It is probable that more types of GM crops will be released both in export countries and in Europe. The current EU regulation, based on the precautionary principle and case-by-case risk assessment and authorisation, might be challenged by the US and other countries also in the future. Please give your judgement on how robust the EU regulatory system will turn out to be to challenges for example at the WTO in the next 10 to 15 years. (Please tick one possibility)

Answers	% of answers	Number of answers
The general principles and approaches of the EU regulation and the varying implementation of the EU Member States can withstand challenges through the WTO.	22,5	16
The general principles and approaches of the EU regulation can be maintained. However, the most restrictive practices of individual EU Member States will have to be changed.	32,4	23
The general principles and approaches of the EU regulation can be maintained, but a more substantial harmonisation among the EU Member States will be necessary.	23,9	17
The EU regulatory system can not be maintained due to challenges through the WTO.	14,1	10
Don't know	7,0	5
Total	100,0	71

FIGURE 22: THE FUTURE ROLE OF THE EU LEGISLATION (*Question 13B; n = 71)*

Question: The EU legalisation has been a model for regulations in some other countries. Will the EU regulation continue to be influential in the future? (Please tick one possibility)

Answers	% of answers	Number of answers
Yes	69,0	49
No	12,7	9
Don't know	18,3	13
Total	100,0	71

FIGURE 23: PRIORITISATION OF POLICY FIELDS (*Question 15; n = 71)*

Question: In order to meet challenges that have been explored in this questionnaire, it could be necessary for government institutions to take further action. Please prioritise the areas below in which you consider action needs to be taken. Please feel free to add areas of action not listed

	Very low priority	Low priority	High priority	Very high priority	Don't know	Total	
	%	%	%	%	%	%	n
Research funding	0,0%	9,9%	46,5%	38,0%	5,6%	100,0%	71
Better implementation of existing regulation	5,6%	29,6%	39,4%	16,9%	8,5%	100,0%	71
Amendment of existing regulation	2,8%	33,8%	32,4%	21,1%	9,9%	100,0%	71
Adaptation to international ruling (e.g. WTO)	9,9%	33,8%	28,2%	16,9%	11,3%	100,0%	71
Reform of competent authorities/institutions	12,7%	25,4%	33,8%	21,1%	7,0%	100,0%	71
Subsidiarity/change in the level of decision making	4,2%	39,4%	35,2%	7,0%	14,1%	100,0%	71
Expert involvement in decision making	2,8%	19,7%	36,6%	35,2%	5,6%	100,0%	71
Stakeholder involvement in decision making	8,5%	26,8%	42,3%	16,9%	5,6%	100,0%	71
Public involvement in decision making	11,3%	31,0%	33,8%	19,7%	4,2%	100,0%	71
None, let the system work as it is	56,3%	15,5%	5,6%	1,4%	21,1%	100,0%	71

FIGURE 24: OBJECTIVES OF PUBLICLY FUNDED RESEARCH (*Question 14; n = 71)*

Question: In view of new developments in the research on GM plants, what will be the objectives of publicly-funded research in your country in the coming years? Please feel free to add other objectives not listed.

	Highly unlikely	Unlikely	Likely	Very likely	Don't know	Total	
	%	%	%	%	%	%	n
Risk assessment and management	2,8%	23,9%	35,2%	31,0%	7,0%	100,0%	71
Development of products/solutions responding to agronomic problems not covered by private research	5,6%	28,2%	39,4%	16,9%	9,9%	100,0%	71
Development of innovative products with the intent to improve economic competitiveness	7,0%	31,0%	32,4%	18,3%	11,3%	100,0%	71

ANNEX 3: REVIEWS

AUSTRIA 1.

ECOLOGICAL MONITORING OF GENETICALLY MODIFIED ORGANISMS (2000) 1.1

BACKGROUND OF THE PROJECT

Context

On March 12th, 2001, the European Union (the Parliament and the Council by the co-decision procedure) adopted Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms. As a significant part of this Directive there is a Monitoring Plan sketched to be further elaborated in Guidance Notes. These supplementing Guidance Notes have been adopted by decision of the Council on October 3rd, 2002.

The present research was realised and finished between these two dates and addresses the need for further elaboration of the monitoring system, presenting preliminary proposals to be discussed on a national Austrian basis and EU-wide, afterwards.

The Austrian situation in the domain of green biotechnologies is characterised by a quite restrictive legislation, regional efforts to completely forbid GMOs and a broad GM-critical consensus between the political parties, farmers, interest groups, NGOs and the public. Already in the 1990s with the Directive 90/220/EEC in force, Austria pushed for a monitoring instrument. Basically, there were and there are two fundamental positions on the EU-level: those who demand an extensive monitoring of the approved GMOs, arguing that it is impossible to know every relevant effect of the product in a risk assessment ex ante; and those who understand a product which is approved after an exhaustive risk assessment as fully admitted. The critique of the latter on monitoring is that it is not affordable and even if it would be one cannot know what parameters exactly to trace – one cannot detect and measure anything which possibly could be of relevance. Austria maintained its pro-monitoring attitude and the present paper has to be read in this stable policy-line.

Demanding institutions

This study was financed by the Austrian Federal Ministry of Agriculture, Forestry, Environment and Water Management. As documented in the Third Report of the Austrian Genetic Engineering Commission (Gentechnikkommission), the study was also demanded and partly financed by the Austrian Federal Ministry of Health and Women. The paper was published in the monograph series of the Austrian Federal Environment Agency. The authors are, partly, from this agency and, partly, scientists from outside (University of Vienna, Austrian Federal Office and Research Centre of Agriculture). The main author Andreas Traxler has no institutional affiliation.

Guiding questions

How can we deal with the uncertainty about potential environmental effects of GMOs? What proposals can be made for the guidance notes to amend and complete Annex VII of the Directive 2001/18/EC with a framework concept for ecological monitoring that satisfies the needs of the EU and the Member States?

BASIC DATA ABOUT THE PROJECT

Type of project:

This project is a survey on ecological monitoring and the translation (to present it to a larger audience) of an abridged version of a more extensive monography (containing more Austrian-specific details) of the Austrian Federal Environment Agency (published in 2000). The methods used are basically a review of the legislative texts and scientific publications on the subject, and an exposition of Austrian ecological protection targets. Two case studies (GM maize and GM oilseed rape) were used in the original German version to delineate the requisites of an ecological monitoring device. However, the focus lies on the elaboration of a method, more than on applying already established methods.

Topics:

At first, the survey presents the EU-wide legal provisions on GMO monitoring. Then, the framework concept and the guidelines for monitoring of GMOs are sketched. There are criteria elaborated, the questions of financing and public participation are addressed and a terminology is elaborated. In a next step, the authors introduce the monitoring parameters and test methods they recommend.. After suggestions for Austrian specific ecological protection targets, the authors conclude with some words on biogeographical regions in Austria.

Duration:

The longer version in German language was published and presented in the year 2000, this paper in 2001. The project work took approximately a year.

MAJOR OUTCOMES OF THE PROJECT

Central findings

The study's analysis of the respective legislative acts on GMOs brought the authors to the conviction that ecological monitoring is one of the few methods to increase GMOs' environmental safety. It is the only way to detect unforeseen effects, to possibly prevent adverse effects in time, and to get to learn about the ecological risks of GMOs. There is a broad agreement, also in the EU (see directive 2001/18/EC) and between the interest groups, that it is a necessary instrument to control possible risks of the release of GMOs. However, there is uncertainty on how to implement it. Representatives of the industry, on the one hand, and ecologists, on the other, have quite

divergent views on the nature, extent and duration of the investigations to be carried out in a monitoring tool.

From the authors' point of view, ecological monitoring must be planned and carried out by ecologists in co-operation with molecular biologists and cannot be accepted as a burdensome necessity involved in the release of a GMO.

In line with the EU directive's indications, there should be a case-specific monitoring (limited in time, hypothesis-based) and general surveillance (nation-wide long-term monitoring without time restrictions, designed to observe the effects of all consented GMOs). The present monography also suggests a monitoring of the state-of-the-art (collect and structure international monitoring results; periodically adjust current monitoring plans in terms of methodology and subject matter) and an ecosystem monitoring (because of the high costs, it would be feasible only at few locations; however, this could unearth important findings and initiate interdisciplinary environmental monitoring on an integrated basis). A list of guidelines for ecological monitoring for releases and for the placing on the market is compiled in the study. The paper votes for the participation of the public (to improve acceptance and increase objectivity) and a broader and interdisciplinary integration of scientific fields and interest groups.

There is a great amount of monitoring parameters and test methods proposed by the contributors, which reflect the inconvenience of not knowing what to detect and assess, exactly. It seems that with the recommended ensemble, there should be reached an integrated, holistic vision able to catch problematic effects on the ecobiological system on various points and as fast as possible: There are standard parameters (biomass, phenology, cover values, vegetation structure, etc.) and methods of plant ecology proposed, furthermore biochemical, ornithological and entomological monitoring methods, and soil analyses.

The ecological protection targets should be stipulated by each individual Member State – the present survey attempts this for Austria.

Options for action

Amend Directive 2001/18/EC in line with the aspects prompted by the Austrian position. Each notification for the deliberate release or placing on the market of GMOs must contain a detailed monitoring plan on a case-by-case basis.

Identified future issues

The survey claims that the following points have to be clarified for future GMO notifications with regard to efficient ecological monitoring:

- determination of the executing institutions
- definition of threshold values
- definition of ecological damage (the term is not sufficiently defined: is it "damage" if a native plant population is suppressed or already if there is a GMO-occurrence in ruderal biotops?)

- establishment of a national and international information network (with a central coordination office for the GMO-monitoring as collector and administrator of monitoring data and findings)

These issues should be discussed at the earliest possible stage:

- planning of a nation-wide, representative monitoring network for animals and plants
- definition of the ecological targets likely to be affected by GMOs
- financing

IMPACTS AND FOLLOW UP OF THE PROJECT

According to the press release of the Austrian Federal Environment Agency, the frame monitoring concept was developed to be placed at the EU-level in the discussion on the monitoring guidelines complementing directive 2001/18/EC. These guidelines were published in 2002 by decision of the Council of the European Union. Only a comparative study of the two documents and the positions of other Member States and the relevant interest groups could clarify the concrete influence of the Austrian proposal.

CHALLENGES IDENTIFIED

The development of this monitoring concept, according to the authors, does by no means give a "clean bill of health" for releasing or placing GMOs on the market. Moreover, ecological monitoring is necessary and a useful tool – however, it does not work wonders: it is expensive, time-consuming, and methodologically limited.

LITERATURE

Traxler, A., Heissenberger, A., Frank, G., Lethmayer, C., Gaugitsch, H. (2000): Durchführung von Untersuchungen zu einem ökologischen Monitoring von gentechnisch veränderten Organismen. Umweltbundesamt, Monographien Band 126, Wien http://www.bmgfj.gv.at/cms/site/standard.html?channel=CH0810&doc=CMS1085490251342

English version (2001): Ecological Monitoring of Genetically Modified Organisms. Austrian Federal Environment Agency, Wien http://www.umweltbundesamt.at/fileadmin/site/publikationen/M147.pdf

AUTHOR OF THE REVIEW

Helge Torgersen

PRECAUTIONARY EXPERTISE FOR GM CROPS (2004) 1.2

BACKGROUND OF THE PROJECT

Demanding institution (initiator):

The research project "Precautionary Expertise for GM Crops" was funded by the European Commission, Quality of Life programme. It was the third in a series of EU funded projects on policy problems associated with the regulation of GMOs in several EU member states, co-ordinated by the Open University, Milton Keynes.

Context:

Background for this project was the increasing need of changes in regulatory procedures regarding GM crops. When Member States blocked the EU–level regulatory procedure in 1999, new legislations were adopted to meet their demands. New procedures were supposed to provide a mechanism to ensure full traceability and labelling of GMO crops and to enhance the application of the precautionary principle on a national level. Although the precautionary principle was widely invoked for dealing with uncertain risks by Member states, criticism remained considering the principle as a pretext for political agendas. One important reason was that largely, a generally accepted coherent view on the scope and modes of application of the principle was considered to be lacking.

The project analysed the different approaches to the precautionary principle and their consequences for regulatory measures as they appeared from regulatory actions by some Member States as well as from statements made by various stakeholders. Particularly the broader accounts leave the scope wide open for different interpretations. As a result, disagreements about the practical meaning emerged. The main goal of the study was to accommodate different views and give guidelines for the implementation of the principle. Thus it was an attempt to construct a comprehensive concept of the precautionary principle in the context of agricultural biotechnology.

The main guiding questions were:

- How do current European practices compare with different accounts of the precautionary principle?
- How are risk research, risk assessment and risk management linked in practice?
- How do stakeholder groups attempt to influence regulatory measures within or
- beyond formal procedures?
- How do expert advisory bodies mediate between regulatory science and public-scientific controversy?

BASIC DATA ABOUT THE PROJECT

Type of project:

The project was performed as an inter-disciplinary policy research exercise, aiming at comparative evaluations of national policy events, investigated by the national partners, and developments on the EU level researched by the co-ordinator.

The research activities mainly consisted of an analysis of relevant documents as well as interviews and workshops with key actors, involving a wide range of stakeholders.

Duration / start and closing date:

Work was performed within the years 2002 -2004, with the final report in 2004.

Topics of the project:

The investigation focused on the practical application of the precautionary principle in the member states with respect to transgenic crops.

Participants:

- D. Wield, S. Carr, L. Levidow, S. Oreszczyn, Open University, Milton Keynes, UK (Co-ordinators);
- H. Torgersen, A. Bogner, Institute of Technology Assessment; Austrian Academy of Sciences, Vienna, Austria;
- B. Gill, K. Boschert. Ludwig-Maximilians-Universität München, Germany;
- J. Toft, Roskilde University Library, Copenhagen, Denmark;
- C. Marris, P.-B. Joly, St. Ronda, Institut National de la Recherche Agonomique, Ivry, France; Ch. Bonneuil, Centre Koyré d'Histoire des Sciences et des Techniques, Grenable;
- L. Lemkow, D. Tàbara, D. Polo, Universitat Autònoma de Barcelona, Spain.

Subcontracts (consultants):

- P. Schenkelaars, Schenkelaars Biotechnology Consultancy, The Netherlands;
- J. Tait, University of Edinburgh, UK.

Events:

- National stakeholder workshops were held in all participating countries (UK, A, D, DK, F, SP, NL) and on the EU level. Workshops proceedings were distributed and, in part, published.

MAJOR OUTCOMES OF THE PROJECT

Central findings

The project places emphasis on the different understandings of the concept of precaution. As the different reports of the member states show, the concept is very contentious in its details and led to many conflicts among experts. In practise, the differ-

ent accounts have a strong impact on regulatory procedures. Narrow and broader accounts differ in three general respects – uncertainties in risk assessment, the trigger for management measures, and the scope of action (including alternative solutions). Despite institutional reforms regulatory disagreements continue, for instance, over the criteria for evidence, definitions of harms and means to manage uncertain risks.

One main outcome of the project is that different accounts should not be seen as fixed types but as dynamic tensions within the regulatory procedures. It is important to note that precaution has obtained its practical meanings through regulatory conflicts, more than by explicit interpretation or application of an a priori principle.

The project draws the conclusion that the diversity of views of member states is not considered impeding coherent policy or decisions. Through dynamic tensions among different accounts regulatory expert-procedures identified and addressed more scientific uncertainties than before. Thus, the precautionary principle helps to raise new questions about various unknowns in risk assessment. It shall be a flexible policy framework offering stronger means for shifting and clarifying regulatory criteria.

Options for action

The project analysed the need of common regulatory standards on EU level in order to handle existing expert conflicts. The establishment of the EFSA was an important step towards harmonizing the different understandings trough objective scientific advice. It is designed to override and reconcile national regulatory differences. However, the project made clear that on the EU-level different views are not being respected unless they are based on relevant scientific arguments. According to EFSA, Member States shall supply the necessary data and explain their scientific basis for different options within their risk management.

Identified future issues:

In future, this might stimulate more transparency in framing uncertainty and assigning a burden of evidence. Since many risks are not clarified yet, a great burden is born on science and expert judgements. Consequently common regulatory standards shall provide a more rigorous and transparent basis to deal with legitimacy problems.

Another future issue identified by this project is the broader participation of the public and stakeholders. The involvement of diverse stakeholders, including critical scientists and NGOs, can help to ensure that as many relevant questions as possible are addressed.

IMPACTS AND FOLLOW UP OF THE PROJECT

In every participating country as well as on the EU level a workshop with stakeholders such as regulators, scientists, industry and NGO representatives was held, where comments were collected and incorporated into the final report. These workshops took on different shapes in every country; in Austria, it was held as a “meeting on neutral grounds” between regulators from different ministries and scientists in order to explore policy future options.

The results of the project were published in a special issue of the scientific journal Science and Public Policy (32/4, 2005) and, individually, in various other scientific journals by several project team members.

CHALLENGES IDENTIFIED

The relation between scientific advice and political decision making on GM plants remains precarious despite agreed policy principles such as precaution. Rather than suggesting a once-and-for-all procedure with fixed and scientifically unambiguous criteria for the assessment of new GM plants, the authorisation, application and marketing of such plants and their products remain politically sensitive and open for negotiation. The issue turns out not to be able to be dealt with on the basis of science and law only, so that changes in the decision making due to political considerations will have to be taken into consideration in the future as well.

LITERATURE

Special issue on precautionary expertise for EU agbiotech regulation. Science and Public Policy 32(4), August 2005

AUTHOR OF THE REVIEW

Helge Torgersen

RISK ASSESSMENT OF GMO PRODUCTS IN THE EUROPEAN UNION. TOXICITY ASSESSMENT, ALLERGENICITY ASSESSMENT AND SUBSTANTIAL EQUIVALENCE IN PRACTICE AND PROPOSALS FOR IMPROVEMENT AND STANDARDISATION (2004) 1.3

BACKGROUND OF THE PROJECT

Context

Toxic and allergenic properties are considered focal aspects in the assessment of potential health risks of GM food. In contrast to other regulatory contexts such as chemicals, plant pesticides and food additives, detailed requirements for toxicity and allergenicity assessment have not been put into concrete terms until recently. During the time this study was carried out there was no detailed guidance available at all[1].

However, a number of genetically modified plants (GMPs) had already been authorised under Directive 90/220/EEC and the Novel Food Regulation. The authors state a distortion between the provided guidance for risk assessment and the complex situation characterised by rapid scientific progress, varying interpretation of EU regulation by the national authorities, and pressures from industry and public interest groups. The assessment practice resulting from this constellation is described as being time-consuming and inconsistent.

Demanding institution

The present monograph was funded by the Austrian Federal Ministry for Agriculture, Forestry, Environment and Water Economy and the Austrian Federal Ministry for Health and Women. The research that provided the basis for this document (two preceding studies in German language) was financed by the Austrian Federal Ministry for Work and Labour and by the Austrian Federal Ministry for Health and Women. Parliamentary documentation states that this compilation was carried out by order of the Austrian Federal Ministry for Health and Women.

Guiding questions

Which risk assessment practices exist regarding potential toxic and allergenic properties of GMPs? How would a consistent toxicity and allergenicity risk assessment approach look like? Which shortcomings can be identified in current risk assessment? Out of this review of the state-of-the-art, which proposals may be given in the context of recent regulatory developments for guidance documents etc.?

1 The authors mentioned the guidance document of EU's Scientific Steering Committee (SSC) that lists toxicity and allergenicity of gene products as issues to be considered. At present, there is the EFSA GMO panel's Guidance Document for the assessment of GMPs published in April 2004 (as an updated version of the SSC document) and actualized in 2006. This document more extensively addresses the aspects of toxicity and allergenicity.

BASIC DATA ABOUT THE PROJECT

Type of the project, methods

The present monograph is an abridged and condensed but updated English version of the content, conclusions and recommendations of two earlier research projects carried out in German language with the main goal to review the practice of risk assessment procedures on GMPs in the EU.

The practice of toxicity and allergenicity assessment was scrutinised in a range of Directive 90/220/EEC and Novel Food Regulation dossiers. Relevant dossiers were selected, investigated and their respective assessment procedure described. The different approaches to risk assessment were compared and evaluated. A literature review on the concept of substantial equivalence was also implemented. Based on this, the study elaborates proposals aiming at improvement and standardisation of risk assessment procedures. Surveys on toxicity and allergenicity assessment in regulatory documents covering GMPs in Europe and the US provided information which was included in the conclusions and proposals.

Topics

- current practice of toxicity and allergenicity assessment
- its shortcomings
- requirements for a comprehensive toxicity and allergenicity assessment
- proposals for improvement and standardisation of risk assessment regulation and practice

Duration

The two studies that form the basis of the present English version were conducted between 2000 and 2003. The English paper was first published in July 2004.

Participants

The current English version is authored by a subset of the original project team which consisted of scientists from the Austrian Federal Environment Agency, the Inter-University Research Centre for Technology, Work and Culture (IFZ) Graz, the ARC Seibersdorf Research GmbH, the Research Center for Biotechnology, Society and the Environment at the University of Hamburg and a range of individually contracted experts.

The subset of this team and, hence, the authors of the updated English version are: Armin Spök (IFZ), Heinz Hofer (ARC Seibersdorf), Petra Lehner and Rudolf Valenta (contracted), Susanne Stirn (University of Hamburg), and Helmut Gaugitsch (Austrian Federal Environment Agency).

Events

In the course of the investigation, various internal project workshops were held.

Prior to publishing the English version an international conference was held in autumn 2003 in Vienna, where the outcomes of the two preceding studies were discussed and a fundament for the updated English version was laid. Besides some of the studies' authors, a representative of the European Commission (Andreas Klepsch) and a member of the environmental NGO Global2000 gave lectures.

MAJOR OUTCOMES OF THE PROJECT

Central findings

With regard to the toxicity and allergenicity assessment procedures and the use of the concept of substantial equivalence, the study points out significant shortcomings in the dossiers based on Directive 90/220/EEC, as well as in the Novel Food Regulation dossiers:

- The formal structure of the risk assessment approach is not based on and does not clearly distinguish between exposure assessment and hazard assessment (which are both necessary). The claims of substantial equivalence are frequently based on trials and analysis that are not properly designed.
- Assessments and conclusions drawn often cannot be entirely verified given the lack of details.
- Although the overall approaches in risk assessment are similar in the dossiers, differences became evident at the level of details – this fact points to a lack of details in the guidance documents.
- Safety conclusions are often based on indirect evidence and/or assumption based reasoning, and they are partly based on questionable methods, approaches and assumptions.
- Unintended effects of genetic modification are usually not investigated and even dismissed. Significant differences found in compositional analysis are disregarded.

Options for action

Proposals were developed aiming at further improvement and standardisation of risk assessment:

- The structure of risk assessment approaches and dossiers should be standardised.
- The role of substantial equivalence for risk assessment should be further clarified.
- Significant differences in the results of analysis of the same GMPs should at least trigger repetition of the analysis.
- Dossiers should be "stand-alone" documents, including full reports of available safety studies, quoted literature, statistical evaluation sheets for compositional analysis, and thorough description of methods applied.
- The direct testing of toxic or allergenic properties should be preferred compared to indirect testing and assumption based reasoning.
- Testing should be extended to include whole-plant/whole-food testing.

Identified future issues

The authors mention that some of these proposals have already been included in most recent guidance documents. Others might require further discussion and even additional studies – the particular minimum set of toxicity endpoints, for example. Some proposals might require further improvement of testing methods or even the development of new methods.

IMPACTS AND FOLLOW UP OF THE PROJECT

Parliamentary debate

Austria refers to the study in an EU meeting of the Standing Committee on the Food Chain and Animal Health, claiming a comprehensive toxicological risk assessment as described in the study. In the Austrian Parliament there is no immediate discussion of the study. However, it details and shapes the Austrian position on GMP risk assessment issues.

Scientific recognition and public perception

An article based on the present study and written by some of its authors (together with other scientists) was published in the International Archives of Allergy and Immunology (137/2005).

Furthermore, the work is cited in Science, Technology & Human Values (32/1), in a Press Release of the Institute of Science in Society, and in a Nature Biotechnology correspondence. It was presented on the Third World Network's website and mentioned as additional material by the Third Meeting of the UNEP Ad Hoc Technical Expert Group on Risk Assessment.

CHALLENGES IDENTIFIED IN THE PROJECT

At the time of this English paper's publication, the 2003 SSC guidance document was the state-of-the-art standards on GMP risk assessment. As mentioned, it contains some of the proposals made by this study, as, for example, the need of complete dossiers containing all information required for a full risk assessment. Other aspects, however, remain unclear, ambiguous, or disregarded: Good Laboratory Practice is only demanded for toxicological studies. The SSC guidance is ambiguous with regard to the toxicological testing of the introduced proteins. The possibility of secondary effects is acknowledged, but in a more limited way than in this monograph. Further guidance for homology studies than the indications given by the SSC document is needed. Unlike the case-by-case basis favoured by the SSC guidance notes, this paper proposes compositional analysis for all processed products.

Taking into account these differences, this monograph sees the challenges in addressing the shortcomings still remaining. If this is not accomplished by further and better regulation, risk assessment practice on toxicity and allergenicity is still to be called deficient.

LITERATURE

Spök, A., Hofer, H., Lehner, P., Valenta, R., Stirn, S., Gaugitsch, H. (2004): Risk Assessment of GMO Products in the European Union. Toxicity assessment, allergenicity assessment and substantial equivalence in practice and proposals for improvement and standardisation. Austrian Federal Environment Agency. Wien

AUTHOR OF THE REVIEW

Helge Torgersen

FEASIBILITY STUDY ON »GMO-FREE« CLAIMS AND THE AVOIDANCE OF GMOS IN FOOD (2005) 1.4

BACKGROUND OF THE PROJECT

Context

The study bases its predications regarding to the feasibility of a correct use of the label "GMO-free", on the one hand, on the definition according to the Codex Alimentarius Austriacus and, on the other hand, on the EU-regulation 1829/2003 concerning the (not required) labelling of animal feed and comestibles as GMO.
The public debate on GMOs in Austria was a more critical one compared to other EU Member States. Moreover, it was characterised by an unusual common understanding between political representatives, social movements and significant parts of the agricultural sector. This constellation led to a more restrictive handling of the label "GMO-free" in Austria. For example, the Austrian label requires additional standards concerning the application of production facilities, the fabrication of additives, and feeding.
The study was carried out while the use of GM-seeds in Austria and other EU Member States was prohibited by regulations of the EU-Council. Hence, the possibility was excludable that in Austria and large parts of the EU there would be GM-seeds employed. In case of additives, the situation in the year 2005 was already different: some of them were almost exclusively accessible from sources involving GM-micro-organisms.

Demanding institution

The Austrian Federal Ministry of Health and Women, the Austrian Federal Ministry of Economics and Labour and the AMA Marketing GesmbH assigned the Austrian Agency for Health and Food Safety with the realisation and coordination of this feasibility study.
The study was realised in cooperation with the University for Natural Resources and Applied Life Sciences and was continuously evaluated by Prof. Maurer, head of the former Ludwig-Boltzmann-Institute for Organic Farming and Applied Ecology and now chairman of the new Bio Research Austria Institute.

Guiding questions

- Is there a transfer of GMOs from animal feed to derived food products?
- Are the raw materials and additives for feed production available?
- From the viewpoint of nutritional requirements, is the use of GMO-free feeds feasible?
- Does a GMO transfer happen via bee products?
- What strategies and efficient monitoring exist to avoid GMO contamination?
- From an economical viewpoint, is the use of GMO-free feeds feasible?

BASIC DATA ABOUT THE PROJECT

Type of project

The present project is a feasibility study that tries to estimate the existing possibilities (taking into account nutritional requirements, economical factors and constraints, etc.) to accomplish the requirements established in the legal frameworks in Austria and the EU. A broad inquiry into Austrian and international scientific studies and publications forms the basis of this study. The study investigates legislative texts and economical measures (market prices; amounts of consume and production of seeds, etc.), and undertakes some basic calculations to estimate the differential costs for the production of food applying GMO-free feeds.

Topics

The topics addressed by the study are basically the legal situation for the denomination of a product as "GMO-free" in Austria and the EU, the necessities to meet the legal requirements and control their compliance (monitoring) and the additional costs of gaining the "GMO-free" label. Besides, the world agricultural product market is taken into consideration regarding the availability of indispensable import products.

With these concrete topics the main problematic of the feasibility of GMO-free products appropriate to the current legal frameworks is addressed.

Duration

The study was commissioned in late autumn 2004, finished and published in November 2005.

Participants

- Austrian Agency for Health and Food Safety: Leopold Girsch (project management),
- Institute for Seeds: Natascha Balarezo (internal project coordination), Christine Kargl
- Institute for Animal Feed: Veronika Kolar, Thomas Kickinger, Herbert Würzner
- Vienna Institute for Comestible Testing: Rainer Bernhart, Klaus Riediger
- Risk Assessment: Roland Grossgut, Daniela Hofstädter
- Institute for Apiology: Rudolf Moosbeckhofer
- Biochemistry Competence Centre: Hermann Hoertner, Rupert Hochegger

Subcontracts

- University for Natural Resources and Applied Life Sciences (Institute for Marketing and Innovation): Siegfried Pöchtrager, Josef Penzinger, Stefan Großauer
- Evaluation: Ludwig Maurer

Events

The study was presented to a broad range of interest groups at the end of 2005. On November 2nd, 2005, there was a press conference at the Austrian Agency of Health

and Food Safety in Vienna. In the following weeks until February 2006 there were presentations, for example, for the Chambers of Agriculture of Austria, Upper Austria, Styria and Lower Austria and other communities of the agricultural sector.

MAJOR OUTCOMES OF THE PROJECT

Central findings

- No evidence was found in the international scientific literature stating that even traces of transgenic DNA were detectable in foods derived from animal production after feeding GM-feed.
- 90% of the imported soy used for feeding in Austria is transgenic. The global share of GM-soy is still increasing. However, following the requirements from the EU directive 1829/2003, in a short- and medium-term raw materials for animal feed production which do not have to be labelled as GMOs will be available. With respect to the provisions established by the Austrian Codex, protein substitutes for soybean extraction meal produced in Austria and the EU will be available. It has to be said that these substitutes can only be used to a certain limit and no forecast can be given for the development of the raw material markets. In terms of the additives for animal feed production, there are products available which do not require labelling in accordance with the EU-directive but would so according to the Austrian law.
- Feasibility of the usage of feed labelled as GMO-free: following the EU directive, it is feasible in a short- and medium term; following the Austrian Codex, it is feasible only for cattle but not for pigs, poultry and turkey (because of the necessary additives)
- The content of pollen in honey is usually noticeably below the labelling threshold levels in accordance with the EU-directive.
- Monitoring and strategies to avoid contamination: self-control of the companies; separated and closed production processes; appropriate cleaning; more provisions in monitoring and surveillance for the Austrian label
- The use of animal feed containing soybean extraction meal labelled as GMO-free or not requiring labelling leads to additional costs of up to over 8%. These costs vary considerably depending on the line of production (beef, pigs, etc.). In the future, by-products from bio-fuel production that contain protein and are available in Austria and the EU will be commercially employable as a protein supplying substitute for soybean extraction meal.

Options for action

- enhance the production of substitutes for soybean (for example, from bio-fuel production)
- try to assure a reliable labelling in the world market's production chains
- try to safeguard Austria's share of Brazilian and US GMO-free soybeans

Identified future issues

- monitor the world raw material market's development and the share of available and affordable GMO-free products
- integrate more aspects into the calculations of the additional costs

IMPACTS AND FOLLOW UP OF THE PROJECT

Parliamentary debate

The Federal Minister of Agriculture, Forestry, Environment and Water Management mentioned in a parliamentary inquiry presented by the Green Party in the year 2006 that the present study was presented to the ministerial working group on genetic engineering. Moreover, he cited the study's insights into the additional costs and technical needs for contamination prevention. In another parliamentary inquiry in 2004, also presented by the Greens, the same Minister explains the financing and planning of the study. He says, inter alia, that there was (as usual) an interchange on the planned contents with the relevant experts, on beforehand. Also in the regional Parliament of Salzburg the study was subject of a parliamentary inquiry.

Interestingly, the study was cited in a parliamentary debate in the German Bundestag by Christel Happach-Kasan (FDP). She exposed and interpreted the study's finding that GM-free pig and poultry breeding is quite impossible because of the additives needed. Not using genetic engineering technologies would lead to a higher mortality in the animal stocks. There was disagreement expressed by the German Greens.

Public perception

After the press conference on November 2nd, 2005, there was ample recognition of the study in local media and partially in the German-speaking world. The Austrian Press Agency published an article delivered by the Agrarian Information Centre. The ORF (the Austrian public news channel) reported, too.

Furthermore, the study was mentioned by the Austrian Federal Chamber of Commerce. Details were cited by the Austrian Chamber of Labour, Greenpeace, Austrian agricultural communities such as BioAustria, the German Information Service on Genetic Engineering (Informationsdienst Gentechnik) and other German citizen's action committees.

The public perception of the study is characterised by the conclusion that GMO-free production of comestibles is feasible, principally, but there are some costs to take into account. However, there are also new opportunities for the Austrian agriculture, especially concerning the production of GMO-free substitutes for soy from bio-fuel.

Scientific recognition

A research paper of the Austrian Federal Ministry of Health and Women on the need to label GMOs already pointed to the study in 2005, before its finishing.

CHALLENGES IDENTIFIED IN THE PROJECT

The development of the international market for reliable GM-free seeds and feed can not be predicted and lies outside the Austrian room for manoeuvre. The availability of GM-free additives is already quite limited.

LITERATURE

Austrian Agency for Health and Food Safety/University for Natural Resources and Applied Life Sciences, Vienna (2005): Feasibility Study on "GMO-free" claims and the avoidance of GMOs in food.

AUTHOR OF THE REVIEW

Helge Torgersen

COEXISTENCE (2005) 1.5

BACKGROUND OF THE PROJECT

The cultivation of genetically modified crops is growing steadily and fast in the ultimate years, mostly in North and Latin America. In the EU there is already an extensive set of legislation on the regulation, admission and limitation of GMO cultivation, import etc.

In 2003, the European Commission released the Recommendation No. 2003/556/EC on guidelines for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming. The Commission underlined that these guidelines should focus on economic consequences of GMO cultivation given that ecological and health aspects are already taken into account in the GMO admission procedure. The scope of the guidelines spans from the agricultural production to the first point of sale – higher levels of elaboration are not considered. In addition, national catalogues of measures, as to be defined by the member states, should allow for every country's specificities regarding topography, climate, the agricultural structures and the production systems. The Commission's Recommendation together with the country's implementation strategies should ensure that the compliance with the threshold values for non-GMOs is not impeded by the diversity of the producing regions, the productive systems and technical matters.

The Austrian situation in the domain of green biotechnologies is characterised by a quite restrictive legislation and a broad GM-critical consensus between the political parties, farmers, interest groups, NGOs and the public. Seeds in the initial examination have to be free of GM contaminations to be authorised in Austria. In the follow-up examination a threshold value of 0,1% is fixed.

BASIC DATA ABOUT THE PROJECT

The present study was conducted (under the guidance of Prof. Georg Grabherr) by Kathrin Pascher and Marion Dolezel from Vienna University's Department of Conservation Biology, Vegetation Ecology and Landscape Ecology between the end of 2003 and March 2005 on behalf of the Austrian Federal Ministry for Health and Women (Section IV). The overall goal of the document is to define rules and measures providing a general framework for coexistence of GM-, conventional and biological crops for the specific Austrian case as demanded by the Commission's Recommendation. The authors argue that measures for the cultivation of GM-crops would assure the farmers the possibility of planting just the crops they want to, as well as the consumers the security and freedom of choice they look for.

Following the Commission Guidelines which establish that the measures have to be crop-specific, the study focuses on maize, oilseed rape and sugar beet – for the authors primarily expect these crops to be commercially cultivated as GMOs in Europe.

Sources of GM-contaminations are outlined and evaluated, then the measure proposals for the reduction of these contaminations are given and experiences from other countries with coexistence of the mentioned crops are incorporated.

The project was realised in terms of a scientific study from an eco-biological perspective. In the course of the project, the authors attended a series of conferences and lectures, amongst others the 1st European Conference on the Coexistence in Denmark, a conference on GMO Risk Assessment in Vienna, other forums on coexistence in Austria and a Conference of the European network of GMO-free Regions.

There were basically two methods applied: Firstly, a theoretical evaluation of the problematic of coexistence and contamination by means of a review of existing studies of a European and non-European institutions and authorities (FiBL, Union of Concerned Scientists, BUWAL, JRC, MAFF, MAF), literature databases, organisational websites (saveourseeds.orf, transgen.de, biosicherheit.de, ucsa.org, etc.), personal contacts to Austrian authorities, organisations and firms (AGES, Saatbau Linz, ZAMG, Chambers of Agriculture, etc.), and conference attendance. Secondly, GMO-crop growing was simulated for different Austrian regions. The amount of field losses due to the necessary belts of isolation (to avoid exogamy) was simulated for random and clustered repartition of GM-crop fields in the cases of maize, oilseed rape and sugar beet.

MAJOR OUTCOMES OF THE PROJECT

The study's outcome is a catalogue of measures to prevent contamination with GMOs and to delineate the exigencies of a reasonable coexistence.

In the case of **maize**, the use of barriere-plants or of varieties with different flowering dates will not be sufficient to reduce GMO contamination rates to 0,9%. Isolation distances of at least 200m seem to be the only viable measure to guarantee this quota. However, if GM proportions grow beyond 10% and if a threshold value of 0,1% in the harvest is to be realised, cultivation, harvest and post-harvest processes have to be thoroughly separated and cross fertilisation completely avoided. Not even isolation distances of one to several kilometres could assure this due to other factors that until now couldn't be exhaustively studied – the establishment of large-scale GMO free zones would be the only possible way to guarantee these low threshold values.

Imports of basis seeds and possible cross fertilisation are the crucial points for contamination control in **oilseed rape**. Necessary measures for the consumption production are, therefore, a purity control of the imported basis seeds, long growing intervals of at least 8 to 12 years (to reduce volunteers of oilseed rape) and isolation distances of 4 kilometres (allowing for the flying distances of pollinating insects). Regional and continuous examinations of their effectiveness could facilitate more flexible isolation distances. The management of the segetal weed flora, barriers with non-GM oilseed rape and the removal of bee hives near the fields seem to be viable measures, too. Transportation routes should be as short as possible. However, the creation of a closed seed production area would be the most effective measure. Considering the specificities of agronomic and topographic structures, climatic particu-

larities, the necessary extent of the isolation zones, regional occurrence of volunteers, etc., the authors argue that coexistence of oilseed rape will not be feasible in Austria.

Sugar beet for consumption is not flowering. Hence, the unwanted hybridisation events affect seed production areas. To achieve a threshold value for GM contamination of 0,5% much larger isolation distances than the currently widespread 300, 600 or 1000m would be needed. The highest risk is currently posed by imported seed. Reliable choice and control is needed; moreover, suitable cultivars, coordination of farmers, at least 2 kilometres of isolation distance, control of bolters, weed beets, volunteer beets and Beta-forms. Pollen barriers should be used and a crop rotation of at least eight years guaranteed.

Beyond these crop specific arguments the study presents measures to avoid **technical contamination** at cultivation and harvest. The technical processes of GM and conventional or organic field crops should either be completely separated or strict guidelines for adjustment, operation and cleaning measures should be provided and demanded. Seeding and harvesting machines have to be cleaned before and after their application for GM crops. Losses during the transport must be prevented, hoppers cleaned and controlled, contracts established (e.g. between vicinal farmers on location of their fields or on the requirements and criteria for a joint use of machines), etc.

IMPACTS AND FOLLOW UP OF THE PROJECT

A Green Party's delegate to the National Assembly asked the Federal Minister of Health and Women and the Federal Minister of Agriculture, Forestry, Environment and Water Management in a written parliamentary request about the costs of coexistence in Austria. As an initial point he cited the present study which, in his interpretation, comes to the conclusion that the coexistence of GMOs and conventional and biological products is possible, if at all, only with high technical and organisational efforts.

The study is also cited by further studies of the Federal Ministry of Health and Women and the Austrian Agency for Health and Food Security, the network of GMO-free regions and an Upper-Austrian text introducing this region's characteristics and the structure of its economy. In a slightly different reading some of the study's findings are presented in an information letter of *Les Professionels des Semences et de la Protection des Plantes*, a French syndicate of the seeding industries. They mention that the study posits the possibility of coexistence always respecting the right isolation distances. It is just rape where coexistence doesn't seen viable in Austria.

CHALLENGES IDENTIFIED IN THE PROJECT

The study's tenor is that coexistence is possible in some cases but not in all. And even if it is possible this would lead to economical and social costs and much regulatory work on a national base. The mentioned feasible measures to assure coexistence

are presented in a sceptical light. The whole issue of coexistence seems to be a problematic one since it is at least an expensive endeavour and potentially impossible, at the end. The reader could get the impression that the study provides and tries to provide scientific arguments underpinning GM-critical positions.

LITERATURE

Pascher, K., Dolezel, M. (2005): Koexistenz von gentechnisch veränderten, konventionellen und biologisch angebauten Kulturpflanzen in der Österreichischen Landwirtschaft – Handlungsempfehlungen aus ökologischer Sicht. Bundesministerium für Gesundheit und Frauen, Sektion IV, Band 2/05, Wien http://www.bmgfj.gv.at/cms/site/standard.html?channel=CH0810&doc=CMS1113391269254 English summary: http://www.bmgfj.gv.at/cms/site/attachments/6/4/4/CH0810/CMS1113391269254/summary_-_coexistenz.pdf

AUTHOR OF THE REVIEW

Helge Torgersen

THE ROLE OF PRECAUTION IN GMO POLICY (2006) 1.6

BACKGROUND OF THE PROJECT

Context

In the year 2000, the European Commission published the so called Communication on the Precautionary Principle. This document proposed guidelines for the handling of scientific uncertainty. Since then, precautionary language and criteria have been integral part of the respective legislation, for instance, in the Deliberate Release Directive concerning GM crops or the Biosafety Protocol. Today, the Precautionary Principle (PP) is firmly established in European law.

Notwithstanding, the principle has not ceased to be contentious and much less to be interpreted in different ways. Besides the narrow account of the European Commission's document, there are broader ones from other sources like the European Parliament, experts, member states and stakeholders. The project "Precautionary Expertise for GM crops" (see section 1.2) studied varying understandings and applications of the PP within and between 7 European States. The scenario in Austria could be sketched as characterised by a wide GMO-critical political consensus between government, stakeholders and the public, despite divergent concepts of precaution.

Demanding institution

The present conference was initiated jointly by the Austrian Federal Ministries of Agriculture, Forestry, the Environment and Water Management and of Health and Women. The Federal Environment Agency was responsible for realisation. The conference took place in the frame of the Austrian EU-Presidency in the first half year of 2006. The actual and possible development of the PP in GMO policy was examined from legal, scientific, and political perspectives as well as on the basis of case studies at national, EU and international levels.

Guiding questions

- What different interpretations of the PP exist?
- Is there room for the principle in the EU legislative framework and how is it specified?
- What are practical experiences with the principle?
- What is the scientific background to be taken into account?

BASIC DATA ABOUT THE PROJECT

Type of project and duration

The project was an international and interdisciplinary expert conference held at the Hofburg in Vienna with the participation of experts and stakeholders from a scientific and a political background. It took place on the 18th and 19th of April 2006.

Topics

Relevant aspects of the precautionary approach towards regulation of GMOs were addressed. The main topics discussed were possibilities and limits of precautionary measures within the existing legal framework, the scientific background of precautionary approaches, as well as the practical experiences of putting to use the principle.

Some of the contributions' subject areas were how EU legislation on GMOs relates to and gives room for the PP, how and where it is discussed controversially, how it is interpreted in the CEE countries and what were practical experiences with the use of the principle, as well as the question of risk assessment.

Participants

Approximately 135 scientists, state and interest group representatives

Speakers: (in order of appearance):

- Hugo-Maria Schally (Chairperson), DG Environment, European Commission
- Christine von Weizsäcker, Germany
- Kathryn Tierney, DG Environment, European Commission
- Liina Eek, Ministry of the Environment, Estonia
- David Wield, Open University, UK
- Eric White, Legal Service, European Commission
- Thomas Jakl (Chairperson), Ministry for Agriculture, Forestry, Environment and Water Management, Austria
- Brian Wynne, Centre for the Study of Environmental Change, Lancaster University, UK
- Jürgen Zentek, Freie Universität Berlin, Germany
- Christopher Pollock, Institute for Grassland and Environmental Research, UK
- Margaret Mellon, Union of Concerned Scientists, USA
- Katja Moch, Öko-Institut Freiburg, Germany
- Michel Haas (Chairperson), Ministry for Health and Women, Austria
- Brian Wynne on behalf of David Gee, European Environment Agency
- Harry Kuiper, GMO-Panel EFSA, RIKILT – Institute of Food Safety, The Netherlands
- Jan Husby, Norwegian Institute of Gene Ecology, Norway
- Simon Barber, Plant Biotechnology Unit, EuropaBio
- Helmut Gaugitsch, Federal Environment Agency, Austria

IMPACTS AND FOLLOW UP OF THE PROJECT

It was concludingly addressed by Helmut Gaugitsch that there is a need for a follow-up. A good starting-point would be the discussion on the PP and ways towards its application. Kathryn Tierney (EU Commission) enunciated that the debate on GMOs and the PP would continue at the EU Environmental Council in Luxembourg in June 2006.

There was no parliamentary debate on the conference. However, it was presented by the authorities as an asset in the Austrian EU-presidency 2006 to address the issue in such an international expert conference, bringing forward the respective EU-wide discussion. The national press (Der STANDARD, 20.4.2006) reported in a short statement. The Institute for Applied Ecology (Freiburg/Germany), the USDA Foreign Agricultural Service, biotrin.cz and the Biosafety Information Centre mentioned the conference on its website.

MAJOR OUTCOMES OF THE PROJECT

Central findings

As Helmut Gaugitsch in his closing remarks points out, there is broad consensus around an understanding of the PP as one of the central aspects of European GMO legislation. It was described as a tool that allows countries to adopt the level of protection that was felt necessary, even in the absence of scientific certainty. However, it remains questionable whether there is a common understanding of the PP and the way it can or should be implemented.

Regarding the question whether the PP is a risk management issue only, it became clear that risk assessment on its own is an important prerequisite for decision making but not enough as it is inadequate to assess uncertainty, by definition cannot assess ignorance and also falls short of acknowledging any benefits. As Bryan Wynne expressed it, precaution should rest on the recognition that knowledge is always limited. The assumption that the need for precautionary policy can be subjugated to preliminary risk assessment is misconceived.

The PP should contribute to protection and not protectionism and should be used to gain further scientific knowledge. It was stated that the PP can be a possible instrument of scientific innovation.

There were also voices who proposed a modification of EFSA's format and inner EU-communication on orientations toward the PP. Others, again, expressed the opinion that Europe-wide universalist approaches to the PP, maybe, will not work (considering that some regions see commercial benefits in being GM-free etc.). There will not be a single understanding and application of the PP. Particularly "ecologically sensitive" areas will have different approaches, for example.

Eric White from the European Commission's Legal Service claimed that the PP is alive and perfectly compatible even with the WTO.

Options for action and identified future issues:

- continue to discuss the concept of the PP in the national, EU and international level towards application and action
- discuss the different national and EU wide conceptions of the PP to get to a more common understanding
- elaborate mechanisms to include statements on the application of the PP in GMO product notifications

- improve, harmonize and standardize the risk assessment instruments nationally and EU wide (should include guidance on which kind of data should be included in notifications and the methodology to generate them), keeping a balance between clear guidance and case-by-case sensibility
- in order to gain further knowledge on GMOs and to address uncertainty and ignorance, research projects could and should take approaches as the PP more into account
- enter into a dialogue with stakeholders (and involve them) at the national and the EU level and between them; risk communication should be improved and a system for public participation needs to be set up

CHALLENGES IDENTIFIED IN THE PROJECT

A considerable challenge identified is to find ways from the PP to an applicable approach and action and to define its relation to the risk assessment framework. The PP should not be used as a technical barrier to trade and a tool for protectionism.

There lies a twofold challenge in the concept of PP as it is present in nowadays' legislation and practice: On the one hand, the PP has to be elaborated and discussed on general grounds, looking for ways to apply and regulate it. On the other hand, the various interpretations of the principle have to be consorted.

The EU legislative framework has to be fine-tuned to provide for a higher degree of transparency and thus to fulfil the expectations on decision-making.

It was argued that the "Sound Science" approach (firmly present in the US policies), with its accents on delaying safety obligations until causal chains of harmful impacts are fully proven, runs counter the PP – with this, originating a possible and already manifest conflict between the US and Europe (see the current WTO dispute). The EU could possibly use the "de facto coalition" with the developing countries in favour of the PP, to enforce its position and foster its understanding of protection.

LITERATURE

Federal Ministry of Health and Women (Ed) (2006): Conclusions of the conference "The Role of Precaution in GMO policy", 18.-19. April 2006, Vienna http://www.bmgfj.gv.at/cms/site/standard.html?channel=CH0810&doc=CMS1145612477419

AUTHOR OF THE REVIEW

Helge Torgersen

DENMARK 2.

GENETICALLY MODIFIED FOODS (1999) 2.1

BACKGROUND OF THE PROJECT

The DBT- project *"Genetically modified foods"* from 1999 was carried out due to the apparent scepticism among the Danish population. At that time, genetically modified foods were about to enter the Danish market, but it seemed that the Danish consumers did not associate any direct advantages with them. However, it was impossible to reject that benefits would eventually emerge in step with the development of the technology.

At that time, legislation on genetically modified foods had not yet been completed within the EU and the potential benefits and risks considering GM foods were still associated with much uncertainty. Thus, the aim of the project was to provide a multi-faceted public debate on GM foods in order to enhance the dialogue between decision makers and the public.

BASIC DATA ABOUT THE PROJECT

The project was designed as a consensus conference that took place during three days. The Danish Board of Technology appointed a panel of fourteen citizens who were asked to consider genetically modified foods. Before the actual consensus conference, the citizen panel met twice and discussed GM foods based on some introductory information. At the conference, thirteen experts were invited to make a presentation of their knowledge and opinion considering GM foods. During the two first days of the consensus conference the experts answered questions from and discussed with the citizen panel. Conclusively, the citizen panel created a final document containing the evaluations and recommendations considering GM foods on which the panel could all agree.

Through the consensus conference ten questions considering genetically modified foods were addressed both by the experts and the citizens. In the final document, each question is evaluated by the citizen panel and followed by some recommendations. The main topics that characterized the ten questions concerned amongst others: environmental impacts, human health, market conditions, national and international regulation, information, and ethics.

MAJOR OUTCOMES OF THE PROJECT

The consensus conference concluded that the production of genetically modified foods undoubtedly affects nature's cycle. However, the experts strongly disagree about the seriousness of the effect and whether or not the effect is hazardous. Argu-

ments for and against GM foods were discussed among the citizen panel and resulted in some recommendations. These recommendations emphasize some of the challenges that the further development of GM foods involves.

The panel emphasized the importance of preserving the biodiversity of plants and animals and to protect the natural eco-systems. Thus, the citizen panel agreed that it should be possible to hold manufacturers of GM foods responsible for adverse effects on human health and the environment.

The laymen panel believed that authorisations for tests and production of genetically modified organisms should be subjected to severe regulations for risk evaluation and requirements of efficient control. Further, public regulation was recommended as a means to offset monopolistic companies from controlling the market for GMO's. It was also suggested that companies should lose their right of use for unapplied patents. The panel also supported the idea of a convention guaranteeing developing countries free access to utilising gene technology patents. Because biotechnological research to a wide extent is concentrated in the private sector, the panel recommended that public funding for research in the field should be increased.

The panel highlighted the importance of ensuring consumers still to be guaranteed a choice between genetically modified and non-genetically modified foods. It was further emphasized that dissemination of information is crucial and that comprehensible and informative declarations of contents are necessary.

The panel further recommended that ethical aspects should be given the same priority as purely technical aspects in relation to applications for testing, production and marketing of GM foods. Thus, the panel recommended that a committee charged with ensuring an ethical evaluation of the authorisation process should be established.

IMPACTS AND FOLLOW UP OF THE PROJECT

The consensus conference kick-started a more widespread debate on genetically modified food in the public. The Danish Board of Technology found that the political interest in the field increased in the wake of the conference. Both national and EU-politicians showed interest in the project and were curious to know what the citizens worried about.

CHALLENGES IDENTIFIED IN THE PROJECT

Different challenges considering genetically modified foods and how to handle them appeared throughout the project. First of all it became clear that there is a conflict between experts when it comes to assessing the risks and benefits of GM foods. Hence, the project showed that experts disagree whether GM foods are predominantly beneficial or if they pose a threat to the environment and/or human health. These disagreements pose a challenge to the further discussions considering GM foods. Another challenge that was identified considered the question of monopoly

highlighting that knowledge about GM foods is only available to very few people. The question of responsibility was further a challenge that appeared during the consensus conference; who can be held responsible if something goes wrong with GM foods? The challenge is to take such matters into consideration. The project further emphasized the importance of ethical considerations when dealing with genetically modified foods. Thus, the question is whether the utility value of GM foods matches up with the ethical issues.

LITERATURE

The Danish Board of Technology, (1999): Gensplejsede fødevarer. http://www.tekno.dk/pdf/projekter/p99_genspl.pdf; English summary: Genetically modified foods. http://www.tekno.dk/pdf/rtt_125_uk.pdf

AUTHOR OF THE REVIEW

Søren Gram

GENETICALLY MODIFIED CROPS IN DEVELOPING COUNTRIES – CHALLENGES FOR THE DEVELOPMENT AID (2003) 2.2

BACKGROUND OF THE PROJECT

The DBT project *"Genetically modified crops in developing countries"* were initiated based on the conclusions of the UNDP's Human Development report 2001, which focused on the role of ICT and biotechnology in the reduction of world poverty. The report stated quite a clear position in favour of biotechnology by emphasizing an opposition to put restrictions on technological developments. Instead, the report called on an examination of what it takes to control and exploit new technology in everybody's interest. The UNDP report gave rise to immediate counter-reactions emphasizing that the problems of hunger and poverty in the third world countries are a matter of distribution because we already produce enough food to feed the whole world. Based on these counter-reactions the DBT set out to assess the pros and cons of using genetically modified crops to fight poverty and hunger in the third world.

BASIC DATA ABOUT THE PROJECT

The project ran from 2002 to 2003 and involved an interdisciplinary task force appointed by the Danish Board of Technology. The task force consisted of six experts all with specialist knowledge within the field of biotechnology and development aid respectively. The objective of the task force was to consider if, and how, dealing with GM crops should be an integrated part of the official, Danish development policy.

The task force arranged three workshops where leading experts within selected areas presented and discussed experiences and the latest knowledge. The first workshop assessed the technical and environmental possibilities and risks regarding already existing biotechnologies. The second workshop assessed social, environmental, ethical and cultural issues. It aimed to assess the implications and desirability of using biotechnology in third world farming structures. The final workshop discussed the compatibility of GM food with the overall aims of Danish development policy in relation to using participatory methods, fighting poverty, the precautionary principle etc. During all three workshops the task force invited other leading experts to contribute with comments, ideas and their expertise on the matter.

Through the project, the task force was asked to answer a two-pronged question, which constituted the starting point of the DBT project; *Can Danish development aid be used positively to 1) incorporate genetically modified crops into the work of improving the living conditions of the poorest population groups in developing countries – and 2) can this be done without conflicting with existing Danish development policy strategies?* The task force approached the questions in view of the fact that the dissemination of GM crops is already taking place – just not considering Danish development aid. The first part of the question was considered to be too complex and

diverse to be answered by a simple yes or no, which is why the task force decided to take a diversified, more pragmatic and action-oriented approach. Thus, the DBT report does not contain arguments for or against GM crops as such but rather provides a basis for the assessment of benefits and drawbacks of the possible use of GM crops in specific contexts. Considering the second part of the question, the task force assessed that the use of GM crops in developing countries would not necessarily conflict with Danish development aid policy.

The result of the project was communicated through a report targeted at institutions and organisations engaged in agricultural development in the poor countries of the world, and further at politicians, researchers, corporate staff or others who, directly or indirectly, influence or are involved in agricultural development, legislation, commerce etc. in the third world.

MAJOR OUTCOMES OF THE PROJECT

The project was concluded by several conclusions and recommendations, which were further supported by a list of premises to constitute a framework for aid organisations when and if a developing country needs assistance in dealing with GM crops. The premises were:

- Each GM crop must be assessed individually.
- The same yardstick cannot be applied to all developing countries.
- Existing GM crops are primarily adapted to the needs of farmers in the rich part of the world.
- Development of GM crops is slow, i.e. there are relatively few GM crops on the market and relatively few on the way in.
- Safety approval of GM crops is expensive since the control procedures are extremely comprehensive.
- Many developing countries do not have the capacity required to undertake needs assessment and control and would find it difficult to make their own assessment of whether they would benefit from the crops, and whether they could comply with the control and safety regulations.
- Patents influence development, and this may cause developing countries major legal and economic problems when it comes to the use and development of GM crops.
- GM crops may have an adverse effect on developing countries' competitiveness and access to western markets.
- The consequences of introducing GM crops are uncertain. No-one knows for sure what their impact will be on the environment, nutrition and biodiversity.

The task force's main message was that GM crops represent one among many technologies that may contribute to solving food supply problems in developing countries, but this form of agriculture is no miracle solution – at least not in the short or medium term. The task force assessed that Danish development aid should continue to focus on a broad range of technological and institutional solutions in the agricultural area with focus on responding to the needs of the poor farmer. Thus, the task

force considered GM crops only to play a relatively limited role in the immediate future. The task force further emphasized that the question of how best to assist countries must be assessed specifically from case to case and from country to country. Besides these more general recommendations, the task force offered more specific recommendations within four focus areas: technology, political policy, institutions and society.

IMPACTS AND FOLLOW UP OF THE PROJECT

In the wake of the project, the Ministry of Foreign Affairs of Denmark, which is in charge of the Danish development policy, invited the Danish Board of Technology to give a presentation of the project. The Ministry does not usually consult external organisations, which is why the interest in the DBT report must be considered quite an acknowledgement of the project.

CHALLENGES IDENTIFIED IN THE PROJECT

Conclusively, the task force emphasized that developing aid organisations will be failing in their responsibility if they fall short to adopt a position with regard to GM crops and their use in developing countries while it is necessary to examine whether certain GM crops might assist developing countries in ensuring sustainable agricultural production and food supply in the future. Thus, the question is not whether Danish development aid should decide on the use of GM crops in developing countries. Instead, the challenge for the Danish development aid organisations is to help the developing countries prepare for the coming of the GM plants. The challenge is to frame some conditions that enable developing countries to deal with and decide on the use of GM plants. It is crucial that developing countries are assisted with the organizing so the given countries are prepared administratively for the GM crops and possess sufficient scientific knowledge on the matter. Further, it is important that the developing countries have developed the necessary control to handle GM crops. Such issues are exactly what development aid should focus on in relation to GM plants.

LITERATURE

The Danish Board of Technology (2003): Genmodificerede afgrøder i udviklingslande - udfordringer for udviklingshjælpen. http://www.tekno.dk/pdf/projekter/p03_genmodificerede_afgroeder.pdf; English summary: Genetically modified crops in developing countries - challenges for the development aid. http://www.tekno.dk/pdf/projekter/p03_gen_mod_crops_summary.pdf

AUTHOR OF THE REVIEW

Søren Gram

CO-EXISTENCE BETWEEN GM CROPS AND NON-GM CROPS (2004) 2.3

BACKGROUND OF THE PROJECT

During the summer 2003, the European Parliament and the Council decided on a regulation concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms. With this regulation the EU reopened for approvals on the growth of GM crops. Based on this regulation, the European Commission recommended some guidelines for the development of national strategies and best practices to ensure the co-existence of GM crops with conventional and organic farming. Thus, the Danish government introduced a bill on co-existence. The bill on co-existence was framed with references to a report from 2003 by the Danish Institute of Agricultural Sciences concluding that co-existence is possible in Denmark considering some crops, but that there are also some exceptions were co-existence seems to be problematic.

To discuss the bill on co-existence, the Danish Parliament (Folketing) committee of Food, Agriculture and Fisheries and the committee of Environment decided to make a hearing to clarify the experiences with the growth of genetically modified crops.

BASIC DATA ABOUT THE PROJECT

The Danish Board of Technology arranged the hearing on the experiences of co-existence between GM crops and non-GM crops (within the framework of BIOSAM, a collaborative forum addressing ethical questions considering biotechnology). The hearing was open to everybody and took place May 11th 2004. Around 90 people (mostly experts and stakeholders) attended the hearing.

The hearing was split up into five sessions with each their theme. The first session of the hearing addressed the risk of GM crops spreading by a presentation of available knowledge on the subject. The next session moved on to discuss how to handle the spreading by either preventing or minimizing the spread of GM crops to fields with either conventional or organic crops. The third session of the day focused on the positive and negative consequences facing the market in connection with a growing of GM crops in Danish fields. The fourth session of the hearing discussed the issue of compensation in cases of spreading. The last session of the hearing invited different stakeholders to present their view on the bill on co-existence. Each session consisted of three short presentations by different experts. After the presentations in each session there were time for questions and discussions from the panel of politicians (committee members). Also a few questions from the audience were allowed.

MAJOR OUTCOMES OF THE PROJECT

The aim of the hearing was to initiate discussions, generate knowledge, and collect experiences on the co-existence between GM crops and non-Gm crops. The hearing was recorded and later transcribed and published in a report. Due to the method of this project the report does not contain any overall conclusions but emphasizes, through the different viewpoints, the challenges that the growing of GM crops causes.

Since Denmark has no actual experiences with the growing of GM crops, several international experts were asked to speak at the hearing to share their experiences with the co-existence between GM crops and non-GM crops. In Austria, the agricultural structure (small farms and narrow fields) makes co-existence problematic. Further, Austria has passed a law that prohibits growing of GM crops in the northern part of the country - GM-free zones. In Spain they have more experience with GM crops and Bt-maize have been grown since 1998. The GM crops have been grown without any kind of precautions, without any control considering the agricultural results and the environmental impacts, and without information and transparency. According to Friends of the Earth, there are several examples of spreading and thus contamination of conventional and organic crops in Spain. Experiences from Canada further show that the growing of GM crops will have a negative impact on organic farming.

Economic potentials and costs of growing GM crops in Denmark were further discussed with reference to international experiences. So far, the growing of GM crops seems to bring both extra costs and savings. GM crops will no doubt become a factor of competitiveness, and in order for Denmark not to loose its competitive advantages it was broad forward that it is necessary that Denmark launch GM crops now. In the end, it all comes down to the individual farmer whether there are economic incentives to grow GM crops. Besides the potential economic benefits that GM crops will bring about, other possible advantages considering GM crops were discussed. The effects of shifting to GM crops vary from crop to crop. Some of the advantages that have been identified include increased yield and productivity, a reduction in the use of pesticides, a more efficient weed control, less erosion and leaching, and a better economy for the individual farmer. If the experiences from the US are transferred to Europe there is thought to be great benefits for the farmer as well as the environment, the consumer and society.

These claims was however dismissed by other experts who emphasized that we should not expect too much from the GM crops since they have not really shown any great potentials yet. Furthermore, some experts questioned the potential environmental advantages that are often highlighted in discussion on GM crops. Thus, the hearing showed that there are quite contradictory opinions considering the potential benefits and detriments of growing GM crops.

The Government’s suggestion for a bill on co-existence includes a system of compensation that guarantees farmers whose crops are polluted by GMO’s to receive compensation. During the hearing both governmental systems of compensation and

private insurance covers were discussed in this context. It was further discussed whether such a system of compensation would cover all losses in a case of spreading from GM fields to conventional and organic fields.

The hearing pointed to a passing of the bill on co-existence in Denmark. Throughout the hearing it further became clear that the provisional proposal for the co-existence were in need of some adjustments before the final decision to pass the bill.

IMPACTS AND FOLLOW UP OF THE PROJECT

Based on the discussions and experiences derived from the hearing, the original bill of co-existence was faced with some proposed amendments. Thus, after the hearing, the bill of co-existence went through two additional readings before the final bill on co-existence was passed in the beginning of June 2004. There were several amendments employed in the final bill on co-existence and the more prominent ones included changes considering the system of compensation in favour of organic farmers and the protection of their interests, and a system of publication that would make information (position, size and type of crop) about GM fields available to the public. The final bill on co-existence further enabled the minister to revoke approvals in cases where there is a danger that an approval might be misused.

CHALLENGES IDENTIFIED IN THE PROJECT

The greatest challenge considering the co-existence between GM crops and non-GM crops is that of spreading. To avoid the spreading of pollen it is necessary to keep a distance (dependent on the biology of the crop and the threshold value) between fields with the same kind of crops, and other cultivated plants that the crop might cross with. Intervals of growing are assessed as one of the most effective methods to avoid the spreading of seeds. However, it is impossible to secure a complete non-spreading. In order to minimize spreading it is necessary to take some overall principles into account. First of all, the methods used to prevent spreading should depend on the crop being grown hereby considering the different characteristics that the different GM crops have. Secondly, the given system of agriculture, whereto the rules of co-existence should be applied, needs to be considered; e.g. geography and landscape. Ultimately, it is necessary to consider the scope of GM crops. Thus, co-existence is assessed to be possible if the necessary precautions are taken.

Conclusively, the hearing emphasized that the ultimate challenge is to make a better and extended system of compensation and that the rules on co-existence are addressed at a EU-level that secures that all member states have common rules considering co-existence and compensation. Considering the widespread scepticism towards GM products that can be identified within the Danish population, it is crucial that consumers are given a genuine choice between GM products and non-GM products. This can be ensured through labelling of products that are genetically modified and through a securing of GM-free production; e.g. that organic alternatives are available.

LITERATURE

The Danish Board of Technology, (2004): Erfaringer med sameksistens: Høring om erfaringer med sameksistens mellem genetisk modificerede afgrøder og konventionelle og økologiske afgrøder. http://www.tekno.dk/pdf/projekter/p04_Erfaringer_med_sameksistens.pdf

AUTHOR OF THE REVIEW

Søren Gram

NEW GM CROPS – NEW DEBATE (2005) 2.4

BACKGROUND OF THE PROJECT

The DBT-project *"New GM crops – new debate"* was initiated with the purpose to investigate how the Danish citizens assess the use of new GM crops involving plants producing medicine and industrial chemicals and new ornamental plants. The project was suggested by the Danish Forest and Nature Agency (part of the Ministry of the Environment). Previous projects and debates had shown a public scepticism towards GM food and feed crops due to the fact that the benefits of this technology are not obvious or directly related to the public. Thus, it became interesting to investigate the public's attitude towards the use of GM plants with completely different purposes than those usually discussed.

Many of these new applications of GM plants appear to bring potential benefits to both human health and the environment. GM plants producing medicine are expected to be able to reduce the production costs of certain expensive medicines, and in other cases to create new possibilities for treatment. For industrial use, plants are genetically modified to be little biofactories that produce raw materials and thus contribute to a minimization of the use of chemicals. Finally, GM ornamental plants would create inventions such as blue roses or durable harebells. Still, these GM plants are grown under the same conditions as GM food and feed crops.

Based on this, the project set out to examine how Danish citizens assess the potential advantages and disadvantages of the new GM plants. The aim of the project was to present arguments for and against: how are the plants' potential benefits and detriments considering health and environment assessed, and what are the economic possibilities and consequences – considering both the societal and the consumer level.

BASIC DATA ABOUT THE PROJECT

The project was addressed through the use of a citizens' jury. 2000 Danish citizens were invited via the Civil Registration Number register to apply for participation in the citizens' jury. On the basis of the applications received, 16 citizens were selected. The aim was to assemble a citizens' jury that was relatively representative regarding gender, area of residence, age, education and job.

The sixteen laymen took part in the citizens' jury that was assembled from the 28th of April to the 2nd of May 2005. A planning group assisted the Danish Board of Technology in planning the project and formulating the questions that the citizens' jury was presented with. During the five days of the citizens' jury, the laymen met with experts and stakeholders and discussed advantages and disadvantages of the new crops. Based on this dialogue, the citizens' jury formulated arguments for and against the new GM plants and conditions for the possible growing of GM plants in Danish fields and general recommendations in connection with this.

Ultimately, the citizens' jury was concluded by a vote upon the arguments, conditions and recommendations that expressed their attitude the best. Thus, citizens were not required to reach a consensus, but asked to prioritise the arguments elaborated by them-selves and then vote for those that they considered most important.

The citizens were asked to consider the new uses of GM plants at three different levels: what are the arguments for and against GM plants within the category in question (medicine, industry or ornamentation); on which conditions can GM plants for medicine, industry or ornamentation respectively be grown in Danish markets; and which general recommendations are there for the future handling of new GM plants. These questions were addressed through 7 votes on which the recommendations and conclusions of the report are based.

MAJOR OUTCOMES OF THE PROJECT

Interpreting the voting results, the main conclusions of the report seem to be that the citizens' jury assessed the new uses of GM plants to be predominantly beneficial. Still, the citizens' jury had reservations considering some specific applications of the technology. Thus, the citizens' jury proclaimed a conditional yes to the new GM plants.

The main arguments *for* the GM plants included improvements with regard to the environment and public health, financial advantages (both for society in general and the individual consumer) and business opportunities. The citizens' jury assessed that Denmark should tap its potential for developing GM plants due to the fact that Denmark has significant knowledge and experience, not to mention effective legislation. The most important argument *against* GM plants referred to the risk of unintentional spreading of foreign or undesirable characteristics. But the majority of the citizens' jury assessed that existing regulations – including the act on co-existence – and approval procedures considers these problematic issues.

Considering the usage of GM plants for **medicine** the voting results showed that the arguments for received more votes than the arguments against them. However, if the production of medicine includes the use of human or animal genes, it was a high priority for the citizens that there are strict requirements for approval of new products, and that the production takes place in closed environments.

The citizens' jury received developments of **industrial** GM plants as positively as plants producing medicine. It was especially applauded that industrial plants have the potential for replacing present production methods with more environmentally sustainable ones.

The attitude towards GM **ornamental** plants was less optimistic than the two other usages. The vote showed that there was slightly more arguments against than for the growing of GM ornamental plants in Danish fields. The citizen's jury further emphasized that the main condition for the growing of GM ornamental plants is that herbicide-tolerant grasses are not going to be approved due to the significant risk of spread to cultivated areas as well as to other vegetation.

An important condition for allowing the new plants that was emphasized was, that the environmental consequences of irresponsible practices should be assessed. Further, the growth of the new plants should not pollute more than existing modes of production - particularly concerning fertilizer or pesticide usage. Thus, any negative impact on ground water and soil should be part of the risk assessment. However, the citizens' jury did not see any reason for alarm while the present legislation and administration is considered adequate to limit the risks. Instead, there should be more focus on public education and information about the new GM plants. In fact, the clearest message from the citizens' jury was not about advantages, disadvantages and conditions with regard to GM plants, but about the necessity of informing the population about these matters as part of an open and nuanced debate.

Conclusively, it appears that the public's estimation of use clearly differs depending on the use of GM plants. The debates on GM plants for food and feed showed that the public questioned these usages by asking: why? The purposes and benefits are not obvious to the public. On the contrary, this project on the use of new GM plants poses the question; why not? In general, the citizen's jury did not see any reasons to impede the further development of GM plants - at least for medical and industrial use - as long as this does not involve environmental or health hazards, that exceed existing or alternative modes of production.

IMPACTS AND FOLLOW UP OF THE PROJECT

The citizens' jury presented their results the 2nd of May 2005 at a conference at the Danish Parliament with the attendance of politicians, experts and various stakeholders. After the citizens' jury's presentation of the results, politicians representing different parties and different stakeholders commented on the assessments and discussed them with the jury. The results of the conference were subsequently mentioned in the media.

In November 2005 the Ministry of the Environment held a conference on the use of GMO's. Whether this conference was a direct follow-up of the DBT-project is difficult to say, but the themes discussed at the conference were, in particular, concerned around new uses of GM plants.

The results of the citizens' jury were furthermore mentioned in a report on a biotechnology strategy considering non-food and feed published by the Directorate for Food, Fisheries and Agri Business in February 2006.

In September 2005 the Danish moratorium (since 1999) on the growing and the marketing of GM crops were finally revoked. The reasons for this action were grounded in the implementation of rules considering labelling, traceability and co-existence. The results of the citizens' jury *might* have had an impact on these decisions, but it would be wrong to link the two incidents directly.

CHALLENGES IDENTIFIED IN THE PROJECT

The citizens' jury identified several challenges considering the use of GM plants for other purposes. One challenge is the retention of a free consumer choice in a way that genetically modified products are labelled. Another challenge is to strengthen public research to form a contrast to private research and development, as public research seems necessary to maintain sufficient control of the new GM plants. The far most obvious challenge considering these new GM plants is that usages do not pollute more than the corresponding traditional modes of production or better alternatives.

LITERATURE

The Danish Board of Technology, (2005): Nye GM-planter - ny debat. http://www.tekno.dk/pdf/projekter/p05_GM-planter_rapport.pdf; English summary: Contitional yes to new GM plants. http://www.tekno.dk/pdf/projekter/p05_gmp_rtt.pdf

AUTHOR OF THE REVIEW

Søren Gram

FINLAND 3.

DEBATE BETWEEN PUBLIC ADMINISTRATION, RESEARCHERS AND GENERAL PUBLIC CONCERNING THE PLANT GENE TECHNOLOGY

During last five years, the Finnish debate between public administration, researchers and general public concerning the plant gene technology can be divided in four types of activity:

- General and plant gene technology focused public hearings
- Public administrative information of field tests and product approval processes
- Special administrative processes which have taken into account the public opinion
- Scenarios concerning possible implications of plant gene technology

PUBLIC HEARINGS

In order to discuss the ethical dimensions of genetics, Ministry of social affairs and health arranged a seminar "Genes and values" in Hanasaari, Espoo in 2002. The audience consisted of over 100 invited participants, and the program consisted of presentations by experts and a panel guided by a media professional.

A booklet introducing in the subject had been composed in advance, and it was delivered for the participants. The booklet served mostly prejudices and popular beliefs concerning plant biology and agriculture circulated by GM critical political movements. The beliefs were discussed by philosophers specialized in ethical problems of gene technology. No scientific experts of plant breeding research were consulted in the booklet.

The popular beliefs were the foci of the meeting, too. The sole discussant representing the science of plant biology - an associate professor in plant breeding - was offered a very short time (5 minutes) to tell about new GM varieties. The media professional chairman had customarily little knowledge of science.

The leaders of the Finnish anti-GM society were invited. Their full handful of members trespassed in the seminar with video cameras and recorded the discussions. Such behaviour did not promote the free atmosphere of the discussions. As their response to the scientific presentations, the "activists" nailed up the ultimatum that the scientist lecturing on plant breeding shall be discharged.

It was no surprise that the seminar resulted in messages putting science under suspicion. But as a trade-off it also brought important science reporters in place. The presentation on plant breeding, albeit minuscule, gave many a first contact with the sub-

ject and its true possibilities. Hence, certain media columns were opened later on for the first time also for scientific facts regarding modern plant breeding.

Special contribution was made by philosophers. They analyzed also in the final report of the conference the quality of typical arguments given for and against gene technology. Logical analysis of superficial statements made by emotional opponents is a good way to promote rationality in the field. Besides that it is highly important that with careful scientific (and not only logical) analysis prejudices and real threats will be separated.

Other ministries have also arranged general seminars in the area. E.g. ministry of agriculture and forestry (MAF) have arranged many seminars as a part of the hearing process of their strategies or laws in preparation. Such seminars have been arranged concerning Gene Technology Strategy[2] (2003, wwwb.mmm.fi/julkaisut/tyoryhmamuistiot/2003/trm2003_18_en.pdf) and Co-existence[3] (2005, wwwb.mmm.fi/julkaisut/tyoryhmamuistiot/2005/Trm2005_9a.pdf). The bulk of the invited participants have been professionals from the field of activities of the ministry, but invitations also cover public interest groups such as societies and other NGOs.

In addition, seminars explaining the biological basics and topical situation regarding GM products in agriculture have been arranged by MAF for media people a few times, with fair success. Presentations are always given by top experts of science, legislation or administration in the field. Experiences of such focused seminars connected with preparatory work of administration and authorities are in general positive in Finland

PUBLIC ADMINISTRATIVE INFORMATION OF FIELD TESTS AND PRODUCT APPROVAL PROCESSES

Applications for GM product approvals are decided at Community level in EU, and all member states participate in the process. When the information concerning a product application arrives in Finland, a short Finnish summary and links to official documents dealing with the application are made publicly available. They are in the Internet pages of Finnish Food Safety Authority EVIRA, the authority ordered to take responsibility of the information delivery in these cases. In the pages, advice is also given how people can give their opinion of the application to EU authorities using Finnish language. In addition, a press release is given in a broad delivery in order to activate the media.

2 Gene Technology Strategy and Action Plan of the Ministry of Agriculture and Forestry 2003-2007. Working Group Memorandum 2003:18, Ministry of Agriculture and Forestry, Helsinki, Finland, 2003.

3 Enabling the coexistence of genetically modified crops and conventional and organic farming in Finland. Mid-term report. Expert Work Group on Coexistence, Ministry of Agriculture and Forestry, Finland, 2005

Finnish Gene Technology Act provides for the applications of GMO field tests to be communicated with public efficiently enough. The act implements Directive 2001/18/EC. Regarding a field test with GM white birch seedlings, public informative meeting was selected as the way of action.

The meeting was thoroughly advertised in local media, starting well beforehand. In spite of that, only two persons representing general public did arrive, the other of these was probably a local farmer. All other audience, a few scores of people, consisted of (mainly local) university scientists, many of whom participated in the GM research program (ESGEMO), and members of the Board for Gene Technology; plus the handful of activists (always the same few ones) from the specialised "GM-free" society.

For public discussion, far more important was the destruction of GM white birch seedlings made by plant GM opponents. As the result of extensive discussions in newspapers, the public opinion turned strongly against destructors. It was realized that there was no point in this destructive act because these non-flowering birches have no real way to diffuse their genetic material to non-GM birches or other plants. Instead, GM birches would have a real positive impact on town environments because of less allergic reactions. Actually based on their safety and positive impacts on health, an environmental organization (Ekosäätiö, Eco Foundation) gave its price to the developers of GM birches. Based on the destructive act, the public opinion is now much more favourable for the limited public information concerning the cultivation places GM plants. The irrationality of the GM opponents became much more evident for the general public.

SPECIAL ADMINISTRATIVE PROCESSES WHICH HAVE TAKEN IN ACCOUNT THE PUBLIC OPINION

We consider that it is highly important for a rational approach concerning the plant gene technology that the administration does not follow prejudices of the public opinion. This is especially important because of the feedback to the public opinion. Critics of gene technology with little science expertise can use the choices of the administration as an evidence for their opinions.

In Finland, the above problem was met related to restaurant criteria proposed for the Nordic Swan ecolabel. The aim of the ecocertificate is declared to be helping people "to choose the most environmentally-friendly products" and to avoid the use of the most environmentally burdening products (www.svanen.nu/Eng/default.asp).

Criteria for Nordic restaurants to fulfil in order to receive the ecolabel were proposed (June 2006). Without any statement of reason based on facts or science, all use of genetically modified constituents was categorically forbidden in the restaurants with ecolabels. That proposition excited Finnish life scientists to express their objections to the misuse of such populist prejudices which only damage true efforts on environmental protection. Among others, the traditional and most prestigious life science society in Finland (Societas Biochemica, Biophysica et Microbiologica Fenniae)

strongly criticized such anti-science attacks detrimental to environment in its statement. Applications of modern biological research, including gene technology and genetic modification, are fundamentally required for environmental ameliorating, and their impacts shall be properly assessed case-by-case.

Notable environmental benefits have already been obtained by producing the so-called traditional GM varieties for 10 years (Sanvido et al. 2006[4], Brookes et Barfoot 2006[5]). Yet essentially greater remedies could be anticipated from "second generation" GM varieties specifically designed for environmental enhancements. Such innovations include resistant plant varieties with better tolerance to drought, cold, flooding, salt as well as pests and diseases.

For example, blight-resistant potato was bred with gene technology by obtaining the resistance gene from a wild potato species. The healthy variety is in field tests for the third year in EU. Cultivating blight-resistant potatoes would save EU each year from 860 million kg of yield being wasted, and 7.5 million kg of fungicides to be sprayed (expressed as active ingredient). Of course that also means great reductions in oil use and greenhouse gas emissions in agriculture (Phipps et Park 2002[6], Gianessi et al 2003[7]). Organic producers could also benefit from the use of blight resistant varieties, because the risk of spreading the disease from other plantations to the fields used for organic production would be smaller.

---

4 Olivier Sanvido, Michèle Stark, Jörg Romeis and Franz Bigler (2006). Ecological impacts of genetically modified crops. Experiences from ten years of experimental field research and commercial cultivation. *ART-Schriftenreihe 1*. Fed. Dep. Econ. Aff. DEA, Switzerland, 108 p.

5 Graham Brookes and Peter Barfoot (2006). Global Impact of Biotech Crops: Socio-Economic and Environmental
Effects in the First Ten Years of Commercial Use. *Agbioforum* 9: 139-151.
Abstract: Genetically modified (GM) crops have now been grown commercially on a substantial scale for ten years. This paper assesses the impact this technology is having on global agriculture from both economic and environmental perspectives. It examines specific global economic impacts on farm income and environmental impacts of the technology with respect to pesticide usage and greenhouse gas emissions for each of the countries where GM crops have been grown since 1996. The analysis shows that there have been substantial net economic benefits at the farm level amounting to $5 billion in 2005 and $27 billion for the ten year period. The technology has reduced pesticide spraying by 224 million kg (equivalent to about 40% of the annual volume of pesticide active ingredient applied to arable crops in the European Union) and as a result, decreased the environmental impact associated with pesticide use by more than 15%. GM technology has also significantly reduced the release of greenhouse gas emissions from agriculture, which, in 2005, was equivalent to removing 4 million cars from the roads.

6 Phipps & Park (2002). *J Animal Feed Sci.*11**:** 1–18.

7 Leonard Gianessi, Sujatha Sankula and Nathan Reigner (2003). Plant biotechnology: Potential impact for improving pest management in European agriculture. Potato case study. NCFAP

The objections of the scientific community were accepted by the administration responsible for the Nordic Swan ecolabel. It was decided in autumn 2006 that genetically modified constituents are allowed in Nordic Swan ecolabeled restaurants.

SCENARIOS CONCERNING POSSIBLE IMPLICATIONS OF (PLANT) GENE TECHNOLOGY

Based on assessment project concerning social impacts of the human genome and stem cell research by the Committee for the Future, a scenario book was made. The aim of the book was to inform the general public about most important results of the assessment project. Beside that it illustrated possible future impacts of gene technology with three scenarios. The scenario book (Kuusi 2004)[8] got considerable publicity in media.

The names of the scenarios characterize their content:

- Safety first of all
- Wealth and employment from gene technology
- Gene information belongs to everybody

All scenarios were discussed as reasonable choices making different assumptions concerning future developments. After the presentation of the scenario story its probability was discussed. For example, in the first scenario the blight-resistant potato resulted in a lagged serious health problem. In the discussion part, the probability of that problem was discussed. It was considered that even taking into account the risk it is reasonable to accept the blight-resistant potato. The conclusion was the same as in the third scenario: Also in order to solve possible problems related to gene technology, the best choice is to make it commonplace.

Like the information technology, gene technology should belong to everybody. It requires an internet based "Gene Information Centre" providing its services to everybody. In a safe environment (compare banking services), it makes sense to integrate this type of personal gene information with one's personal electronic patient records.

AUTHORS OF THE REVIEW

DSc(Agr&For) Jussi Tammisola

PhD Osmo Kuusi

8 Osmo Kuusi (2004) Geenitieto kuuluu kaikille (Gene information belongs to everybody), Edita, Helsinki

FLANDERS 4.

PUBLIC FORUM »NEW IMPULSES FOR THE DEBATE ON GENETICALLY MODIFIED FOOD« (2003) 4.1

BACKGROUND OF THE PROJECT

On September 25th 2001 a hearing was held in the Flemish Parliament to discuss the advices published by five Flemish advisory bodies[9], by request of the Flemish Parliament[10], on the topic of genetically modified organisms(GM organisms). A recurring element in the five reports was the importance of organizing a public debate on this topic.

The Flemish Institute for Science and Technology Assessment, viWTA, established by Decree on 17/07/2000 provided the opportunity to respond to this advice. The Board of the viWTA decided in December 2001 to organise a pilot project on this topic. In Spring 2002 this topic was narrowed down to 'genetically modified food'. The project was officially launched in May 2002 with a pre-study. The goal of this study was to map the existing debate on genetically modified food in Flanders (actors, positions, legal situation,…). The report of this study was published in November 2002, in December 2002 the Public Forum was launched. On the 26th of May 2003, the 15 members of the citizens panel submitted their final report to Mr. Norbert de Batselier, President of the Flemish parliament.

MAJOR OUTCOMES OF THE PROJECT

The report of the Flemish lay panel contained 28 recommendations, centred around six major themes:

- Legislation, control and consultation
- Information
- Ethics
- Health issues
- Global and economic issues
- Environmental consequences

Most important of these recommendations, also in the light of European legislation, are:

9 De Sociaal Economische Raad van Vlaanderen (SERV), de Milieu en Natuurraad van Vlaanderen (Mina-raad), de Vlaamse Raad voor wetenschapsbeleid (VRWB), de Vlaamse Land- en Tuinbouwraad (VLTR) en de Vlaamse Gezondheidsraad.

10 Adviesvraag van 11/02/2001 van Trees Merckx-Van Goey houdende raadpleging van diverse adviesorganen over de problematiek van genetisch gemodificeerde organismen.

Legislation, control and consultation:

- Even after the discussion it is still not clear who is liable in case of problem (product liability as well as environmental liability). The reference persons did not know the answer. This leaves the initiative to politicians. The liability has to be regulated so as to be legally binding. It has to be unambiguous, leaving little room for interpretation and for dodging responsibilities.
- It is hard to choose between genetically modified foodstuffs or food without GM organisms: you cannot choose for something that is not available yet. But when genetically modified food arrives, there is a real danger that non-genetically modified food will be under pressure. The choice has wider implications than mere labels. If you want to sell both (labelled) genetically modified food and non-modified food, you need two completely separate circuits. Freedom of choice has to be guaranteed. This is a complex issue. Both those who want to purchase genetically modified food as those who do not, need to be able to make a choice. If nothing changes, the situation will not improve.
- The introduction of genetically modified food on the market might lead to increasing production costs for non-GM food, a.o. because of extra checks. The sector of genetically modified food will be able to compensate this extra cost because of cheaper production techniques.
- The European rules for permits are not bad; they are the result of hard work. The E.U has a procedure for quickly recalling GM products in case of problems. But the rules are not watertight: the evaluation of permits is left to scientists and politicians. The evaluation of permits ought not to be restricted to scientists, but extended to other areas of expertise (economists, sociologists, philosophers).

Information:

- The new EU legislation allows for public consultations, but the form in which this will happen is still vague (active or passive approach?) A large majority of the Flemish laypanel believes the government ought to provide clear and neutral information. A majority thinks the existing website of the Belgian Biosafety Server (http://biosafety.ihe.be) can fulfil this role, but is must be translated from English. The site can be expanded into a portal site.
- Labels must be uniform throughout Europe (using clear icons)
- Citizens prefer an active consultation of the public under EU legislation. This allows the citizen to voice his opinion. Participation can only be useful after an awareness-raising campaign.

Ethics:

- There is no universally accepted ethical position, but there are nevertheless clear ethical limits. The different scope of arguments (based on risks vs. based on duties) makes an ethical debate difficult. However, ethical considerations must play a role in allowing genetically modified foodstuffs.

Health issues:

- The health risk of genetically modified foodstuffs that are introduced in the market are negligible. Strict and reliable checks have convinced the lay panel that the health risks of regulated genetically modified food are negligible. Consumers can regain their confidence if they are informed in a reliable way about the health issues related to genetically modified food. But permanent checks and controls stay necessary for genetically modified food. Because of the complexity of the issues, this debate must be conducted in public.

Global and economic issues:

- The authorities have to provide a framework and the means for the transfer of knowledge and technology between North and South, and for establishing local research facilities in the South.
- The authorities should continue to support fundamental research and the technological development of genetically modified organisms. But the subsidies have to be made dependent on promises to share the relevant knowledge with the Third World.
- Research into traditional and biological agriculture must not be neglected, but should continue to exist as a full area of research.

Environmental consequences:

- Evaluation of the environmental hazards is extremely important. Each case has to be thoroughly investigated.
- Biotechnology must make a responsible choice, respecting biodiversity, the biotope of the crop and the ecosystem. These elements must be taken into account during risk analysis.
- Once genetically modified food is brought to market, environmental risks still need to be monitored. The present post-marketing plan does not provide for adequate control. The costs for more systematic controls have to be borne by the biotech industry.

CHALLENGES IDENTIFIED IN THE PROJECT

Potentially problematic issues, that could be further explored in the questionnaire, seem very generally:

- Ways to engage the public in decision making processes on GMO's: active/passive?
- Importance of understandable, down to earth communication about GMO's
- Freedom of choice/possibility of creating complete separate circuits
- Effect on introduction GM-food on production costs for non GM food (extra checks and quality control systems)
- Multi-disciplinary evaluation of risks
- Challenges to labelling
- How to involve ethical considerations in future approvel procedures?

› How can the south benefit from European research?

AUTHOR OF THE REVIEW

Els van den Cruyce and Stef Steyaart

FUNCTIONAL FOODS. STATE OF THE ART (2006) 4.2

BACKGROUND OF THE PROJECT

Functional foods represent one of the most intensively investigated and promoted area in the food and nutrition sciences today. Functional foods are fortified or enriched foods that provide health benefits beyond the provision of essential nutrients, when they are consumed at efficacious levels as part of a varied diet on a regular basis. Linking the consumption of functional foods with health claims should be based on scientific evidence. However, not all foods on the market today that are claimed to be functional foods are supported by enough solid data to merit such claims. What are the benefits and what are the risks?

In this comprehensive study, the consortium Food2Know (University of Ghent) and Flanders' FOOD (knowledge centre for the Flemish Food Industry) made an overview of different functional food products on the market in Flanders. Using a questionnaire, the societal issues were elaborated by 30 experts in this field (diet and nutrition experts, retailers, consumer and patient organisations, regulatory bodies, academic researchers and stakeholders from the Flemish food industry). Information was gathered on issues such as the scientific evidence linked to the health claims, the regulation in Flanders and Europe and the role of functional foods in the Flemish health policy.

The results were summarized in a report (only available in Dutch) and were presented during a debate with experts and policymakers in the Flemish Parliament. The project had no further impact on policy making.

MAJOR OUTCOMES OF THE PROJECT

The study focused on the following issues:

Scientific evidence for health claims:

There is a need for stricter control of the scientific basis of health claims on functional food products. Today, health claims are not reliable enough. More precise understanding of the mechanisms of actions of functional food and more scientific evidence is required.

Functional foods and health policy:

A frequently asked question is if functional food can be a part of the disease risk-reduction public health program? This study concluded that government policy and action must keep focussing on healthy lifestyle, balanced food intake and sport. Functional food cannot solve what has been damaged by ignoring these points.

Safety:

The products that are on the market today, are considered to be safe. Nevertheless, enrichment of food products with specific nutrients can imply much higher doses of intake by consumers. The experts in this study supported the idea of mentioning a maximum dose on the label of each functional food product. Another important risk is that functional food can give a false feeling of safety. Functional food could become an excuse to give less attention to sport and food habits.

Price of functional foods:

Functional food products are quite expensive. Experts recommend actions to make the possible advantages of functional food available for everybody.

Information overload:

News articles are often contradictory. It is very difficult for consumers to select the relevant and scientific based information.

Food and medicine:

Experts see a clear trend towards the use of food for medical purposes.

CHALLENGES IDENTIFIED IN THE PROJECT

Potentially problematic aspects of functional food, that could be useful to the subject of GMO's, seem very generally:

- Scientific evidence for benefits of these type of food products
- Safety of the products
- Price of the products: Who can benefit? Who will pay for GM food?
- Challenges to labelling: information overload for consumer
- Consumers attitude towards GM food: experience of food, food culture.

AUTHOR OF THE REVIEW

Els van den Cruyce and Stef Steyaart

INDUSTRIAL BIOTECHNOLOGY IN FLANDERS: STATE OF THE ART (2006) 4.3

BACKGROUND OF THE PROJECT

Industrial or white biotechnology is the application of biotechnology for the processing and production of chemicals, materials and energy. White biotechnology uses enzymes and micro-organisms, such as yeast and bacteria, to make products in chemistry, food, paper and pulp, textiles and energy. White biotechnology uses biomass as an alternative to fossil resources for the production of biochemicals such as biofuels and biopolymers. In the future, genetically modified crops could be developed, as a renewable source for non-food applications.

In this comprehensive study, the Laboratory for Industrial Microbiology and Biocatalysis (University of Ghent) made an overview of the applications and fields of expertise in Flanders. Using a questionnaire, the societal issues were elaborated by 30 experts in the field of industrial biotechnology. Information was gathered on issues such as Flanders' chances to evolve to a bio-based economy, the opportunities for a more sustainable production, the implications for the economy in Flanders, and more specific for the agricultural sector.

The results were summarized in a report (only available in Dutch) and were presented during a debate with experts and policymakers in the Flemish Parliament. The project had no further impact on policy making.

MAJOR OUTCOMES OF THE PROJECT

The study focused on the following issues:

- *Sustainability*:
  Industrial biotechnology offers opportunities for a more sustainable production. Enzymes can drive chemical reactions towards the desired end product in a very effective and efficient way, under circumstances of normal temperature and pressure. Less energy is consumed and waste production is reduced. However, only a complete life cycle analysis can asses whether the use of industrial biotechnology is more eco-efficient.
  Secondly, instead of fossil fuels, agricultural raw materials, such as cereals and coleseed are used. This reduces the emission of greenhouse gasses. Some experts expect that production of crops will be more geographically spread, in contrast to the concentration of power within the limited amount of petroleum producing countries.
  Thirdly, the agricultural raw material must be produced in a sustainable way, avoiding deforesting, erosion and soil impoverishment.
- *Safety of the use of micro-organisms for industrial applications*:
  The (genetically modified) micro-organisms are bred in a closed reactor. After

use, the micro-organisms are separated from the product and killed. This is called "contained use".

- *Perception of the public*:
  Recent Eurobarometer results show that more than half of the interviewees believe that biotechnology can improve the life standard. Especially the medical applications receive a lot of support. However, the European citizen is still very critical towards the modification of agricultural crops or green biotechnology. Experts fear that this negative attitude will also involve genetic modification of crops for non-food applications.
- *Implications for the agricultural sector*:
  The agricultural sector of the future will not only produce food, but will more and more become a producer of chemicals, industrial raw materials and biofuels. Because the area of land in Flanders used for the agricultural production is limited, some experts fear that this competition will threaten the production of food. Proponents argue that the Belgian and European agriculture suffer from overproduction and that the European agriculture requires a high proportion of the overall EU budget to subsidise it. Another argument is that a lot of area is available in the member states that integrated the EU in 2004.
  In the future green biotechnology could make a substantial contribution in the production of agricultural production such as cereals for non-food uses.
- *Can Flanders evolve to a biobased economy*:
  In a biobased economy, an increasing number of chemicals and materials will be produced in biorefineries using renewable resources. Biomass derived energy is expected to cover an increasing amount of the energy consumption.
  The agricultural sector in Flanders will be unable to meet the demand for biomass. Import from neighbouring countries, Eastern Europe, America and even Africa will be necessary. Because of its central location and extensive transport infrastructure, Flanders is well placed for import and transport of these raw materials.
- *Financial investment in research and development of industrial biotechnology*:
  The biotechnological research in Flanders is mainly focused on green and red biotechnology. Therefore the experts from the questionnaire propose to invest more in the research and development of industrial biotechnology in Flanders.

CHALLENGES IDENTIFIED IN THE PROJECT

Potentially problematic issues, that could be further explored in the questionnaire, seem very generally:

- Sustainability of GM crops for non-food issues
- Perception of the public towards GM crops for non-food issues
- Implications for the European agricultural sector
- Europe and the biobased economy

AUTHOR OF THE REVIEW

Els van den Cruyce and Stef Steyaart

FRANCE 5.

INRA PROJECT »CO-CONSTRUCTION OF A RESEARCH PROGRAMME« (2002)

BACKGROUND OF THE PROJECT

The French National Institute for agronomic research (INRA) has been working for many years on the elaboration of a transgenic rootstock potentially resistant to Grapevine Fanleaf Virus (GFLV), together with a private partner. In 1999, the private partner decided to stop its participation to this research, because of the hatred public discussion on GM grapevine. INRA decided to continue its research and passed on all material to its laboratory in Colmar.

However, in 2001, and because the public debate on transgenic was still going on, INRA decided to suspend the ongoing experiments and to initiate a discussion on their pursuit within a working group integrating researchers, professionals and consumers, using a participatory process.

The initial question the working group had to answer was about the opportunity to realise field trials of rootstock potentially resistant to Grapevine Fanleaf Virus (GFLV). However, the working group reformulated the demand in the following direction:

- Which are the philosophical, social, economical and technical aspects at stake in this field trial? Knowing that there are many research needs related to grapevine diseases, how to define priorities et how to choose the types of arbitration.
- Should INRA continue to research on GM-grapevine and, if yes, which conditions have to be met in order to pass to the stage of field trials?

BASIC DATA ABOUT THE PROJECT

The selected method was based on the so-called “Technology assessment through interaction”[11]. It consists in putting together various worldviews, so that deliberations are nourished from a variety of arguments and standpoints.

The number of participants was limited to 14, so as to allow deliberation on complex problems and heterogeneous questions. Whereas some participants had no special expertise in the topic (so-called “laypersons”’), the group also comprised researchers and wine-professionals. The selection process was based on the results of a sociological study, which displayed a social cartography of worldviews around the topics of grapevine, wine and GMOs. The conceptions of science have also been considered

11 See Grin, J., van de Graaf, H., Hoppe, R., (1997). Technology assessment through interaction. A guide. Den Hag, Rathenau Institute (available at http://www.rathenau.nl).

in the selection process, as well as attitudes towards research on a transgenic rootsock for grapevine. Based on this analysis, the organisers invited:

- Four researchers working on research on grapevine diseases, but who hold different worldviews.
- Six grapevine and wine professionals, stemming from different geographical regions and holding different worldviews.
- Four citizens, also invited for the variety of their worldviews.

The working group met 7 times, from April to September 2002.

Various instances were part of the experiment:

- The General Direction of INRA, which initiated the project.
- 2 project managers.
- One research assistant.
- A steering group (comité de pilotage), composed of the project managers and the INRA Direction.
- An evaluation committee, composed of personalities external to INRA, specialized in the analysis of controversies and of participation.
- A moderator for the working group sessions.

MAJOR OUTCOMES OF THE PROJECT

The working group came to the following conclusions:

- Wine has a strong symbolic dimension. As a consequence, a genetic modification done on grapevine dedicated to the fabrication of "wine-food" could have a negative impact on "wine-pleasure" and on high quality wines.
- There is a strong attachment to a system production based on biological, technical and cultural variety. With respect to the threats related to grapevine diseases, various fighting methods should be developed, so as to contribute to the various production modes of vinegrape.
- Considering research activities, there is a lack of integrated and transversal approaches. There is a necessity for a better understanding of the interaction between the plant and its environment.
- INRA should continue to do research on genetically modified vinegrape in laboratory and green house. Field trials should also be implemented. But, on this last point, all group members did not agree on the opportunity to have field trials (2 persons against). Opponents to the field trials considered that even the solution may be technically satisfactory, it is not socially acceptable. In this respect, it could prejudice the status and image of French wine. The other 12 members considered as acceptable field trials with transgenic grapevine. But their positive opinion is limited to a given experiment and no opinion has been formulated on a possible commercialisation.

IMPACTS AND FOLLOW UP OF THE PROJECT

The report of the working group has been passed on to the INRA Direction in September 2002. In January 2003, INRA decided to ask for an authorization for the implantation of field trials in Colmar, to set up a local follow-up committe and to create a mix commission in charge of defining the major orientations of wine and vinegrape research.

CHALLENGES IDENTIFIED IN THE PROJECT

- role of public research.
- transgenic wine and vinegrape
- dialogue and interaction
- The issue of trust
- Ability of public resarch institutions to set a boundary between research and its applications

LITERATURE

Co-construction d'un programme de recherche : une expérience pilote sur les vignes transgéniques. Rapport final du groupe de travail et réponse de la direction de l'INRA.2003. INRA: Paris. http://www.inra.fr/genomique/rapport-final-ogm-vigne.html

AUTHOR OF THE REVIEW

Danielle Bütschi

GERMANY 6.

GENETIC ENGINEERING, BREEDING AND BIODIVERSITY (1998) 6.1

BACKGROUND OF THE PROJECT

The TAB-project "Genetic engineering and breeding from the viewpoint of biodiversity in agriculture" (short title: “Genetic engineering, breeding and biodiversity”) was based on a recommendation by the Committee on Food, Agriculture and Forestry and was approved in Autumn 1996 by the Committee for Education, Science, Research, Technology and Technology Assessment of the German Parliament.

Background for the project was the 4. International Technical Conference on Plant Genetic Resources of the FAO at Leipzig in June 1996, which approved the Global Action Plan and the Leipzig Declaration for the “Conservation and Sustainable Utilization of Plant Genetic Resources for Food and Agriculture”. Further, the Convention on Biological Diversity – ratified by Germany in 1993 – had defined objectives for the protection and use of the global biodiversity. These international commitments, to be implemented on national level, were one starting point. The other starting point was the questions, which impacts on biodiversity results from modern biotechnology.

The goal of the TA-project was to investigate what negative influences the use of genetic engineering in plant breeding can have on biodiversity, what contributions breeding and genetic engineering can make to conserving biodiversity and finally, what potentials can be derived for policy-making. A restricted, technology-centred perspective was not adequate for this theme. Particularly for the issue of potentials for conserving plant genetic resources and biodiversity in general, the approach was expanded in order to cover the significance of genetic engineering and breeding in the overall context.

BASIC DATA ABOUT THE PROJECT

The TA-project was executed in one and a half year, and finished in 1998. Four scientific studies were awarded in the project. The draft final report of TAB was based mainly on these studies and was evaluated by a number of experts from science, government and stakeholders.

The investigation area was limited to the field of plant breeding and - as far as possible - was restricted to the agricultural sector in Germany, taking into account European framework conditions. The topics of the project were:

- biodiversity and plant genetic resources – status and development,
- plant breeding – its goals, economic development and legal regulation,

- direct and indirect impacts of new (conventional and genetically engineered) varieties on biodiversity – systematic analysis of impact chains,
- biodiversity conservation measures – ex-situ, in-situ and on farm measures,
- international agreements and implementation of international obligations,
- options for action in the areas of research, agricultural, environmental and development politics.

MAJOR OUTCOMES OF THE PROJECT

The results of the project showed that modern agriculture has made a considerable contribution to reducing the biodiversity of many crops and wild plants in Germany through intensification, rationalisation, specialisation and concentration of production. Impacts on biodiversity have in particular been generated by changes in fertilisation, plant protection, rotation and land reallocation and consolidation. Plant breeding and modern plant varieties are all part of the changed agricultural production system and their impact on biodiversity is more of an indirect one. The central conclusion of the project was that in Germany and Central Europe the use of genetic engineering procedures in plant breeding will not have a specific, significantly negative influence on biodiversity compared to conventional breeding practices in the short to medium term. On the other hand, however, genetic engineering in plant breeding will not make any significant contribution to conserving or extending plant genetic resources.

To achieve the goal of "conserving biodiversity", there was seen a particular need for action on direct conservation measures. To this end the ex-situ, in-situ and on-farm conservation measures must be improved and developed. As Germany did not have a coordinated procedure on the conservation of plant genetic resources which incorporates all conservation measures, it was recommended to develop a combined conservation strategy. This would simultaneously be a major contribution to conserving biodiversity in Germany. In order to implement international agreements at national level and to develop and apply a national strategy to conserve biodiversity (including plant genetic resources (PGR)), close coordination and cooperation was regarded as necessary between the various policy fields and levels affected. Interested and affected societal groups should be incorporated into the national strategy development and implementation process.

A matter of central importance for the sustainable conservation of biodiversity was seen in a full-coverage change towards sustainable agriculture, in which the promotion of agricultural diversity and the protection of wild flora and fauna is a major component. The principles of organic farming which, in contrast to the still predominant conventional farming, involve more extensive and diversified farming practices, could therefore provide significant guides. It was pointed out that changes in basic framework conditions for agricultural and environmental policy do not make specific conservation measures (as discussed in the project) become superfluous, but their scope and urgency would take on a relative basis.

A broad spectrum of options for action in the different areas of the project was identified and discussed. As future issues were identified:

- monitoring of the impacts of patenting on plant breeding and variety protection;
- research on the impacts of the introduction of new varieties (conventional and transgenic plant varieties) on biodiversity of agro eco-systems and adjacent eco-systems, with special attention to the issues of changes in cropping systems, resistance development and resistance management;
- long-term ecological impacts require comprehensive post-marketing monitoring, coordinated and combined with fundamental research activities on biodiversity and plant genetic resources.

IMPACTS AND FOLLOW UP OF THE PROJECT

The report was published as parliamentary document (Bundestagsdrucksache 13/11253). In the following electoral term, the report was deliberated in the leading Committee for Nutrition, Agriculture and Forestry and two consulting committees. The result of the deliberation in the committees was a recommendation and report for the plenary (Bundestagsdrucksache 14/1716), with a detailed catalogue of actions based on the options for action in the TAB-report. This recommendation was approved in the plenary meeting of the German Bundestag on 16th December 1999, by the governmental majority and the PDS.

In the federal agricultural report 2000 (Bundestagsdrucksache 14/2672), the Federal Government had pointed out that measures for the national programme on plant genetic resources and a research programme on biodiversity has been prepared, in order to implement the above mentioned decision of the German Bundestag.

CHALLENGES IDENTIFIED IN THE PROJECT

In the project identified (future) challenges which are still valid (conclusions of the reviewer):

- preservation of plant genetic resources
- impacts of patenting on plant breeding and variety protection
- uncertain future of small and medium seed producers
- impacts of the introduction of new varieties (conventional and gm varieties) on biodiversity of agro eco-systems and adjacent eco-systems

LITERATURE

Meyer, R.; Revermann, C.; Sauter, A. (1998): Biologische Vielfalt in Gefahr? Gentechnik in der Pflanzenzüchtung. Studien des Büros für Technikfolgen-Abschätzung beim Deutschen Bundestag Band 6. Edition sigma: Berlin

English summary: http://www.tab.fzk.de/en/projekt/zusammenfassung/ab55.htm

AUTHOR OF THE REVIEW

Rolf Meyer

RISK ASSESSMENT AND POST-MARKETING MONITORING OF TRANSGENIC PLANTS (2000) 6.2

BACKGROUND OF THE PROJECT

The TAB-project "Risk assessment and post-marketing monitoring of transgenic plants" was demanded by the Committee on Food, Agriculture and Forestry of the German Parliament.

Background for the project was the ongoing debate in the EU on the authorisation of transgenic varieties and the amendment of the Deliberate Release Directive 90/220/EEC. The development culminated in the summer of 1999 in a de facto moratorium on approval of transgenic plants for marketing by the Council of Environmental Ministers, combined with the demand that the reforms in progress be completed before any new approvals are issued.

During the project execution, the German marketing approval for the maize variety Bt176/ "Windsor" (about to receive variety approval from the "Bundessortenamt" – German Federal Plant Variety Agency) was suspended in February 2000 under Article 16 of the Release Directive, which constitutes a safeguard clause. This event has sparked off forceful political and scientific controversy in Germany, which has also involved the German Bundestag and its committees on a number of occasions. In June 2000 the German Chancellor announced an initiative seeking to agree a three-year transitional phase with the companies involved during which commercial cultivation of transgenic plants would be possible only on a limited scale and in combination with increased research into safety aspects, and particularly an intensive monitoring programme. This was not implemented due to the emerging of the BSE crisis in Germany.

The goal of the TA-project was to give a focused overview of the status of the scientific and political debate. It was not the purpose of the project to provide novel answers to the outstanding questions on biosafety or develop separate proposals for the post-marketing monitoring.

BASIC DATA ABOUT THE PROJECT

The TA-project was executed in fifteen months (July 1999 – November 2000). Five scientific studies were awarded in the project. The draft final report of TAB was based mainly on these studies and was evaluated by a number of experts from science and government.

The investigation was limited to a status report on risk assessment and post-marketing monitoring of transgenic agricultural crop plants. The main topics of the project were:

- the status in safety research (inc. post-marketing monitoring) and the debate on risks,

- the state of regulation and treatment of authorisation procedures in the EU for the release, marketing and variety licensing of gm agricultural crop plants,
- the state of implementation of the Novel Food Directive (licensing and labelling).

MAJOR OUTCOMES OF THE PROJECT

For the **scientific debate on risks**, it was worked out that controversies regarding both general and specific impacts relate primarily to three different levels:

- first, the fundamental likeliness of occurrence (e.g. of outcrossing or development of resistance by insect pests),
- second, the degree of possible damage (e.g. reducing biological diversity or adversely affecting organic farming), and
- third, the possible or necessary measures to avert risk (e.g. size of the protective zones around fields with transgenic plants or design of resistance management).

Generally, the state of data appeared deficient in many respects, as while there had been over 1,300 release experiments in Europe alone, fewer than 1 % of release experiments worldwide have been linked with accompanying ecological research (although in Germany the figure was 15 %). Another reason why there was virtually no "real knowledge about risk" is the safety requirements needed for the accompanying ecological research. Critical voices pointed out that the lack of evidence of adverse ecological impacts suggests more that the wrong questions are being asked (with a resulting lack of corresponding studies) than the absence of any risk. Conversely, it is true that conventionally bred plants (i.e. not using genetic engineering) have never been subjected to biological safety testing, so that the impacts of transgenic varieties are always more thoroughly researched than those of conventional varieties. Many scientists also stressed that the new characteristics of transgenic plants are in principle much more clearly defined – and hence more easily documented and researched – than the results of conventional breeding.

However, a whole series of questions will in any event be impossible to answer in research projects with a limited life. First, the results of scientific research always generate not only answers but also new questions, and second because long-term indirect effects can generally only be observed in the course of longer-term cultivation of transgenic plants on a significant scale. This realisation had led to virtual unanimity among all involved on the development and implementation of long-term monitoring of transgenic plants under cultivation.

For the **risk assessment in the approval procedures**, the report looked in detail at how far the status of the scientific risk debate, and specifically the ecological aspects, were taken into account in the opinions in the framework of the approval procedures for marketing under Directive 90/220/EEC of both the EU scientific committees and national agencies (in Germany, Austria, the UK and – in part – Sweden), and how differences identified in the opinions can be explained. The result was that

- scientific contributions and arguments have been very much selectively used and variously interpreted,

- diverging conclusions have been drawn from gaps and areas of uncertainty in our knowledge, and
- above all, the possible consequences have been very differently evaluated in terms of the scale of damage and resulting implications.

Even after the amendment, there is still no definition of damaging impacts, so that there will still be considerable scope for different assessments. Not least, the question will be which agricultural paradigm the impacts of transgenetic agricultural plants are measured against. It will not be possible to derive a normative framework for this paradigm simply from the debate about GE applications: instead, this will require a serious definition and specification of the term "sustainable agriculture" as a stated goal of European agricultural policy.

For the **post-marketing monitoring** was pointed out that three dimensions or distinctions have special relevance:

- monitoring based on cause-and-effect hypotheses (even if partly unexplained or uncertain) versus unexpected or rare events,
- surveys of the agricultural ecosystem (and adjoining marginal structures) versus surveys of the environment generally,
- monitoring for limited periods versus long-term or unlimited monitoring.

The **overall main conclusions** of the report were:

No excessive expectations should be raised for the amended Deliberate Release Directive 90/220/EEC and the introduction of post-marketing monitoring. Their potential for resolving problems will inevitably remain limited until such time as fundamental agreement is reached on definitions of damage and desirable agricultural practice.

Both the amended Deliberate Release Directive and the Novel Food Regulation require operationalisation and specific guidelines for implementing the safety assessment and approval procedures. This is the only way to reduce discussions about the scope, coverage, methodology and interpretation of the safety assessments. This should build on the current state of the scientific risk debate. To this extent it will be an ongoing task, rather than a one-time exercise.

New instruments – such as post-marketing monitoring or revised labelling regulations – should only be introduced when their integration into existing statutory provisions and their implications have been carefully considered and widely discussed. To avoid new areas of conflict and controversy, e.g. in post-marketing monitoring a distinction should be made as early as possible between this and pre-marketing safety research and risk assessment and the criteria for incorporating information from monitoring in the approval procedure should be clarified.

Finally, new areas of conflict should be identified at the earliest possible state and investigated in advance. Attention is drawn particularly to the announced second-generation transgenic plants, which are e.g. supposed to have a health-promoting effect as "functional food". These will probably result in a shift in the debate from possible ecological impacts towards potential health impacts and also pose entirely

new and possibly even greater problems in safety assessment than the current transgenic plants.

IMPACTS AND FOLLOW UP OF THE PROJECT

The report was published as a parliamentary document (Bundestagsdrucksache 14/5492). The report was deliberated in the leading Committee on Consumer Protection, Food and Agriculture and two consulting committees. Thereby, the report was discussed controversial. The governmental majority presented a motion which included the whole spectrum of the report issues, proposed a further development of the concept sustainable agriculture and demanded a consequent application of the precautionary principle. In contrast, the motion of the opposition (CDU/CSU) concentrated on the rapid implementation of the new Deliberate Release Directive 2001/18/EC and was demanding a strengthened research and use of transgenic crop plants.

The result of the deliberation in the committees was a recommendation (of the governmental majority of SPD and the Greens) and report for the plenary which was approved in the plenary meeting of the German Bundestag on 14th June 2002. The TAB report was once again unanimously noticed by the plenary.

The part on post-marketing monitoring of the report was used in a documentation of the Federal Environmental Agency (UBA 2001) which summarise the state of debate at that time.

The report had pointed out that TA should be started on the new generations of transgenic plants at the earliest state as possible because these will probably result in a shift in the debate from possible ecological impacts towards potential health impacts and also pose entirely new and possibly even greater problems in safety assessment than the current transgenic plants. Following this recommendation, TAB was commissioned with a project on transgenic plants of the second and third generation in 2003.

CHALLENGES IDENTIFIED IN THE PROJECT

In the project identified (future) challenges which are still valid (conclusions of the reviewer):

- need for more accompanying ecological research to assess possible risks of gm plants
- missing definition of damaging impacts, so that there is still a considerable scope for different assessments
- missing normative framework for desirable agricultural practice or sustainable agriculture, against which impacts of gm plants can be measured
- insufficient implementation of post-marketing monitoring
- need for clear distinction between post-marketing monitoring and pre-marketing safety research

- development of criteria for the feed-back of information from the post-marketing monitoring to the authorisation agencies and for impacts on running approvals or re-approvals
- importance of the second and third generation of gm plants (in particular plant-made-pharmaceuticals, plant-made-industrials, functional food) with potentially a shift in the debate from ecological impacts towards health impacts and new problems in risk assessment

LITERATURE

Sauter, A.; Meyer, R. (2000): Sachstandsbericht Risikoabschätzung und Nachzulassungs-Monitoring transgener Pflanzen. TAB-Arbeitsbericht Nr. 68. Berlin http://www.tab.fzk.de/de/projekt/zusammenfassung/ab68.pdf

English Summary: http://www.tab.fzk.de/en/projekt/zusammenfassung/ab68.htm

UBA (2001): Stand der Entwicklung des Monitoring von gentechnisch veränderten Organismen (GVO) – Materialsammlung. UBA-Texte 60/01

AUTHOR OF THE REVIEW

Rolf Meyer

DISKURS GRÜNE GENTECHNIK (GREEN BIOTECHNOLOGY DISCOURSE) (2002) 6.3

BACKGROUND OF THE PROJECT

The so-called "Diskurs Grüne Gentechnik" ("Green Biotechnology Discourse" was initiated by the federal Ministry of Consumer Protection, Nutrition and Agriculture (Bundesministerium für Verbraucherschutz, Ernährung und Landwirtschaft, BMVEL) in 2001.

The situation in the starting year was characterised by the worldwide growing commercialisation of gm crops, the amendment of the EU regulation on genetic engineering, the abandonment of the three-year transitional trial phase of introducing gm crops in agriculture due to the BSE crisis (see review on the TAB project 2000), and the new direction of the German agricultural policy (so-called "Agrarwende").

The goal was to "establish a forum for clarification of facts and for debate among all relevant societal groups" (BMVEL 2003, p. 5).

BASIC DATA ABOUT THE PROJECT

The "Green Biotechnology Discourse" was started in December 2001 and finalised in September 2002. 30 stakeholder groups – industry, agricultural organisations, environmental and consumer groups, churches, trade unions – took part in the discourse. Further, representatives of different other ministries were present. The steering committee of the discourse consisted of representatives of the stakeholder groups and was chaired by a representative of the BMVEL.

The discourse was split in two phases, the starting phase (with a kick-of meeting, the selection of the moderator, the constitution of the steering committee and a hearing) und the phase of so called "discourse rounds". The stakeholder and representatives of the ministry met in five "discourse rounds" of two days duration und in a conference. At these meetings opinions of 53 experts were heard and discussed by the participants. Care was taken to have an equal proportion of "pro-GM" and "anti-GM" experts. The moderator had prepared in the starting phase a "basic reader" which gave an overview on scientific, economic, ethic, social and legal issues.

The steering committee agreed on the main topics to be discussed in the five "discourse rounds":

- preservation of biodiversity,
- innovation potential and future chances of green biotechnology,
- benefits and risks for consumer and producer,
- preconditions, chances and consequences of an abandonment of green biotechnology,
- information, participation of the public and freedom of choice.

The results were published in a final report written by the steering committee (BMVEL 2002). The BMVEL published in addition a booklet in which the results are resumed as seen by the ministry (BMVEL 2003).

MAJOR OUTCOMES OF THE PROJECT

For major points, a consensus was not achieved. The final report lists for the different topics the points of consensus and dissent, and open questions. Some major outcomes are (BMVEL 2002):

- Biodiversity: Consensus on the importance of preservation the biodiversity, but dissent on what is a negative impact on biodiversity (e.g. out-crossing); important open questions are seen in the definition of ecological damage and in the responsibility for damages on biodiversity;
- Risk assessment: Fundamental disagreement on the deliberate release and use of gm plants; as most important open question was identified the understanding of the precautionary principle;
- Benefits of GM plants: Consensus about the importance of plant breeding, the potentials of conventional breeding and the need of molecular-genetic and ecosystem research for successful plant breeding, but dissent on specific benefits from GM plants; important open questions are seen in the clarification of potential fundamental differences between conventional breeding and genetic engineering and in the regulation of intellectual property rights;
- Benefits of GM foods: Consensus on the high standards of food security and quality in the industrial countries, but disagreement on the consumer benefits from product innovation in the past and from gm food; as prior open questions are regarded the definition of improved foods and the possibilities of healthier nutrition through gm food;
- Freedom of choice and coexistence: Consensus on the freedom of choice for producer and consumer, the labelling of gm foods and that with zero tolerance coexistence is not possible, but dissent on thresholds, measurements and accountability; to the identified open questions belong feasibility of coexistence, coexistence rules and liability;
- Labelling: Clear and practicable regulation for labelling is demanded; a consensus for seed thresholds was not achieved.

IMPACTS AND FOLLOW UP OF THE DISCOURSE

All important stakeholders in the field of green biotechnology have participated in the discourse. But no changes in the German discussion on gm plants and foods resulted from this exercise – there was no successful mediation across the GM divide. The discourse is extensively documented on the "transgen" website (www.transgen.de). This official website declares: "In the end the discourse had little effect. The various views continue to stand opposed to each other. A number of questions that were discussed at the time have meanwhile been settled politically, but this has hardly calmed down the controversies." (Transgen 2007) For the in 2002 re-

elected red-green coalition government, freedom of choice and coexistence remained the leading policy goals for the area of biotechnology and food. Following the new EU regulation, an amendment of the German regulation on genetic engineering took place in 2004 [?]. Pro-GM participants regarded this new regulation as blocking the use of gm plants.

It has been suggested that the discourse had a built-in design to cement rather than to mitigate the controversy. A fundamental divide between two sides appeared due to the requirement of the pro/contra proportionality in the selection of experts. This arrangement offered organisations with more outspoken views greater leverage on the kind of expertise that would be presented. Any substantive debate between different experts was frustrated. Experts were used as strategic resources by the participating organisations. One effect of the discourse was apparently that cooperation and coordination within each side of the GM controversy was strengthened (Paula/van den Belt 2006, p. 32).

CHALLENGES IDENTIFIED IN THE DISCOURSE

In the discourse identified (future) challenges which are still valid (conclusions of the reviewer):

- definition of ecological damage
- definition and operationalisation of the precautionary principle
- regulation and impacts of intellectual property rights and patenting
- consumer benefits from gm foods as improved food products and healthier nutrition
- feasibility of coexistence, coexistence rules and liability
- working labelling regime for gm food
- thresholds for labelling of seeds

LITERATURE

BMVEL (Bundesministerium für Verbraucherschutz, Ernährung und Landwirtschaft) (2002): Diskurs Grüne Gentechnik. Ergebnisbericht, durch den Lenkungsausschuss am 27. August 2002 verabschiedet

BMVEL (Bundesministerium für Verbraucherschutz, Ernährung und Landwirtschaft) (2003): Diskurs Grüne Gentechnik. Hintergründe, Standpunkte und Erwartungen zum Einsatz der Gentechnik in der Land- und Ernährungswirtschaft

Heine, N.; Heyer, M.; Pickardt, T. (2002): Basisreader der Moderation zum Diskurs Grüne Gentechnik des Bundesministeriums für Verbraucherschutz, Ernährung und Landwirtschaft – BMVEL. Osnabrück, April 2002

Paula, L.; van den Belt, H. (2006): INES – The Institutionalisation of Ethics in Science Policy: practices and impact. Work Package 5: Ethics in Food Technologies. Final report

Transgen (2007): Diskurs Grüne Gentechnik: Wissen, Informationen, Meinungen. http://www.transgen.de/wissen/diskurs/ (27.02.2007)

AUTHOR OF THE REVIEW

Rolf Meyer

GENETIC ENGINEERING AND ORGANIC FARMING (2003) 6.4

BACKGROUND OF THE PROJECT

In December 2000, the German Federal Environmental Agency (Umweltbundesamt – UBA) held a professional conference on the subject of "Green genetic engineering and organic farming". During this conference, possible approaches for protecting organic production sites as the use of genetically modified plants increase in conventional agriculture were discussed with persons representing organic farming from the research, production and administration sector.

The experts participating in the conference agreed that the only way to minimise contamination due to introgression from genetically modified plants is to use suitable prescribed distances between organic farming areas and fields containing genetically modified plants. Additionally, the establishment of zones that are free of GMOs should be considered within protected areas.

At the starting time of the project, there was no basic legal stipulations in Germany or in Europe with regard to these calls for minimum prescribed distances and GMO-free protected areas.

The objective of the "Green genetic engineering and organic farming" project was thus to present different legal scenarios for establishing regulations on minimum prescribed distances between organic farming areas and fields containing genetically modified plants within the German und European legal systems.

BASIC DATA ABOUT THE PROJECT

The specialist report entitled "Green genetic engineering and organic farming" (Barth et al. 2003) was prepared on behalf of the German Federal Environmental Agency by the Forschungsinstitut für biologischen Landbau Berlin e.V. and the Öko-Institut e.V. in the time between June 2001 and August 2002. The report includes the results of two workshops held on 29 October 2001 and 16 January 2002 in Berlin during which the initial results were discussed with various experts.

MAJOR OUTCOMES OF THE PROJECT

There is a world wide consensus among organic farmers not to use genetically engineered organism (GMO). Initially implemented through the guidelines of organic farming associations, this rule now gained accession to consumer protection legislation in the USA, Japan and the European Union.

EU LAW PERMITS PROTECTIVE MEASURES FOR ORGANIC FARMING

At the European level neither the EU regulation on organic agriculture nor the seeds directives prescribe mandatory measures for the protection of organic crops against

pollination by GMO pollen. An evaluation of EU Directive 2001/18/EC on the Deliberate Release of GMO shows, however, that the permission to market GMO may include an order to take measures to avoid property damage through pollination as one of the "specific conditions of use and handling" of the GMO. This results from a systematic and parallel interpretation of the EU Directive on the release of GMO and the EU regulation on organic agriculture. Only inasmuch as the interpretation of the Directive on the release of GMO takes into account the legislative targets of the EU regulation on organic agriculture will a balance of interests between organic agriculture and the cultivation of GMO be accomplished.

PROPOSALS FOR ISOLATION DISTANCES

Currently the most widely discussed option for affording protection against property damages is to provide isolation distances between cultures with GMO plants and organically managed cultures; another is to demarcate GMO-free regions.

Isolation distances have for a long time been used in seed production to maintain purity of breed. The goal is to keep impurity to a minimum. Statutory minimum isolation distances are based on past experience with seed production and they do not completely rule out hybridisation. Nevertheless, the imposition of safety distances does offer itself as one possible way of protecting organic agriculture.

An analysis of empirical data with a view of defining isolation distances revealed many gaps and hence an urgent need for further research. Despite this shortcoming, and for pragmatic purposes, the present survey was based on what data were available to derive first recommendations for isolation distances.

Measures for protection against property damages through GMO pollination in organic agriculture, such as the declaration of isolation distances on commercial packaging of GMO seeds, could be imposed by way of commercialisation permits. Implemented through commercialisation permits such measures could even today have an effect on civil-law relationships between organic farmers and GMO farmers, under certain conditions entitling organic farmers to claims for damages caused by genetic introgression.

PATHS TOWARD CONCILIATION BETWEEN NEIGHBOURS

In Germany the private legal rights and spheres of interest of organic farmers and users of transgenic varieties are defined and delimited by civil law. The borderline is drawn by a system of legal claims governing neighbourly relationships. § 906 of the German Civil Code is the central norm of private environmental law. Under this paragraph users of transgenic plants can be required to avoid or minimise genetic modifications in neighbouring cultures. When an organic farmer suffers market losses due to the pollination of organic cultures by GMO pollen, the owner of the neighbouring transgenic cultures can be ordered to pay damages. At present it is difficult to assess the level of enforceable claims. The complex intercalating system of claims to desist or to compensate will have an inhibitory impact on the use of transgenic seeds, and the economic burden of having to avoid GMO pollination of

neighbouring cultures or pay compensation, will not be calculable in advance. However, organic farmers are so burdened with having to secure cogent proofs of causality that many will see this as an intolerable manacle. Under these conditions there will be little hope of arriving at a state of peaceful coexistence.

The idea of a self-organised mediation system for temporal and spatial isolation in connection with a compensation scheme financed by GMO producers and users is introduced.

PUBLIC REGISTER OF PRODUCTION SITES

All member states of the European Union are required by the Directive 2001/18/EC to establish public registers documenting GMO cultivation sites and the identity of cultivated GMO varieties for the purpose of monitoring environmental effects. This register could at the same time serve as a production register for GMO. The directive leaves it up to the member states to determine the details of register management. The directive contains no impediment to requiring farmers to provide precise information on the location of their GMO cultures for the register. Information concerning the precise design of the GMO and the analytic measures to detect it could be included along the lines of the draft of the EU regulation concerning traceability and labelling. However, this draft only requires that the codes of GMO sequences be published. Since organic farmers must be in a position to reliably detect GMO sequences, the cultivation register would need to contain precise information on their identity.

INTRODUCTION OF GOOD PRODUCTION PRACTICE IN GMO CULTIVATION

Protective measures to avoid GMO pollination could be imposed on users of GMO seeds through the introduction of a code of "Good Production Practice in GMO cultivation" (GPP). Such measures could include, for example, defensive cultivation planning and the maintenance of specific distances between transgenic and susceptible organic cultures. For the implementation of the GPP code the administration must be empowered to impose specific single protective measures. Non-observance of such an order must be penalised as a regulatory offence. GPP could be introduced by an amendment to the Gentechnikgesetz (German act on genetic engineering) or the Saatgutverkehrsgesetz (German act on the marketing of seed). Alternatively, it could be introduced through an amendment to a specific (organic) agriculture statute.

DAMAGE FUND FOR GMO POLLINATION

For pollination by GMO from non-determinable sources a system for compensating organic farmers for market losses is necessary and indeed feasible. Compensation could be provided by a governmental compensation system or a fund model based on a statutory regulation or a voluntary self-commitment of producers and users of GMO.

PROTECTION OF ORGANIC SEED PRODUCTION

The protection of organic seed production necessitates closed regional production areas. This requires the development of an appropriate legal basis.

IMPACTS AND FOLLOW UP OF THE PROJECT

Some points are incorporated in the amended German legislation on genetic engineering, but many other points are still discussed controversial.

CHALLENGES IDENTIFIED IN THE DISCOURSE

In the project identified (future) challenges which are still valid (conclusions of the reviewer):

- definition of isolation distances and Good Production Practice
- liability and compensation fund
- protection of organic seed production
- coexistence which does justice to consumers' right to freedom of choice is not easily to be arrived

LITERATURE

Barth, R., Brauner, R., Hermann, A., Hermanowski, R., Nowack, K., Schmidt, H., Tappeser, B., Meier, J. (2003): Genetic Engineering and Organic Farming. UBA-Texte 02/03, Berlin

AUTHOR OF THE REVIEW

Rolf Meyer

GREEN GENETIC ENGINEERING – TRANSGENIC PLANTS OF THE SECOND AND THIRD GENERATION (2005) 6.5

BACKGROUND OF THE PROJECT

The TAB-project “transgenic plants of the second and third generation” was demanded by the Committee for Education, Research and Technology Assessment. The term "second generation" was used to describe those genetically modified plants (GMP) which are in the pipeline (i.e. in industrial development and shortly before licensing), while “third generation” is applied to those in research or a very early stage of development.

The origin of this project can be clearly traced back to the previous TAB project "Risk assessment and post-marketing monitoring of transgenic plants", where the investigation of this topic was brought up as an important recommendation concerning future TA need (see review 6.2).

A second motivation was the (as well since a long time especially in the political debate repeated) assumption, that a shift in the European consumers' hostile attitude towards GMP can't be expected as long as no products from GMP with a convincing benefit are on the market. The TAB project to study the potential and risks of future transgenic plants was limited to the subset of GMP with modified use properties for the consumer (so-called “output traits”). The TA project aimed to answer the following questions:

- how the targeted additional benefits of these GMP are defined,
- how they are supposed to be achieved,
- what economic potential can be expected,
- what new (types of) risks should be assumed,
- what new questions of safety assessment result from these,
- whether existing safety measures appear adequate, or whether they need to be modified, expanded or supplemented,
- what regulatory challenges result, and also
- what effects on consumer acceptance are to be expected.

BASIC DATA ABOUT THE PROJECT

The TA-project was executed in 21 months (November 2003 – July 2005), subdivided into two phases. Eight scientific studies (expert opinions) were commissioned during the project. In the first phase (until August 2004), based on three of the expert opinions, an overview of research and development as well as concerning the economic potentials and the international debate on risk evaluation and assessment was worked out. The second phase of the project was devoted to an in-depth analysis of "molecular farming" which means the use of GMP for the production of industrial materials (so-called PMI or plant made industrials) and especially as a source of

pharmaceutical substances for human and animal medicine (so-called PMP, or plant made pharmaceuticals). The draft final report of TAB was based mainly on the commissioned scientific studies and was evaluated by a number of experts from science and government.

The main topics of the final report were:

- a detailed description of GMP for functional foods, for PMI and PMP[12]
- including an in-depth discussion of their economic potentials and
- their possible ecological and health risks;
- the possible performance of biological and physical confinement measures;
- the regulation of molecular farming (in the EU, compared to the U.S. and Canada):
- areas for action (with regard to the German national and the EU level).

MAJOR OUTCOMES OF THE PROJECT

OVERVIEW OF RESEARCH AND DEVELOPMENT – LICENSING AND RELEASE

GMP with output traits were divided into six groups:

1. improved contents in plants which are a source of food (functional foods - FF);
2. improved contents in plants which are a source of animal feed;
3. optimised or modified plants for production of industrial materials (PMI) or
4. for production of pharmaceutical substances (PMP);
5. GMP for phytoremediation (plants for the treatment of contaminated soils);
6. modified properties of decorative flowers (colour) or plants (e.g. lawn).

GMP with output traits play no role in global cultivation, which is still completely dominated by herbicide and insect resistance. Until 2005 eleven GMP with modified output traits have been licensed in various countries (2006: plus one), nine of them without relevance for the TAB report (tomatoes with longer shelf life, modified decorative flowers, tobacco with reduced nicotine content). The two remaining varieties, a rapeseed with high lauric acid content and a soy bean with increased oleic acid content, have been unsuccessful on the US market, and are accordingly not grown to any effective extent. In the *EU*, only the three modified carnations have been licensed (since 1997/98). The licensing pipeline contains (since 1997) 21 applications, including one PMI GMP, the "famous" potato with modified starch composition.

Among the releases in the U.S. (1988-2003), GMP with modified output traits account for c. 20% of the c. 10,000 applications, equivalent to 150-230 a year since 1994. In the EU, GMP with modified output traits account for c. 15% of all releases in 1988-2003 (over 270 of 1,850 applications). In line with the trend for GMP gener-

12GMP for animal feedstuff were not dealt with in depth, as their uses are more comparable with agronomically modified GMP, and hence do not open up new prospects for use in the same way as the other three groups, and because they play only a minor role in Europe, quantitatively speaking.

ally, there has been a very definite decrease in release applications since 1996/97. A breakdown by individual groups shows a much smaller significance of the feedstuff sector than in the USA.

GMP FOR THE PRODUCTION OF FUNCTIONAL FOODS OR THEIR INGREDIENTS

The range of functional ingredients produced or (to be) modified in plants by genetic engineering is still very manageable. The GMP developed so far are predominantly prototypes to demonstrate fundamental feasibility, which need further development for commercial use and must be tested not only in the field but also on humans in nutrition studies.

For most functional ingredients, the current genetic engineering approaches – overexpressing or reducing the activity of individual genes directly involved in the relevant metabolic pathways – are not sufficient to achieve commercially attractive content of the functional ingredients in the GMP. Hopes involve conceptual and methodological further developments in metabolic engineering, which seeks to affect entire metabolic pathways and regulatory networks in a coordinated way. Whether FF GMP can be established in the medium term as a source of functional food raw materials and ingredients depends crucially on whether the assumed cheaper production of functional ingredients in GMP can be actually achieved. This is not easy, as there are established production platforms already in existence (e.g. chemical synthesis, microbial production, isolation from natural sources) for most of the ingredients currently being researched in GMP, which FF GMP will have to compete with. The resource-intensive and comparatively long development period for new GMP varieties and the functional foods or ingredients produced from them represent a comparative disadvantage, as the regulatory requirements mean tying up resources in the long term in a dynamic market which actually requires a rapid and flexible response. In addition, GMP approaches generally have to be supplemented by other food technology options, as functional GMP for direct consumption can only meet a small segment of the possible entire supply of and demand for functional foods, for reasons of shelf life, seasonal availability, convenience and bioavailability.

PLANT MADE PHARMACEUTICALS

GMPs have been discussed for many years as a highly promising new production platform for drug production. The hope is particularly for low-cost production in large quantities. Products produced using genetic engineering methods account for the overwhelming part of pharmaceutically effective proteins and peptides, which are also called “biopharmaceuticals”. Significantly less important (and also in very early stages of development) are genetic approaches to influencing pharmaceutically effective so-called secondary metabolites, which were not discussed in the report.

To date, no PMP GMP has been licensed for placing on the market anywhere in the world. There are intensive research and release activities in the USA and Canada, while the activities in the EU come predominantly from two French firms (Meristem Therapeutics and Biocem). The plant species used are predominantly maize and tobacco, followed by rapeseed and soy bean. No PMP has yet been given “real” ap-

proval as a drug. Several proteins which also have pharmaceutical uses are already on the market, although so far they can only be sold as research or diagnostic reagents. They come from experimental releases (in the USA).

Of those PMP in development, so far only two have been recognised as having so-called orphan drug status (for treating rare diseases). In the EU orphan drug status (for use with mucoviscidosis sufferers) was granted in 2003 to a so-called gastric lipase (from maize). To date the protein comes from experimental releases in France, and could be the first PMP for application for approval as a drug in the EU. In the USA a so-called galacosidase was granted orphan drug status in the same year. 15 PMP were identified in various phases of clinical testing. In addition to gastric lipase, an antibody for caries prophylaxis and patient-specific antibodies for treating non-Hodgkin lymphomas are in an advanced stage of testing. Several PMP are currently being developed for veterinary use, with the option of extending these to human indications later if successful. Besides these concrete examples, there is a vast number of PMP in preclinical R&D stages. A key area is developing antibodies, presumably because possible specific advantages of production in GMP seem most within reach.

To assess the future potential of PMP GMP, comparison with competing production platforms is needed. To date, biopharmaceuticals have almost entirely been produced microbially or in animal cell cultures, and transgenic animals are rather more advanced than PMP approaches (although here again no drug has yet been approved). The various production platforms are briefly presented and described in the report.

Possible specific advantages of PMP GMP were considered in terms of freedom from human-pathogenic agents, correct glycosylation and of investment and production costs including scalability. These were found to be predominantly dependent on the product. For example, it is clear that glycosylation closer to mammalian cells (modification of the protein in the cell) from PMP has an advantage over microbial systems for many drugs, although this may also prove a pharmacological disadvantage for others. It is fairly certain that general cost advantages cannot be assumed for production from PMP – these are only plausible on the unrealistic assumption of only slightly regulated open cultivation (plus ideal yields). An in-depth investigation of the foreseeable potential of possible oral vaccines showed that oral vaccines do not seem very important for vaccine development, and particularly that the idea of ingestion in the form of unprocessed fruits (still frequently cited) is entirely unrealistic.

An overall assessment of the currently foreseeable economic potential concluded that in view of the major and growing importance of biopharmaceuticals generally, there is probably also growing potential for production in PMP, without the general cost advantages generally assumed. Their competitiveness is decisively determined by advances in competing production systems and development of specific regulations for cultivation and corresponding risk management measures.

PLANT MADE INDUSTRIALS

Use of PMI GMP seems comparatively further away. This is a little surprising, given the intensive work on relevant GMP concepts over many years, and the fact that the

first two such GMP were approved and commercialised years ago. The only currently foreseeable example here in the EU is the starch potato, which has been in the approval pipeline for years.

For all other approaches (whether in "designer oils" or "designer starches", production of industrial enzymes, biopolymers or other special ingredients) it is virtually impossible to assess how far the work has come in concrete terms. In some cases, this is in-house work, in other cases the development work – e.g. on bioplastics from GMP – seems to be taking significantly longer than hoped. The reasons for this differ, depending on the development goal and plant species, but the examples presented suggest possible general assessments (which also apply e.g. to development of FF GMP).

- In several cases, expectations particularly of attainable product yields have been not been satisfied even after many years of development. In the course of maximising content, apparently undesired side effects have emerged (are emerging) in many cases which then result in lower yields. While this does not make the concept (economically) unusable, it does affect the range of substances which can be produced on a commercially competitive basis.
- In several cases, the transition from the highly promising model plants to specifically usable ones did not proceed as hoped, as the genes failed to "function" accordingly.
- In other products, the alternative production systems (cell-based systems, transgenic animals) developed faster or more efficiently.

An assessment of the prospects for PMI concepts is accordingly (even) more difficult than for PMP. Production of bulk products seems unlikely in the foreseeable future, the production of renewable raw materials is more likely to be optimised through breeding of non-genetically-modified plants. Industry sees realistic prospects for high-price special applications, if these can only be produced in GMP and not in conventional varieties or the cultured varieties otherwise used. Dual use (e.g. bioplastic and feedstuff) depends on relevant approval, which is only conceivable for selected approaches. Transgenic trees for plantation farming could become more significant worldwide, but cultivation in the EU is unlikely for a long time.

POSSIBLE ECOLOGICAL AND HEALTH RISKS

Given the early stage of GMP modified for output traits, no risk discussion has developed for most sub-aspects, so that no presentation in detail was possible. This applied particularly to the possible ecological risks of FF GMP and the possible health risks of PMI GMP. The risk discussion for FF GMP is focusing on the basic question of safety evaluation of innovative and primarily functional foods, while for PMP GMP the emphasis is on possible release into the environment and food and preventing this. Therefore the risk debate on molecular farming (of PMP and PMI) generally has so far concentrated almost entirely on the question of reliable sequestration and containment of GMP.

Basically, GMP modified for output traits fundamentally change the situation for risk regulation (i.e. risk assessment, risk evaluation and risk management), because at least PMP GMP as well as some PMI GMP have an inherent risk because of the medical and physiological impact of their ingredients.

The current goal of risk regulation is to approve only GMP which are risk free as compared to "conventionally" bred plants. This concept must be at least modified by developing comprehensive and rigorous safety requirements for cultivation and processing e.g. for PMP GMP with their potential environmental and health risks (as is the case in Canada and the USA). It will probably be necessary to impose group-specific measures which imply moving away from the pure case-by-case principle, or at least supplementing it.

At the same time, the discussion of benefits is taking on new priority compared with the 1st generation of GMP, including risk evaluation and regulation. So far, it has been possible to ignore doubts about the benefits of the genetically introduced properties from the regulatory point of view (because no concrete risks to health and the environment were established as a prerequisite for approval), and to leave evaluation to market forces. In future, the desired benefit (e.g. production of life-saving drugs) is likely to play a greater role – at least in some cases – in risk evaluation, including in the approval decision.

BIOLOGICAL AND PHYSICAL CONFINEMENT MEASURES

In considering possible risk management measures for GMP modified for output traits, it is necessary to distinguish between two groups of GMP which pose very different requirements for regulation, namely those which can be regarded as just as safe as the approved 1st generation GMP, and all others.

The first group could include several of the conceivable PMI applications, e.g. if these involve modified food plants which are currently being used for industrial purposes in their conventional form. At least if the relevant GMP has explicit approval for food and feed, large scale cultivation is conceivable subject to the prevailing variety-specific coexistence regulations, and would not differ substantially in quality from the food sector. The second group presumably includes most PMP, together with a range of conceivable PMI plants for which special containment/confinement will be required. In the event of open cultivation, and possibly greenhouse cultivation, particularly strict biological and physical confinement measures must apply, as the current regulations in Canada and the U.S. require.

The report discusses in detail the question how reliable the various methods in preventing undesired dissemination of GMP are. The overall conclusion was that the present state of science and technology is unable to offer any system for confinement of transgenic nonfood plants which permits coexistence in open cultivation of GMO and non-GMO species completely free of any influence. But it was emphatically stressed that the extent to which such influence can be tolerated and under what conditions are matters for society to decide.

Only few biological confinement methods have reached a state of development where substantial studies on integrity and leak tightness can be carried out. An (almost) complete prevention of the escape of a transgene is up to now only possible in closed systems.

REGULATION ISSUES IN MOLECULAR FARMING

Consideration of the state of regulation of genetic engineering showed that the present regulations and procedures for molecular farming are not entirely appropriate or adequate. For molecular farming of "high price" products or ingredients on comparatively small areas, approval for release under Part B of European Directive 2001/18/EC is inadequate in many cases (because the relevant products may not be placed on the market), although approval for placing on the market under Part C would actually not be required, because free trade and unlimited cultivation are not goals of GMP development. At least in the medium term, there will accordingly be a need for change, particularly in the regulation of genetic engineering. By contrast, there is currently hardly any need for change apparent in drug and chemical regulation.

Activities and discussions in the EU (until summer 2005) showed that very little attention had been paid to the issue of molecular farming so far, particularly in comparison with Canada and the U.S. *[this has changed a little bit since then, as EFSA and IPTS have started several activities, both of them taking notice of the TAB report; see below]*. This implies a need at EU and national level for more intensive consideration of the opportunities and potential risks of GMP modified for output traits.

AREA FOR ACTION: OPERATIONALISATION OF VISIONS AND SCENARIOS

Although molecular farming has been described as a future option for many years in the debate on genetic engineering, it has mostly been presented in very vague terms, either as largely unsupported assumptions about possible benefits (and/or risks) or as visions of the future. The relevant documents typically focus on scenarios for the use of possible products from GMP modified for output traits, describing scenarios for production and cultivation which have little contact with reality, and completely ignore regulatory aspects and realistic coexistence scenarios. Such operationalisation accompanied by greater social opening seems very important for the coming debates on possible future use of transgenic plants. These tasks should be addressed with a view to the coming Framework Programme 7, together with more substantial links to the relevant policy areas, strategies and goals (including more extensive use of renewable raw materials, development of rural areas, sustainability of agriculture, healthier nutrition).

AREA FOR ACTION: GERMAN RESEARCH POLICY

Facing the new and complex questions regarding the benefit as well as novel risks and their management, for German research policy the development of interministerial promotional R&D measures for research into molecular farming was assessed

as being adequate. A viable and societally acceptable approach would require not only bringing together the ministries' technical points of view but also including various interest groups in developing such promotional programmes and projects.

No assessment was performed for R&D approaches in detail, e.g. deserving promotion or safety issues requiring particularly urgent investigation. However, a specific proposal was made for a “Progress report by the Federal Government on the status of publicly funded activities in connection with research, approval, cultivation and marketing of GMP”, which should in detail review the aims and outcomes of the last 10 to 15 years and draw conclusions for the future promotion and funding of R&D devoted to biotechnology and plant sciences (a proposal, which seems to be suited for every other country as well as the EU level). Such a report could possibly offer a basis or at least a point of reference for more constructive and sustainable further development of research policy on green genetic engineering and alternative strategies.

AREA FOR ACTION: MODIFICATION OF REGULATION AT EU LEVEL

The need for action concerning modification of regulation was clearly located at EU level. The regulation has to come under review if it is suited for the production of PMP and PMI (which seems not so; see results above). With regard to national regulations, it was concluded that they have to be revised in a second step according to the EU regulation.

IMPACTS AND FOLLOW UP OF THE PROJECT

Parliamentary debate and/or decision:

The proposal of the "Progress Report" was picked up several times in parliamentary debates (on GMOs, but not directly connected with the TAB report) and has been integrated in the official statement of the (together with the christian democrats governing) social democrats concerning the current amendment of the gene technology law.

Public perception:

Compared to other TAB projects, a relatively broad press coverage in print and web-based media began directly after the acceptance by the Committee for Education, Research and Technology Assessment and publication of the report in February 2006. In June 2006, TAB together with the Committee for Education, Research and Technology Assessment organized a public workshop in the German Parliament and invited stakeholders from industry, regulatory authorities and academia to answer to and to discuss the report's view. The workshop was very well attended, by all kinds of stakeholders. The usual heavily polarized debate was astonishingly moderate, in our view the outcomes of the report were completely validated, although "the industry" tried to proof a too negative judgement concerning the economic potentials (but failed to show any other perspective than was discussed by TAB).

Scientific recognition:

The performance of the report was appreciated a lot (there is up to now no publication of comparable comprehensiveness in Germany, maybe in Europe?), accompanied by heavy criticism from scientists who refuse to concede that the results of molecular farming up to now are in many respects of a poor nature (and probably are opposing the proposal of the reviewing "Progress Report"). The websites on GMOs and biosafety of the German research ministry refer to the report (especially concerning the risk regulation of PMP) and integrated links to TAB. IPTS invited TAB to a workshop on molecular farming which was then attended by Armin Spök from IFZ (Graz, Austria) who was responsible for two of the expert opinions on risk regulation, and who has published its results recently in TRENDs in Biotechnology.

CHALLENGES IDENTIFIED IN THE PROJECT

Due to the up to now very limited presence of the topic "molecular farming" in the debate on GMOs (at least in a detailed manner), an overall need at EU and national level for more intensive consideration of the opportunities and potential risks of GMP modified for output traits is obvious.

- Technical dimension: The possible performance of future GMP could be assessed in a more realistic way (via an in-depth "Progress Report"); with respect to the cultivation of PMP and PMI GMP, the development and assessment of biological and physical confinement measures are of special and fundamental importance;
- Social dimension: The possible acceptance of PMI and PMP GMP will (in my opinion, A. Sauter) depend on an early and transparent participation already in the R&D phase, beyond promotional communication activities like "Plants for the Future" (see "operationalisation of visions and scenarios");
- Political / regulatory dimension: The whole EU regulation has to be checked for appropriateness for molecular farming (EFSA has started a self tasking activity, IPTS is also working by order of the Commission).

LITERATURE

Sauter, A., Hüsing, B. (2005): Grüne Gentechnik - Transgene Pflanzen der 2. und 3. Generation. TAB-Arbeitsbericht Nr. 104, Büro für Technikfolgen-Abschätzung beim Deutschen Bundestag, Berlin http://www.tab.fzk.de/de/projekt/zusammenfassung/ab104.pdf

English summary: http://www.tab.fzk.de/en/projekt/zusammenfassung/ab104.htm

Spök, A. (2006): Molecular farming on the rise – GMO regulators still walking a tightrope. In: TRENDS in Biotechnology 25(2), pp.74-82

AUTHOR OF THE REVIEW

Arnold Sauter

GENTECHNOLOGIEBERICHT (GENE TECHNOLOGY REPORT) (2007) 6.6

BACKGROUND OF THE PROJECT

The “Gentechnologiebericht” (Gene Technology Report) of the Berlin-Brandenburg Academy of Sciences and Humanities is a monitoring project that focuses not only on GM plants or GM foods but includes also medical applications. The report assesses the entire field of gene technology, because unlike other technologies this particular field is affecting the basic principles of life, human existence and that of all other living beings.

The report surveys carefully all present facts and the latest developments in the field of gene technology and presents a critical study from an impartial viewpoint.

BASIC DATA ABOUT THE PROJECT

The report is edited by an interdisciplinary study group consisting of several members of the Berlin-Brandenburg Academy of Sciences and Humanities. The participating authors are impartial. They are experts on different disciplines of the subject, and they observe the subject beyond their own specific discipline as well. Acknowledged external experts are involved additionally for further detailed questions.

The report was published for the first time in 2005 (Hucho et al.). It consisted of four main chapters representing different case studies, which were chosen following public controversies at that time. One of these case studies is on gene technology applied to plant breeding, farming and foods (green gene technology). A separate supplement published in March 2007 updates the data and adds news topics (Müller-Röber et al., 2007).

MAJOR OUTCOMES OF THE PROJECT

The monitoring of the report consists of three parts: The first part is a documentation of today's state of technological development including scientific progress and the recent range of applications. The second part is a detailed overview of economic, ecological, social, political, legal, and ethical aspects. The third part is a system of indicators that are suitable to unravel and describe the topics connected with the application of gene technology to plant breeding, farming and foods.

The first part of the monitoring report, the documentation of technological developments, gives a detailed view on recent research and describes the aims of this research as well as the applied techniques. Cisgenic plants and smart breeding are examples for two newly invented techniques that were presented in the media as alternatives to transgenic plants, which is the “classic” way of modifying plants. The report draws the conclusion that both techniques could be useful extensions of the scientific methods. But they will not be able to replace the methods of genetic engineer-

ing transferring foreign DNA from other species since the available genes are restricted to closely related species.

Further topics are the DNA sequencing of plant genome, the use of genetic engineering in research on biodiversity and ecosystems, enabling technologies in modern plant breeding, new methods of selection and both the creation and phenotyping of genetic diversity. On top of giving an overview over current scientific progress, the monitoring report includes an overview of the input and output traits that are worked on in the field of GM plants. Several examples are being examined, including insect resistant maize, the cultivation of which has been started in Germany recently, “golden rice” that could arouse a great deal of interest especially for poorer people in developing countries, and “energy plants” which gain high yield of biomass and are being discussed in public as an alternative form of energy production.

The second part of the monitoring report examines different topics concerning GM plants and GM foods, which are debated controversially in the general public. Public opinion on GM plants and GM foods is a major factor and has to be taken into account, not only in Germany but in the whole European Union. The scepticism about these particular applications of gene technology is much higher in Europe than in the US, Canada or Argentina, where GM plants have been cultivated for almost ten years now. The report investigates the background to this poor acceptance. On the one hand, GM plants meet with criticism because of possible unforeseen negative ecological side effects, on the other hand GM foods are criticized because of the risk of unpredictable health effects. The report examines both argumentations. GM plants that are resistant against herbicides or insects are used as two examples to document the recent scientific findings on ecological and health effects. Furthermore, the report focuses on economic aspects being of particular interest to political debates. An overview over several studies on the economic potential of GM plants is being presented. The topics being discussed are the development of the areas cultivated with GM plants, the question who will profit from GM plants, the preconditions for benefiting of today's GM plants, the potential benefits of GM plants for the future, and the number of jobs being connected with the use of GM plants in agriculture and food production. Furthermore, a portrayal of the current situation of European and German laws on GM plants and GM foods is presented, which includes the topics coexistence and liability. Despite the fact that ethical questions might be less important for the agricultural use of gene technology than for medical use, the report even examines ethical problems that could be associated with the use of gene technology during the process of plant breeding.

The third part presents indicators that allow to describe the different current developments in the field of green gene technology clearly and easily to understand. A single indicator stands for a “measuring device” which allows to depict complex issues that cannot be measured directly and to assess these issues representatively. An indicator reduces complexity through which developments at long and at short intervals are less difficult to spot. A set of indicators makes it possible to back up subjective perceptions of developments or to falsify them. Proven developments can be analysed and interpreted with the help of further data. A misleading concentration on certain details frequently produces wrong results or misleading interpretations. The

report tries to prevent this serious risk by relating the indicators to one of the specifically defined problems that are connected strongly or weakly with the subject. All these defined problems seen as a whole should describe the issue of green gene technology entirely. This methodological step prevents observation loopholes if no suitable indicator could be found. In detail, the several defined problems take up again the different economic, ecological, social, political, legal, and ethical questions and also latest scientific research and current applications, which are presented in the second part of the report. In addition, connections between these aspects are pointed out and even problems connected to GM plants and GM foods less obviously are part of the overall picture. The definition of the problems is an important task of its own. The definition of what is seen as a problem is based on the public point of view on chances and risks, which might be diametrically opposed to an experts viewpoint. Nevertheless, this guarantees that the report does not deal with an experts debate only.

The following indicators represent some examples: The number of traits, the number of field trials and the number of traits in these field trials are used to examine the potential that green gene technology has developed currently. The sales and profits being made with genetically modified seeds, the worldwide area under cultivation with GM plants and several cultivation data for Germany are some of the indicators being used to determine the current economic relevance of GM plants and GM foods. The amount of money being spent on research on GM plants and the number of applied patents are two of the indicators that try to measure the scientific and economic importance of green gene technology. Ecological effects are observed for example by the number of proven cases, when a GM plant interbreeds with another plant outside the field, and the use of pesticides on GM plants compared to the amount used on non-GM plants. The dissemination of GM foods can be described for example by the number of GM plants being approved for food use in the EU and by the market share of these products. The consumers' and the farmers' acceptance of GM plants and GM foods are two indicators being used to measure the intensity of conflicts that the introduction of these products might cause. Generally, the indicators are used to describe the situation in Germany. The data is updated yearly. The report makes use of appropriate and valid sources like scientific studies or official databases of the government. The particular scientific work of the monitoring report is the selection of the indicators that has to base on intelligible criteria and that should cover all different aspects of green gene technology. Single results are linked with each other to achieve a more precise assessment and a balanced interpretation. Finally, the report publishes recommendations based on this work.

IMPACTS AND FOLLOW UP OF THE PROJECT

The monitoring report is not only addressed to the policy makers in parties, government, administration, non-profit organisations, scientific societies etc. but also to the general public interested in this particular issue. The report would like to make a good case for public discussions without taking a position for one side or the other. Thus the report wants to achieve a more objective public debate.

The next report is going to be published in 2008. Therein the issue of genetically modified animals will be dealt with additionally. Further and current information can be found at www.gentechnologiebericht.de.

CHALLENGES IDENTIFIED IN THE PROJECT

The annual update of the indicators does not only include the presentation and the interpretation of the recent data. It includes also a discussion if the indictors themselves. The main stress within the complex topics could have changed during the time and new additional data could be necessary for a conclusive interpretation. New topics have to be recognized as well, for example the debate about the consequences of the recent discoveries in the field of epigenomics.

LITERATURE

F. Hucho, K. Brockhoff, W. van den Daele, K. Köchy, J. Reich, H.-J. Rheinberger, B. Müller-Röber, K. Sperling, A. M. Wobus, M. Boysen, M. Kölsch (2005): Gentechnologiebericht - Analyse einer Hochtechnologie in Deutschland. Forschungsberichte der Interdisziplinären Arbeitsgruppen. Berlin-Brandenburgische Akademie der Wissenschaften, Berlin

Bernd Müller-Röber, Ferdinand Hucho, Wolfgang van den Daele, Kristian Köchy, Jens Reich, Hans-Jörg Rheinberger, Karl Sperling, Anna M. Wobus, Mathias Boysen und Meike Kölsch (2007): Grüne Gentechnologie - aktuelle Entwicklungen in Wissenschaft und Wirtschaft, Supplement zum Gentechnologiebericht (mit Beiträgen von Volker Beckmann und Christian Schleyer). Berlin-Brandenburgische Akademie der Wissenschaften, Berlin

AUTHOR OF THE REVIEW

Mathias Boysen

NORWAY 7.

RECONVENING THE LAY PEOPLES PANEL ON GM FOOD 4 YEARS AFTER (2000) 7.1

BACKGROUND OF THE PROJECT

The lay people's panel was commissioned in 1996, by the Norwegian Biotechnology Advisory Board (NBAB) and The National Committees for Research Ethics (NCRE), based on government grants. It consisted of 15 persons randomly chosen among 400 applicants. None of these had particular affiliations concerning the question of genetically modified food.

After several meetings to develop internal reflection on the issue of GM-food, the panel teamed up with a panel of experts to discuss central challenges regarding GM-food. After the conference, the lay people's panel delivered a consensus report with advice for action.

In 2000, the panel reconvened to discuss the issue with a new panel of experts, under the auspices of NBAB, NCRE and the Norwegian Board of Technology (NBT). In the meanwhile, some members of the panel had continued their involvement in the issue, thus establishing themselves as experts on the issue. Again, the lay people's panel delivered a consensus report.

The conference had the following aims:

- give a summary of central developments on research and use of GM food since the conference in 1996
- present a consensus report with advice on whether a moratorium on importing and marketing GM-food should be imposed and eventually on other relevant topics
- to strengthen the emphasis on lay people's insights in technology assessment and management

BASIC DATA ABOUT THE PROJECT

The project was a consensus conference based on a hearing of experts. The conference was undertaken on 15th-16th of November 2000. Participants included 15 lay people, 18 experts took part in the hearing. In addition there were a number of facilitators.

The hearing focused on the following topics:

- Status of knowledge about effects on health and environment
- Status of regulations and control: Are present regulations comprehensive and efficient?

- Is a moratorium feasible and legitimate?
- What are the interests of consumers, retailers, processors and producers?

MAJOR OUTCOMES OF THE PROJECT

The panel gave the following conclusions:

A moratorium should be imposed, prohibiting cultivation of GM food and feed with the exception for test purposes. Imports and marketing of GM food and feed should also be prohibited. The moratorium should only be lifted when certain criteria are met:

- - Knowledge of the long-range consequences of the technology should be improved
- - Laws and regulations should be coordinated internationally
- - Monitoring, control and traceability should be strengthened

A group representing broad interests should be convened to elaborate these criteria and evaluate when these are met.

Within health, no evidence of harm is given, but this cannot be excluded. Further, the technology has not contributed within promising fields of increased nutrition or lower allergenic effects.

There is no evidence that use of pesticides or herbicides have been reduced as a result of GM-cultivation. On the other hand, GM-agriculture has accentuated the use of monocultures and industrial approaches, which is harmful. There are indications that GMOs can disturb ecosystems, thus causing irreversible harm. There is an urgent need for better knowledge about effects on the environment.

Although the GM-plants marketed so far are not useful for Norway, they could prove advantageous in other regions of the world. However, despite promises that GM would especially benefit the poor, such applications have not been delivered. On the other hand, the development towards monocultures cannot be seen as serving the poor.

There is a mismatch between regulations on living matter and regulations on food and feed. While, according to the Norwegian Gene Technology Act, living matter is evaluated on criteria such as societal benefit, ethics and sustainability, these criteria are not considered in the Food Act which regulates food. Thus, food imports are not evaluated on the same criteria as domestic products.

The panel expressed disappointment that some members of the expert panel presented their own judgment of the consensus report, and that they were not able to distinguish between normative and factual topics/discussions.

Insights from experts:

There is no evidence of adverse health effects of GM food, but knowledge is insufficient. On environmental effects, knowledge is almost non-existent. Views on the

appropriateness of a moratorium vary, the strongest arguments against a moratorium is that it would challenge WTO rules. Further, the risk for GM contamination is limited to imports, and controlling this is dependent on systems for screening and tracing, rather than legal restrictions.

Acceptance of GMOs can be seen as a combination of risk, benefit and moral acceptance. While risk and benefit are quantitative factors, moral acceptance is a qualitative factor, constituting a veto. Opposition to GMOs up to 2000 can be based on perceptions of low benefits, rather than perceptions of high risk.

The Norwegian agricultural sector, including farmer unions and cooperatives, are sceptical towards GMOs, and practice a self-imposed restriction. This is based both on internal attitudes, but also on the lack of confidence among consumers. Although certain producers may be tempted to consider GM products, experiences with growth hormones and foreign cattle breeds indicate that producers are generally sceptical to growth-enhancing technologies.

Norwegians became more sceptical towards bio- and gene technology from 1996 to 2000, and are relatively more sceptical than the average European. As long as the consumers are sceptical, both retailers and food processing businesses try to avoid such products – also from imports. Thus, GM production is disadvantageous to Norwegian interests. Regulations that can be trusted by all parties will be advantageous.

To control products, methodology to reveal GM contamination is necessary. It is also necessary to establish a system of traceability to control products based on GM but where there are no trace of transgenes in the end-product. However, who shall pay for a system of traceability? If the businesses shall cover such expenses, can this be something that only the major actors can afford?

IMPACT AND FOLLOW UP OF THE PROJECT

The project got overall good coverage by the press and mass media and was looked upon as a valuable contribution in the further public debate. The project was described in detail in the Norwegian biotechnology journal “Genialt”, published by the Norwegian Biotechnology Advisory Board. Furthermore the facilitators were invited to present the major conclusions and recommendations from the project in the Norwegian Parliament on January 18th 2001.

In recent years, several of the challenges identified during the project (see underneath) have been met by the Norwegian Government. At present, routines for analysing imported food and feed for GM content are in place and running, legislation for traceability and labelling are established and there is a high degree of legislative harmonization.

CHALLENGES IDENTIFIED IN THE PROJECT

(The panel identified a number of challenges. The reviewer is not in a position to judge to what extent these challenges have been met through recent developments.)

- Systems for screening GMOs for adverse effects must be developed
- Systems for controlling GM-contamination must be developed. Existing schemes often only indicate GM-contamination, they cannot prove such contamination.
- Systems for labelling and traceability must be developed.
- Laws and regulations must be coordinated at the international level.

While health effects can be expected to be the same across regions, environmental effects may vary. Therefore, there is a higher need for independent Norwegian studies on environmental effects.

LITERATURE

Bioteknologinemnda, Forskningsetiske komiteer and Teknologirådet (2000): Oppfølgingskonferansen om Genmodifisert mat. Genialt nr. 4/2000. Web: http://www.teknologiradet.no/dm_documents/genialt42000_O6pbG.pdf

AUTHOR OF THE REVIEW

Jon Magnar Haugen

PUBLIC MEETING ON COEXISTENCE (2004) 7.2

BACKGROUND OF THE PROJECT

The Norwegian Biotechnology Advisory Board (NBAB) arranges a number of meetings and seminars to strengthen public reflection and debate on GMOs and to prepare hearings and statements on policies.

BASIC DATA ABOUT THE PROJECT

The meeting was held on 29th of April 2004. There were 94 participants, including a mixture of stakeholders, government officials and experts, with only a few lay people. The project did not intend to build consensus. Thus, outcomes presented underneath do not represent common understandings.

The debate covered the following topics:

- Case-study on gene flow between GM crops and their relatives – the case of canola
- Potential for gene flow in important crops for Norwegian agriculture
- Possible practical measures to reduce gene flow
- Possible political measures to minimize gene flow
- Specific co-existence challenges for organic agriculture
- Co-existence: strategies in a feed company
- How to ensure GM-free feed imports
- How to ensure GM-free seed

The presentations and key comments are documented in a report based partly on documents submitted by participants, and partly on transcripts from recordings.

MAJOR OUTCOMES OF THE PROJECT

Closing remarks:

- New regulatory frameworks for co-existence should not be used as a political instrument to introduce GM crops, but also to secure GM-free production.
- Co-existence is not only about biology, but also a question of commercial interests and economic compensation. Central stakeholders believe that the "polluter pays-principle" should apply and that the burden of proof should be placed on the producer.

Comments from participants (given without consensus):

- EU-regulation on co-existence is tailored to give consumers a choice. However, believing that GM may allow for choice may prove naïve. Separation measures either in cultivation or in transport and processing may be prohibitively expensive,

thus one type of farming will be harmed if the other is allowed. Which side to loose is a political question – and this should be what regulation is all about.

- Producers, feed industries etc. want to follow a restrictive line, but these sectors are dependent on imports of seed and feed. Imports from countries outside EEA raises particular challenges: Which can guarantee GM-free products? Can there be conflicts b/w objective of avoiding GM and other objectives such as contributing to income generation in developing countries?
- Norwegian producers, including fish farmers, avoid using GM feed because of consumer demand. However, this is not displayed on the final products. Wouldn't it be to farmers own interest to establish systems of labelling?

Perspectives on gene flow

The challenge of separation is not entirely new as organic products are already handled separately from conventional. However, the challenge of handling gene flow between crops/crop rotations is new.

There are a number of criteria on which the likelihood of gene flow can be evaluated. Gene flow through pollen is related to degree of out-crossing. The likelihood of gene transfer vary, dependent, inter alia, on the occurrence of related crops nearby. It also depends on whether the traits give a fitness advantage (for instance pest tolerance). Further, pollen flow is of highest concern when the seeds are the harvest of interest. For many vegetables, grasses etc., pollen flow is less relevant. Mitochondrial and chloroplastic DNA is not transferred with pollen, so transgenes within will be less susceptible to gene flow.

Particular challenges to particular sectors, some are also particular to Norway:

- For aquaculture, there is a challenge that soy meal and oils is gaining importance but GM-free soy is limited. On the other hand, the combination of fatty acids of today's soy is not entirely suitable for aquaculture – a challenge that could be solved by GM. Aquaculture therefore faces particular challenges in relation to GM feed, first by securing GM-free soy, and second by being tempted to adopt GM feed.
- In conventional agriculture, the strong position of agricultural cooperatives, alongside a high degree of regulation, favour a standard approach shared by neighbouring farms.
- Organic agriculture may have a higher diversity – both intentional and unintentional (weeds). This may allow them to be sinks of GM-volunteers – especially for Bt-crops and other GM-crops that may have a fitness advantage.

IMPACTS AND FOLLOW UP OF THE PROJECT

Insights from the meeting have been communicated in relation both to the development of general regulation, and in relation to specific submissions for deliberate release. The meeting marked the opening of the debate on co-existence in Norway. After the meeting, researchers and experts have been mandated to draft a bill for co-

existence, addressing crucial issues such as the risk for gene flow in different crop species, systems for compensation, and the right to information about GM fields.

CHALLENGES IDENTIFIED IN THE PROJECT

(Remaining challenges, based on judgments by the reviewer)

- What are the defining differences between GMOs and non-GMOs? The technology that is applied, or the traits that the organisms carry? While it is the (potentially harmful) traits that one wants to control, the regulations are defined by the techniques employed.
- Which properties/practical measures can reduce risk for gene flow? Can for instance mitochondrial/chloroplastic transgenes pose lower risk, thus be treated differently from regular transgenes?
- Systems for accountability, liability and compensation.
- The issue of organic farming becoming a sink of transgenes must be examined, including legal and economic aspects.
- Imports of meat, and of feed from 3rd party countries, increase likelihood of meat based on GM feed. This could create an urge for a labeling system for such products. However, should this be a mandatory labeling of meat based on GM feed, or should it be voluntary labeling of non-GM meat?

LITERATURE

Linnestad, Casper (ed) (2005): Co-existence. Report, The Norwegian Biotechnology Advisory Board. ISBN 82-91683-34-4.
http://www.bion.no/publikasjoner/20050905_Sameksisten_web.pdf

AUTHOR OF THE REVIEW

Jon Magnar Haugen

EVALUATING THE CRITERIA OF SUSTAINABILITY AND SOCIETAL IMPACTS IN RELATION TO GM FOOD – THE WORK OF THE NORWEGIAN BIOTECHNOLOGY ADVISORY BOARD 7.3

BACKGROUND AND BASIC DATA

GM food on the market today is partly consisting of living entities, for instance intact corn grains or entire fruits or vegetables (containing viable seed). In Norway, such commodities must be evaluated not only in the food legislation context, but also in relation to the act relating to the production and use of genetically modified organisms. This act strongly emphasizes that the deliberate release of genetically modified organisms (GMOs) should have no detrimental effects on either health or the environment (at the same taking into account that we are not living in a risk-free society). This emphasis is fully in line with the legislation of other nations concerning the regulation of GMOs. Distinct from the regulations of most other nations, however, the Norwegian Gene Technology Act also stresses that the deliberate release of such organisms should represent a "benefit to the community" and enable "sustainable development". In general, the GM applications under directive 2001/18/EC or regulation 1829/2003 do not contain information that makes such a comprehensive GMO evaluation process possible.

It is not self-evident how "sustainability" and "benefit to the community" should be considered in terms of the practical application of the Act. The Norwegian Biotechnology Advisory Board is appointed by the Norwegian government with a mandate to give advice on these additional requirements.

The Norwegian Biotechnology Advisory Board

The Norwegian Biotechnology Advisory Board (NBAB) is an independent body established in 1991. The Board is founded in the Act relating to the application of biotechnology in medicine and the Act relating to the production and use of genetically modified organisms. The Board consists of 21 members, including 13 persons mandated by the government, and 8 persons mandated by different organisations. Representatives of six ministries have observer status. The Board's secretariat has seven to eight employees.

The main tasks of the NBAB are to identify and examine the ethical questions raised by applications of modern biotechnology on humans, animals, plants and microorganisms and to provide advice that can assist policy-making and stimulate public debates on the issues. The Board gives recommendations both concerning the development of general regulation, and in relation to specific submissions for deliberate release.

The work of NBAB can be described as a form of technology assessment done by a standing expert committee, with a specific emphasis on sustainability and societal

impacts. The activities involve meetings, dissemination, statements etc. Statements and advice are generally not based on consensus, but on majority votes.

This document explores how the NBAB interprets and addresses the issues of sustainability and societal impacts. The text is based primarily on conclusions from activities that were dedicated to discuss these issues broadly. However, insights from statements and advice in specific cases are also included.

MAJOR OUTCOMES OF THE PROJECT

The Norwegian Biotechnology Advisory Board finds that it is not clear whether the provisions relating to "benefit to the community" and "sustainable development" are to be considered as additional requirements or as a softening-up of the requirement for non-detrimental effects on either health or the environment. "Sustainable development" and "benefit to the community" can be understood as either:

- additional requirements to the absence of detrimental effects on health and the environment; or
- a softening-up of the requirement of non-detrimental effects; or
- an additional requirement that alone could be sufficient grounds for refusing approval or for a softening-up of the requirement of non-detriment.

According to the first alternative, the requirement would be that, in addition to having no detrimental effects on health and the environment, the "deliberate release represents a benefit to the community and a contribution to sustainable development". If the deliberate release fails to fulfil this requirement, the recommendation would be to reject an application for approval. Under this alternative, any softening-up of the requirement of non-detriment would be impossible.

The second alternative does allow for the approval of deliberate releases even when the possibility of detrimental effects on health and the environment have been established, if it can be demonstrated or argued that the "deliberate release represents a benefit to the community and a contribution to sustainable development". Consequently, the requirements of "sustainable development" and "benefit to the community" are being used as an opportunity for softening up or counterbalancing the requirement of non-detriment, but may not be applied as an additional requirement that alone could be sufficient grounds for rejecting an application for approval.

In the third alternative, the requirement of "benefit to the community" and/or "sustainable development" could constitute independent grounds for rejecting an application for approval. Furthermore, "sustainable development" and "benefit to the community" can be used to soften up the requirement of non-detriment. This could be considered as a combination of the first two alternatives and is the alternative the NBAB judges to be the best interpretation of the Act.

In the opinion of the NBAB, the Norwegian Gene Technology Act should be interpreted to mean that the requirements of "sustainable development", "benefit to the community" and other "ethical and social considerations" represent prerequisites that

alone could carry decisive weight against granting an application, but that should also be considered in relation to, and weighed against the risk of detrimental effects, when such risk is low.

Hence, an assessment of an individual GM application (also GM food, se above) will have the following structure:

1) Danger of detrimental effects on health and the environment:

   - what are the possible negative consequences?
   - what is the likelihood of such consequences occurring?

2) The precautionary principle:

   - is the risk assessment associated with justified uncertainty?
   - is there a possibility of substantial or irreversible harm?

3) Is it:

   - in compliance with the principle of "sustainable development"?
   - of "benefit to the community"?
   - "ethically and socially justifiable"?

Sustainable development

"Sustainable development" could be said to build on a series of ideas, including the following:

- the idea of the global effects of human activities;
- the idea of ecological limits and that these limits have been exceeded in several areas;
- the idea of meeting basic human needs;
- the idea of just distribution between generations;
- the idea of just distribution between wealthy and poor nations;
- the idea of a new form of economic growth.

This final point indicates that it is not a matter of just any form of economic growth. On the contrary, two types of qualification are required. Firstly, it should be economic growth involving an absolute – and not only a relative – efficiency improvement in the use of energy and other natural resources. Secondly, this economic growth must entail a more balanced distribution between poor and wealthy nations.

The six points listed above can serve as a structure for assessing whether the deliberate release of a genetically modified organism is in compliance with the requirements of "sustainable development". The same type of checklist questions could be asked for each of these points as those considered when assessing health and environmental risks and the precautionary principle. The responses to and the discussion of all the questions would, in this case, provide an overall picture of the extent to which there is compliance or non-compliance with the requirements set.

Furthermore, a clarification of the relationship between biodiversity (i.e. diversity of genes, species and ecosystems) and ecological sustainability is needed. Effects on

biodiversity would be assessed in relation to detrimental effects on health and the environment and the precautionary principle, thus be included in standard assessments also within the EU. However, relating biodiversity to the question of "sustainable development" implies a shift of focus in time and space. Assessments of the possible detrimental effects on health and the environment refer primarily to local, regional and national contexts. Assessments of the issue of "sustainable development" apply globally and also, to a longer time span (generations). When diversity is reduced, humankind's opportunities of promoting "sustainable development" are reduced accordingly. Preserving biodiversity represents a form of long-term life insurance – for the existence of species, ecosystems and humankind. Another aspect worth underlining is the type of ethical assessments associated with the notion of intrinsic value. The concept of "sustainable development" encompasses two different types of intrinsic value. The first is nature's own intrinsic value; the second applies to certain forms of humankind's absolute intrinsic value. In the opinion of the NBAB, assessments of this kind might be more usefully made in relation to the issue of "other ethical and social considerations" and not in relation to the issue of "sustainable development".

Global effects

- Is biodiversity affected on a global scale?
- Is the functional capacity of ecosystems affected?
- Do these effects differ between production and use?

Ecological limits

- Is the efficiency of energy use affected?
- Is the efficiency of other natural resource use affected?
- Is the distribution between the use of renewable and non-renewable natural resources affected?
- Are discharges of pollutants with a global/transboundary range affected?
- Are emissions of greenhouse gases especially affected?
- Do these effects differ between production and use?

Basic human needs

- Is the fulfilment of basic human needs affected?
- Do these effects differ between production and use?

Distribution between generations

- Is the distribution of benefits between generations affected?
- Is the distribution of burdens between generations affected?
- Do these effects differ between production and use?

Distribution between rich and poor

- Is the distribution of benefits between rich and poor countries affected?
- Is the distribution of burdens between rich and poor countries affected?
- Do these effects differ between production and use?

Economic growth

- Is economic growth's demands on energy and other natural resources affected?
- Are economic growth's global/transboundary environmental impacts affected?
- Is economic growth's distribution between rich and poor countries affected?
- Do these effects differ between production and use?

Comment

Compliance with the requirements of "sustainable development" will have to be based on an overall assessment and discussion of all these questions. However, not all the questions above may be relevant in all cases.

Benefit to the community

As mentioned above, the concept of "benefit to the community" appears in the Gene Technology Act as one of several criteria for granting an application. It is, in any case, a complex concept, for which neither the Act itself nor its legislative history provides any clear guidance as to how it should be understood. In the current context, the NBAB has opted for a relatively pragmatic approach, and try to ask some "check-list questions" that may be relevant:

Product characteristics

- Is it reasonable to say that there is a need for the product in terms of demand or otherwise?
- Is it reasonable to say that the product will solve or possibly contribute to solving a societal problem?
- Is it reasonable to say that the product is significantly better than equivalent products already on the market?
- Is it reasonable to say that there are alternatives that are better than the product in terms of solving or possibly contributing to solving the societal problem in question?

Production and use of the product

Among the relevant aspects to be considered are:

- Does the product contribute to creating new employment opportunities in general and in rural areas in particular?
- Does the product contribute to creating new employment opportunities in other
- countries?
- Does the product create problems for existing production whose existence should otherwise be preserved?
- Does the product create problems for existing production in other countries?

(This list of questions is not meant to be exhaustive, but is meant primarily to serve as an indication of the type of questions that should be considered).

Comment

Any assessment of benefit to the community must be based on a discussion of the responses as a whole. However, it should be emphasized that every question may not be equally relevant in all instances.

IMPACTS AND FOLLOW UP OF THE PROJECT

The statements made by the NBAB are generally regarded as high impact contributions by the competent authorities. Such statements are publicly available and quite often they spark a public debate. The statements are communicated to the decision-makers both through letters and by regular meetings, as the decision-makers have status as observers during the relevant NBAB discussions. NBAB is planning a conference on sustainability and GMOs late in 2007.

CHALLENGES IDENTIFIED IN THE PROJECT

Operationalizing the criteria of sustainability and societal benefit in relation, for instance, to specific submissions for deliberate release, remains challenging. Even more challenging than defining the "checklists", is to access relevant information regarding the products. As Norway appears to be unique in using these criteria, submissions within the EU do not generally include relevant data. And so far, applicants do not seem to find it worthwhile to provide such data just for Norway. Without relevant documentation, Norway cannot fully undertake the relevant assessments, and thus, based on this lack of information, Norwegian authorities may end up not authorising a given product. However, the EU might not consider such terms legitimate to reject an authorisation, which could be necessary under Norway's commitment as member of the EEA. Thus, a number of questions regarding the harmonization of regulation within the EU/EEA remain.

As described above, there also remains a question of whether criteria of sustainability and societal impacts should be interpreted as additional requirements to the absence of detrimental effects on health and the environment; or as a softening-up of the requirement of non-detrimental effects.

LITERATURE:

Linnestad, Casper (ed) (2003): Sustainability, benefit to the community and ethics in the assessment of genetically modified organisms. Discussion Paper, The Norwegian Biotechnology Advisory Board. ISBN 82-91683-21-2. Web: http://www.bion.no/publikasjoner/sustainability.pdf

The Norwegian Biotechnology Advisory Board: http://www.bion.no

The Norwegian Gene Technology Act: http://www.regjeringen.no/en/doc/Laws/Acts/Gene-Technology-Act.html?id=173031

AUTHOR OF THE REVIEW

Casper Linnestad

SWITZERLAND 8.

PUBLIFORUM »GENETIC TECHNOLOGY AND NUTRITION« (1999) 8.1

BACKGROUND OF THE PROJECT

The *PubliForum on Genetic Technology and Nutrition* took place in 1999, under the lead of the Swiss Centre for Technology Assessment, referred to below as TA-SWISS. This centre has been set up in 1992 by the Swiss Parliament and is attached to the Swiss Council for Science and Technology. Its mission is to support the political decision-making process, firstly by carrying out expert analyses, and secondly by canvassing the opinions of the citizens themselves through participatory projects. The *PubliForum on Genetic Technology and Nutrition* was the second participatory project ever organised by TA-SWISS[13].

The aim of the *PubliForum on Genetic Technology and Nutrition* was to set up an encounter between the people actively involved in the development of genetic technology (i.e. scientists, but also industry, public authorities and NGOs) and the public. Genetically modified organisms (GMOs) had already been extensively discussed about a year before, as Swiss citizens had to vote on an initiative demanding a halt to genetic engineering in Switzerland (the "initiative for genetic protection"). During the political campaign preceding the vote, all of the interested parties involved debated the issue at great length, but the fact that the rules of the game did not allow for a win-win situation (voters had to answer "yes" or "no") meant that it was difficult to get a real dialogue going. For the PubliForum on genetic technology in nutrition, the rules of the game were changed, to allow for win-win situations. The inclusion of ordinary citizens in the process would then provide greater awareness of their wishes, alternative solutions and needs. It would also provide an opportunity to learn about their argumentation patterns: how did they perceive and understand the implications of genetic technology in nutrition, what were their hopes and fears, and on which basic values and standards did they judge the issue?

Discussing these questions was considered as crucial, as the debate on GMOs was, at that time, far from being closed. As a matter of fact, when the Initiative for Genetic Protection had been first discussed by Parliament in 1996 and 1997, the Federal Assembly charged the government to fill all juridical gaps regarding genetic engineering in the non-human domain (Motion GENLEX). At the time of the PubliForum, government was working on this adaptation of the legislation[14].

13 TA-SWISS has been undertaking participatory projects since 1998.

14 The Swiss government presented its conclusions regarding the GENLEX motion in 2000, in form of a modification of the Law on environmental protection. This govern-

BASIC DATA ABOUT THE PROJECT

The *PubliForum on Genetic Technology and Nutrition* is a participatory project, using the "consensus conference" model developed by the Danish Board of Technology. This model has been adapted for the multilingual reality of Switzerland: instead of 15 citizens being invited to discuss the effects of new technologies, about 30 citizens from all parts of the country were invited to discuss and an interpretation service has been offered so that each participant could use their own language. All in all, the citizens met three times:

- In a first preparatory week-end, participants could meet and get to know each other, familiarize with the working method and inform themselves about the subject implications of genetic technology in food and plants. They also selected those aspects which they wanted to investigate more closely during the PubliForum.
- At the second preparatory weekend, the panel members defined their questions more clearly and chose the information persons who were to reply to these questions during the main PubliForum session. Their questions were related to research, environment, health, ethics and economics.
- The actual PubliForum lasted three days. During the first two days, which was open to the public, the information persons answered the questions of the citizen panel. Then the panel went behind closed doors and had 24 hours to draw up a report.

In order to create an as neutral as possible framework for the PubliForum, an accompanying group had been formed consisting of representatives from industry, research, administration, media, politics and various non-governmental organisations (NGOs). This accompanying group had the task of putting the content of the PubliForum into concrete terms and to make sure that the preparation and realisation of the event took place in an as balanced as possible way. The accompanying group was also responsible for the preparation of information sheets meant to help the Citizen Panel familiarise themselves with the subject. Another assignment was that of helping find reference persons to answer the questions and, finally, influence could be made on the composition of the Citizen Panel.

MAJOR OUTCOMES OF THE PROJECT

In its report, the Citizens' Panel acknowledged that today's level of scientific knowledge does not permit the existence of specific risks resulting from genetically modified organisms to be ruled out. And, as one cannot quantify these risks, the Panel was not in a position to make any judgement on their acceptability. Half of the Panel,

mental proposal addressed many issues, such as biodiversity preservation, civil responsibility regarding GM crops, authorization procedures and the introduction of a declaration for GM products. But the Parliament, after having examined this proposal, decided to write a specific law on genetic engineering. It took more than two years of political debate for the Parliament to come to a final text.

however, was of the opinion that genetic technology is an encroachment on life-processes, whereas the other half saw no difference between genetic technology and traditional production methods. This gap could be seen in the notion of imposing a moratorium on the production and marketing of genetically modified organisms[15], which was endorsed only by a slender majority of the Panel. Despite these differences of opinion, the Citizens' Panel agreed that freedom of choice for consumers should be maintained and that GMOs should thus be clearly labelled. It also demanded more research on risks and monitoring studies and showed some concern about the financial independence of public research.

IMPACTS AND FOLLOW UP OF THE PROJECT

The *PubliForum on genetic engineering in nutrition* caught a great deal of attention of the media and political groups, mainly for its proposal of a moratorium made by the Citizens' Panel. TA-SWISS could also present the PubliForum's results in the Parliamentary commission for science, education and culture. Many articles also were published in specialized magazines and journals.

Interestingly, what was a minority position at the time of the publication of the results of the PubliForum (the idea of a moratorium was in fact only defended by ecologists groups) became, with time and the support of farmers' representatives (who became conscious, through the PubliForum and other surveys, that consumers didn't want to consume GMO crops), a potentially majority position. Indeed, during the discussions on the new law on genetic engineering by the relevant Parliamentary Commission, a slender majority amended the law with a moratorium of 5 years (excluding field trials for scientific purposes). This proposal was ultimately rejected in the final vote in Parliament, where the Commission's slender majority was unable to gain enough support for its proposal. Interestingly, groups in favour of a moratorium tried a second time to anchor a 5-year moratorium on GMOs in Swiss legislation. This time, they tried to integrate it in the agriculture law, which was revised in 2003. And for a second time, they just failed[16]. Parallel to all these parliamentary debates, environmental groups, consumer associations and farmers group have launched an Initiative demanding a five-year moratorium on the farming GM crops for use in food (the use of GM crops for research purposes would be authorized under strict conditions). The group collected over 120'000 signatures in only seven months[17].

This initiative was contested by the government and Parliament (whereas a minority of the representatives had been supporting it), as well as by research and industry

15 Clearly defined field trials (specifically by public institutions) should, however, be permitted and supervised in order to obtain extended knowledge on any risks.

16 The proposal was in fact accepted by the lower chamber of the Parliament (National Council), but rejected by the upper chamber (State Council). In an ultimate vote, the lower chamber decided to align its position to that of the State Council in order not to bring down the whole revision.

17 To be valid, an initiative must be supported by 100'000 citizens and have to be found in a period of 18 monthes.

representatives. In November 2005, 55.7% of the Swiss citizens accepted the initiative demanding the five-year moratorium[18].

CHALLENGES IDENTIFIED IN THE PROJECT

In its report, the Citizen's Panel gave its opinion on several topics and formulated several recommendations. From these, we can consider that the challenges for GM plants and food, seen from a citizen perspective, are the following:

- The freedom of public research must be guaranteed and public funding should remain assured.
- The current supervisory mechanisms are sufficient, but citizens call for an intensified dialog between the general public and research.
- GMO-specific risks cannot be ruled out. Therefore, monitoring is absolutely necessary, in order to be able to estimate risk potential in a better way.
- Switzerland needs to have trained personnel, able to carry out monitoring research into GMOs.
- Backing out of genetic technology in the sense of a unilateral Swiss policy doesn't seem to be an option any more, since this would lead to important economic disadvantages, primarily in the Swiss research area and secondarily because of the dependence of Switzerland on imported raw materials, which could in the future contain GMO-components. Nevertheless, the question on how far a need for the use of genetically modified organisms exists in Switzerland must be answered.
- The existence of traditional, genetic-technology-free agriculture as well as organic farming must be guaranteed, in order to provide consumers with a free choice, both today and in the future. Moreover, instead of GMO production, organic farming could be a chance for Switzerland, as at the moment of the PubliForum no contamination is to be feared.
- The smaller seed producers may disappear in the long term because they will not be able to compete with large multi-national industry, which would mean that dependence could develop.
- The patenting of living organisms is for many of the members of the panel not acceptable. On the other hand, patenting creates more transparency, as the applicant has to publish his research results before the patent is granted. It is also understandable that the high costs of research have to be made to pay for themselves somehow.
- The unequivocal tracing of damage back to a GMO is very difficult. If such evidence exists, it must in all cases be possible to prosecute those responsible (e.g. the producer).

18 A survey conducted just after the vote showed that among those who voted against the initiative, 13% were actually convinced to vote against gene technology. In other words, these persons didn't correctly understand that the question they had to answer ("do you agree or not with the initiative and, eventually, the initiative should have been accepted by about 68% of the voters – an extremely high score for a popular initiative (Hirter and Linder 2006).

LITERATURE

PubliForum «Genetic Technology and Nutrition». Citizen Panel Report, Centre for Technology Assessment, TA-P1/1999e, Bern, 1999 (http://www.ta-swiss.ch/a/erna_gent/1999_TAP1_gentech_e.pdf)

AUTHOR OF THE REVIEW

Danielle Bütschi

RIBIOS FORUM »THE FUTURE OF PLANT BIOTECHNOLOGY IN SWITZERLAND« (2003) 8.2

Excerpts from the report: "The Future of Plant Biotechnology in Switzerland", Les Cahiers du RIBios, No7

BACKGROUND OF THE PROJECT

The Forum entitled « The future of plant biotechnology in Switzerland » took place at the University of Lausanne on November 3rd, 2003. It was jointly organised by the RIBios (Biosafety Interdisciplinary Network, based at the Graduate Institute for Development Studies of the University of Geneva) and by the Interface sciences-société of the University of Lausanne.

The aim of this Forum was to bring together stakeholders involved in the decisions about experimental field releases of transgenic plants in Switzerland.

BASIC DATA ABOUT THE PROJECT

The participants of the Forum were representatives of three main groups of stakeholders: public scientists involved in plant biotechnology research, the governmental bodies involved in the decision-making process, and other institutions directly involved in science policy at the national level. All the participants had been invited personally, in order to make clear that they should speak in their own name rather than in their institution's name. This sensitive issue was dealt with by agreeing with the participants that no material would be published on the content of the debates without their prior review of the documents.

Before the forum, the participants received a position paper written by the organisers. This paper was divided into six sections corresponding to important topics that would be discussed during the forum. It was aimed at giving some factual information, but also some analytical overview to stimulate the debate.

The forum lasted one day. The debates were organised by topics. In the morning, three questions were discussed: «Risk negotiation», «Coordination at the level of assessment and decision» and «Coherence between research and environment policies». In the afternoon the debates focused on «"Socially robust" research policies», «Biotechnological research in Switzerland» and «Decision-making under uncertainty: the controversial implementation of precaution».

The organisers decided to adopt a non-directive strategy for the debate regulation. Three persons were assigned to that task. One was in charge of handing over to the participants and to keep the schedule. The two other persons acted as facilitators by introducing factual or analytical elements pertinent to the debate, and by redirecting the discussion when it was clearly out of the topic of this forum.

MAJOR OUTCOMES OF THE PROJECT

Following the forum, a document restituting the main discussed points have been published in the "Les Cahiers du Ribios". The core of the text is made of participants' quotations, which are introduced by a short summary.

CHALLENGES IDENTIFIED IN THE PROJECT

The richness and diversity of the discussions during the forum show that many open questions are remaining with respect to research on GMOs. The lecture of the report shows that there is a certain frustration from the side of researchers, or at least a difficulty to cope with the social and political dimension of the issue.

CHALLENGES IDENTIFIED WITH RESPECT TO PUBLIC RESEARCH:

- To regain the public's confidence, it is necessary to define research priorities that correspond to agronomical problems which have been clearly identified and which benefit from political support.
- The distinction between fundamental and applied research must be taken into consideration. There is a sharp difference between commercialisation and experimental releases. The frontier between these two facets of research is nevertheless difficult to draw. This distinction is however important as soon as risk assessment is concerned. The standards and procedures used in the assessment do indeed depend on the nature of the trials, experimental or commercial.
- The position of Switzerland on the international scene in terms of knowledge and competitiveness in plant biotechnology is an issue to consider. There is a risk to see the competitiveness of Switzerland in the field of plant biotechnology decrease, as a result of industrial delocalisations and disinterest on behalf of students. While Switzerland has still a good knowledge base in the field of plant biotechnology, research is locked in, in part because of the difficulty to make field tests experiments.
- Research is facing important economical, political or administrative constraints. These difficulties have prevented researchers from accumulating the knowledge needed to perform an adequate risk assessment of the plants under development.
- The time lag between the application for an experimental release and the decision of the authority may be incompatible with the scientific rationale.

CHALLENGES IDENTIFIED WITH RESPECT TO RISKS:

- Rather than talking about the risks of doing research, one should also take into account the potential benefits, namely benefits that will derive from this research in the future but are still not known. In other words, the risks of doing research should be balanced with the risks of not doing it.
- Risks related to a new technology such as GMOs must not be discussed in isolation but rather in comparison with the risks of the technology it is replacing.

CHALLENGES IDENTIFIED WITH RESPECT TO PUBLIC DEBATE:

- The perception of risk by the public may sometimes be irrational. Risks related to GM food are typically over-estimated in comparison to other risks.
- Some participants pointed out the fact that communication policies have not been able until now to reverse this trend, and thus generate a positive picture of plant biotechnology in the public.
- It is more difficult to find support in the public for innovation, than to exploit the fears of the public related to these innovations.
- There is clearly a lack of communication in the field of plant biotechnology. The scientific community should do more grassroot work. However, the social acceptability of GMOs does not onlydepend on the level of information. In other words, more information does not necessarily end up with more people accepting the technology:
- There is a need to find new forms of public debate. Moreover, people and groups concerned by new technologies shoudl be included upstream (i.e.when a technology is still at the stage of research), so as to make research policies "socially more robust".

CHALLENGES IDENTIFIED WITH RESPECT TO DECISION-MAKING PROCESSES:

- There is a risk that scientific arguments are "instrumentalised" by political authorities in the decision-making process.
- Science should be more able to recognize the limits of its knowledge. This would surely be a way to improve society's confidence in science.
- Any decision in the field of risk mangement is somehow political, since a zero risk level is not achievable. Political decisions consist therefore in determining an acceptable level of risk:

LITERATURE

The Future of Plant Biotechnology in Switzerland", Les Cahiers du RIBios, No7, RIBios and IUED, Geneva, 2005.
(http://www.ribios.ch/en/documents/docs/Brochurespdf/Brochure7Forum.pdf)

AUTHOR OF THE REVIEW

Danielle Bütschi

REPORT ON THE COEXISTENCE OF DIFFERENT GM AND NON-GM AGRICULTURAL CULTIVATION SYSTEMS (AGROSCOPE RECKENHOLZ-TÄNIKON RESEARCH STATION ART, 2005) 8.3

BACKGROUND OF THE PROJECT

Worldwide GM0 cultivation is increasing year by year. Even though there is little likelihood of such cultivation in Switzerland at present, cultivation of GMOs in the future cannot be excluded. According to the Gene Technology Law (GTL), when GMOs are grown, non-GMO production and consumer's freedom of choice must be safeguarded. So-called "coexistence" must be guaranteed by segregating production flows (Warenflussstrennung) during the whole productions chain (from the field to shelves of the stores), by regulations and by technical measures. In this respect, legal threshold values were defined because it is impossible to rule out mixing completely no matter how much care is taken. They specify the percentage of genetically modified material which can be included in food and animal feeds without having to label them as «genetically modified». In line with the EU, a threshold limit of 0.9% is set in Switzerland. This limit is for approved GM crops. For non-approved GM crops there is, theoretically, a zero-tolerance.

Agroscope Reckenholz-Tänikon Research Station ART was commissioned by the Federal Office for Agriculture (FOAG) to carry out a study on whether GM and non-GM agricultural systems in Swit-zerland can coexist from a scientific and technical point of view within the present legislative framework. Maize, wheat and oilseed rape were selected as model crops.

BASIC DATA ABOUT THE PROJECT

The aim of the project was to present a concept for a coexistence of GM and non-GM cropping systems in Switzerland. In a first step mechanisms were analysed which can lead to a mixture of agricultural products during cropping. Subsequently, technical and organisational measures were listed which can minimize or prevent mixing. The study was limited to the agricultural production, i.e. from planting to the delivery of the harvest to storing or processing facilities. The cost of segregation of different cropping systems varies according to the specific biological characteristics of the crops and according to the level of segregation required. Three model crops (maize, wheat and oilseed rape) have been chosen as case studies to show what specific measures are needed in order to maintain the legally binding GMO threshold for food and feed.

The study was entirely funded from the Agroscope Reckenholz-Tänikon Research Station own resources, with no third party funding that could have cast doubts upon their independence. The scientists based their statements on objective foundations.

MAJOR OUTCOMES OF THE PROJECT

The investigations on the possibilities and limits of the «coexistence of GM and non-GM cultivation systems in Switzerland» reached the conclusion that, with the requisite crop-specific distances, discussion and agreement between farmers, and careful segregation during product handling on the farm, the cultivation of GM maize, GM wheat and GM oilseed rape in Switzerland would be technically possible.

This assessment was based on the threshold limit of 0.9 % GM content and covered cultivation up to the delivery of the harvested material at the collection point. Additional time and costs related to coexistence was not examined. The measures necessary for coexistence are detailed in the "Schriftenreihe der FAL" No 55[19]. They are for example:

- Usge of certified seed
- Optimal soil preparation after the harvest and cultivation of non-GM crops before subsequent GM planting.
- The degree of out-crossing between fields with GM and fields with non-modified plants of the same species can be reduced through isolation distances and "buffer zones" between GM an non-modified crops.. Moreover, it is possible to avoid that cross-pollination happens at the same time.
- The intermingling of GM and non-modified crops in various machines can be avoided by carefully cleaning them after having used them for GM-crop fields.
- Segragation during harvest, transport, storage and processing of the crops, as well as a documentation of these processes is essential to minimize intermingling.

IMPACT AND FOLLOW UP OF THE PROJECT

In June 2005, a conference named "Coexistence of GM and non-GM crops - scientific data, practical applications and perspectives for the next decade has been organised by the authors of the study. About 120 Swiss and international experts discussed the issue of coexistence (more info on the conference on: www.coexistence.ethz.ch/). The group took part in many other conferences dedicated to the issue of coexistence, in Switzerland or at the European level. But, at the time being, it doesn't carry any project on the theme.

In June 2006, The Federal Office for Agriculture adapted the legislation on coexistence (ordinance on coexistence) and considered some elements analysed in the study. There is, however, no evidence on how far the study influenced the legislative process.

19 Study summary as pdf (http://www.reckenholz.ch/doc/en/publ/schrift/sr55vz.html): To order Study (http://www.reckenholz.ch/cgi-bin/sql/order.pl?ref=4&lang=en&sort=-feld_0).

CHALLENGES IDENTIFIED IN THE PROJECT

- How to guarantee coexistence? This implies regulatory, technical and organisational aspects.
- The probability of intermingling depends on the biological properties of the various plants. The necessity for coexistence measures must then be separately assessed, for each cultivated plant.

LITERATURE

Olivier Sanvido, Franco Widmer, Michael Winzeler, Bernhard Streit, Erich Szerencsitz, Franz Bigler, 2005, Koexistenz verschiedener landwirtschaftlicher Anbausysteme mit und ohne Gentechnik, FAL-Schriftenreihe Nr. 55, edited by: Agroscope Reckenholz-Tänikin Research Station ART, Switzerland (http://www.art.admin.ch)

AUTHOR OF THE REVIEW

Danielle Bütschi

COORDINATION MEETING OF INSTITUTIONS OFFERING BIOSAFETY-RELATED TRAINING AND EDUCATION PROGRAMS (2004) 8.4

Excerpts from the "REPORT OF THE COORDINATION MEETING OF INSTITUTIONS OFFERING BIOSAFETYRELATED TRAINING AND EDUCATION PROGRAMS",(http://www.biodiv.org/doc/meetings/bs/bscmet-01/official/bscmet-01-01-en.pdf)

BACKGROUND OF THE PROJECT

The first Coordination Meeting of institutions offering biosafety-related training and education programs was held 4-6 October 2004 in Geneva, Switzerland. It was organized by the Swiss Agency for Environment, Forests and Landscape (SAEFL) in collaboration with the CBD Secretariat, the UNEP/GEF Biosafety Unit and the Geneva Environment Network.

Thirty-seven (37) participants from 28 institutions attended the meeting, including representatives from academic and other organizations. The participants came from all over the world (Belgium, Namibia, Switzerland, Mexico, New Zealand, USA, England, Netherlands, China, Kenya, Norway, Cuba, Thailand, Canada, Austria, Chile, Italy, Japan).

The meeting was a follow-up to the offer made by the Government of Switzerland at the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP MOP). In its decision BS-I/5 on capacity-building, the COP-MOP emphasized the need for a coordinated approach towards capacity-building at all levels and accordingly established a Coordination Mechanism to promote partnerships and maximize complementarities and synergies between various capacity-building initiatives contributing to the effective implementation of the Protocol. In this regard, the Government of Switzerland offered to sponsor a coordination meeting for representatives of academic and research institutions actively involved in education, training and research programs in biotechnology and biosafety in the autumn of 2004. The Swiss Government contracted RIBios – Réseau Interdisciplinaire Biosécurité – (Biosafety Interdisciplinary Research Network), which is part of Institut Universitaire d'Études du Développement (IUED), to organize the meeting.

The primary objective of this meeting was to bring together representatives of institutions involved in biosafety training and education to share information and compare notes regarding their ongoing programs and to learn more about the about the Protocol and the capacity-building needs and priorities for its effective implementation. The specific objectives of the meeting were:

- To review the current status ("state of the art") regarding training and education programs in biosafety, including consideration of the draft compendium of existing programs;
- To review the needs and priorities of countries and discuss ways and means for enhancing training and education programs to respond to those needs and support effective implementation of the Protocol;
- To identify and discuss key components of biosafety training and education programs;
- To explore mechanisms to enhance coordination, networking and collaboration among institutions offering biosafety training and education programs.

BASIC DATA ABOUT THE PROJECT

The agenda of the meeting consisted of two parts. The first part (day one) included presentations on: overview of the Cartagena Protocol and the COP-MOP decisions; the capacity building needs of countries and the role of training institutions in addressing those needs; the experience from the UNEP-GEF projects on capacity-building in biosafety and overview of the draft compendium. These were followed by short presentations by participants on their ongoing and planned programs.

The second part of the meeting included three plenary session discussions and one session of group discussions. The deliberations focused on the compendium; ways and means to improve biosafety training and education programs to address the needs of different target audiences; possible mechanisms for future networking/ collaboration and the next steps.

MAJOR OUTCOMES OF THE PROJECT

Overall, the meeting was a big success. It provided the first opportunity for institutions offering training and education in biosafety to meet and interact and laid a good foundation for their future collaboration and active involvement in biosafety processes at international, regional and national levels.

The meeting represented an important first step in preparing education and training institutions to play an effective role in building capacity for effective implementation of the Cartagena Protocol on Biosafety and other relevant instruments. It provided them with an insight into what the key training need are from the point of view of the countries that are now in the process of establishing and implementing their national frameworks and an the opportunity to learn more about what other institutions are offering and develop ideas for improving their programs.

The main outcome of the meeting was the development of a common format (questionnaire) for the compendium of existing biosafety training and education programs. The meeting also developed a set of draft recommendations for consideration by COP-MOP, governments, education and training institutions and other stakeholders in order to enhance biosafety training and education in support of the Protocol implementation.

IMPACT AND FOLLOW UP OF THE PROJECT

No concrete action has been implemented after the coordination meeting. Nevertheless, the meeting created a dynamic, in the sense that Malaisia University decided to organise a second meeting in April 2007, in Kuala Lumpur. The RIBios network (which organised the first meeting) will be participating and hopes that it will be able to interact and create synergies with african universities, so as to establish education programmes on biosecurity.

CHALLENGES IDENTIFIED IN THE PROJECT

While the meeting had resulted in fruitful deliberations, it also raised many new important questions. For example, questions were raised regarding:

- how to effectively to involve the newly trained experts in biosafety activities of their own countries;
- how to insure the sustainability of the biosafety training and education programs,
- how to mobilize adequate funding for biosafety training programs and for scholarships to support students from developing countries;
- how to insure the availability of technical infrastructure in all countries for the effective delivery of biosafety education and training programs and
- how to fill the gaps in the existing courses. All these questions underline the arduous challenge ahead.

LITERATURE

Report of the coordination meeting of institutions offering biosafety related training and education programs, 4-6 october 2004, by the Swiss Agency for Environment, forests and landscape, the CBD secretariat, the UNEP/GEF Biosafety Unit and the Geneva Environment Network.
(http://www.biodiv.org/doc/meetings/bs/bscmet-01/official/bscmet-01-01-en.pdf)

AUTHOR OF THE REVIEW

Danielle Bütschi

UNITED KINGDOM 9.

PROJECTS SINCE 2000

BACKGROUND

The most important activities concerning GM crops and food carried out in the UK since 2000 are

- the government commissioned dialogue on GM issues (GM dialogue)
- the Farm-scale evaluations (FSEs) of GM crops

As the latter study is scientific, this review will focus on the GM dialogue. However it should be noted that the FSE's were one of the pieces of information used by the government to inform its policy on GM crops in 2004 – see section on Impact and follow-up. POSTnote 211 *GM crops in the UK* (2004) gives an overview of the GM dialogue and the FSEs and discusses the issues raised. It was published prior to the Government setting out its policy on GM in March 2004. Other POSTnotes in this area published since 2000 are POSTnote 172 *Labelling GM foods* (2002) and POSTnote 146 *GM farm trials* (2000).

GM DIALOGUE

The GM dialogue ran from May 2002 to January 2004 and consisted of three main strands:

- GM science review –an assessment of the state of current scientific knowledge on GM crops and foods;
- economics review - an evaluation of the potential costs and benefits of GM crops in the UK;
- GM Nation? - a nationwide public debate to find out what people really think about GM.

Information on each strand and its outcome is discussed below.

GM SCIENCE REVIEW[20]

The science review was led by the Government's Chief Scientific Adviser working with the Chief Scientific Adviser to the Secretary of State for the Environment, Food and Rural Affairs, and with independent advice from the Food Standards Agency. The science review was carried out by a 26-member panel comprised of leading scientists from a spectrum of disciplines and perspectives, two lay representatives, a social scientist and a leading scientist with cross membership with the Public Debate Steering Board. It considered peer-reviewed published scientific literature and was

20 http://www.gmsciencedebate.org.uk/

focused on science-based issues identified by the public and the scientific community.

In July 2003 the panel concluded that for current GM crops and GM food:

- the risk to human health is very low;
- these crops are unlikely to invade the countryside and become problematic plants;
- it is unlikely that these crops, if consumed, would be toxic to wildlife;
- there is insufficient information to predict the long-term impact of the herbicide regimes associated with herbicide-tolerant GM crops on wildlife;
- the balance of risks and benefits will vary for each GM crop, therefore case-by case regulation is appropriate.

The panel reconvened to consider comments on its July report and the results of the FSEs, reporting in January 2004 that:-

- none of the new research published since the first Report significantly altered the earlier conclusions;
- the FSEs were of high scientific calibre. The panel found that if GM herbicide tolerant (GMHT) crops are managed as in the FSEs, a significant reduction would be expected in weeds with GMHT beet and spring oilseed rape, whereas the opposite would be found with maize. These effects arise from the herbicides and are not a direct consequence of the GM process. The different findings for different GM crops reinforced the conclusion of the first Science Review that GM crops must be assessed on a case-by-case basis.

ECONOMICS[21]

An evaluation of the costs and benefits of the possible commercial cultivation of GM crops in the UK, published in July 2003, was conducted by the Prime Minister's Strategy Unit (SU). The SU performs long term strategic reviews of major areas of policy, studies of cross-cutting policy issues, strategic audits and joint work with Departments to promote strategic thinking and improve policy-making across Whitehall. It reports directly to the Prime Minister. The study focused on the GM crops that were currently available, as well as possible developments in the next 10-15 years, and developed five scenarios to explore a range of possible futures. The study was informed by experts, the public, science and the best available economic data.

The study concluded that although existing GM crops could offer some advantages to UK farmers, at least in the short-term, any economic benefit is likely to be limited by negative public attitudes and retailer policies. Over the next 10-15 years, the SU considered that there is significant potential for benefits from future developments in GM crop technology as well as potential for impacts on wider science and industry. The key conclusion of the study was that the future of GM crops will depend on the nature of the regulatory system and public attitudes.

21 www.number-10.gov.uk/su/gm/index.htm

GM NATION? THE PUBLIC DEBATE[22]

A public debate, organised by a steering board independent of government, took place in summer 2003. The aim was to promote a programme of debate on GM issues, framed by the public, against the background of the possible cultivation of GM crops in the UK.

- The debate was overseen by a Steering board which comprised of people with different perspectives on GM and people with expertise in public engagement. A number of external contractors were appointed to manage the debate programme and deliver the different strands of the programme. Foundation Discussion workshops -nine workshops of 18-20 participants from different backgrounds/age - groups held in different regional locations.
- Public events - a series of public events organized in three 'tiers' at national/regional, county and local levels. These events included different methods - round-table discussions, expert speaker Q&A, debating a motion – but were informed by stimulus material approved by the steering board. Participants were self-selecting.
- Narrow-but-deep element – series of reconvened discussion groups that involved a selected cross-section of the wider population, who would be exposed to GM issues over a period of two weeks.

Over 37,000 people provided feedback from this range of activities which including more than 600 meetings and visits to the *GM Nation?* website. Key messages emerging from the debate include:

- people are generally uneasy about GM crops;
- there is little support for early commercialisation;
- there is a widespread mistrust of government and multi-national companies;
- there is a broad desire to know more and for further research to be done;
- the debate was welcomed and valued.

IMPACT AND FOLLOW-UP

The Government considered the reports from all three strands of the GM dialogue and published both a detailed response and a Parliamentary statement in March 2004[23]. In these the Government set out its policy on GM crops and said it would:

- assess GM crops on a case-by-case basis, taking a precautionary and evidence-based approach, and making the protection of human health and the environment the top priority
- provide choice for consumers through mandatory labelling of GM food products
- consult on measures to facilitate the co-existence of GM and non-GM crops, and on options to provide compensation to non-GM farmers who suffer a financial loss through no fault of their own

22 www.gmnation.org.uk/docs/GMNation_FinalReport.pdf
23 http://www.defra.gov.uk/corporate/ministers/statements/mb040309.htm

There are currently no GM crops being grown in the UK and no commercial cultivation is expected before 2009 at the earliest. However GM crops have been grown for research and development purposes at a number of sites, for example in the FSEs.

Co-existence

When GM crops are grown commercially measures will need to be applied to ensure that they can coexist with non-GM production. The Department for Environment, Food and Rural Affairs (Defra) consulted on proposed coexistence measures for England between July and October 2006. A summary of responses to the consultation should be available by the end of this year. Defra expects to have measures in place before GM crops are grown commercially.

CHALLENGES IDENTIFIED IN THE PROJECTS

- Generally the UK public is uneasy about GM crops. How will consumer attitudes develop over the next 5-10 years? This is likely to be key to any future success of GM crops.
- Which future developments in GM technology will offer economic benefits?
- Assessment and monitoring of the long-term impact of GM crops on the environment.
- Co-existence of GM crops with non-GM crop production. Particular problems include (1) no legal threshold for the presence of GM crops in organic crops. In practice the organic sector works to the limit of detection of the presence of GM. (2) EU seed purity levels (less than 0.9%) will challenge the seed industry, who work to 1-2% seed purity, while the organic sector would like a level of less than 0.1%.
- Liability – who will pay if there is any environmental damage as a result of GM crops being grown?
- WTO – how will the EU respond to the WTO dispute panel's findings on the implementation of GM crop regulations in Europe.

AUTHOR OF THE REVIEW

Jofey Craig

EPTA
European Parliamentary Technology Assessment

10/10/2007

JOINT EPTA PROJECT
"GENETICALLY MODIFIED PLANTS AND FOODS"

QUESTIONNAIRE

– FINAL VERSION –

INTRODUCTION

Although GM crops and food can be considered an established technology and regulation is in place in many parts of the world, the issue still gives rise to controversy.

Different countries have taken different approaches to regulating GM crops and foods. In the USA, product regulation does not imply any mandatory requirement to tell consumers if a product contains GM material. In contrast, it is a central tenet of the EU approach that consumers should be made aware that a product contains, or has been produced using, GM material. This has required the EU to introduce regulations on labelling and traceability so that GM and non-GM products can be segregated through the entire production and marketing chain.

The difference in regulatory philosophy across continents has already created some tension in international trade relations. In 2003 the WTO was asked to rule on the legality of the EU's failure to process marketing applications for new GM agricultural products between 1998 and 2001.

In addition to the possibility of similar challenges in the future, a range of other factors might bring pressure to bear on the current EU regulatory approach to GM foods and crops. These include inconsistencies among EU Member States on the way that they have implemented EU regulations or have dealt with the issue of co-existence.

So far, the EU regulatory framework has not entailed that all aspects of the regulation of GMOs are dealt with uniformly throughout the EU. Member States have been left to

devise and implement their own regulations concerning the co-existence of GM and non-GM crops and approaches vary considerably across the EU.

Another key factor may be technological developments particularly if these introduce new traits with perceived benefits to consumers or if they render the traditional distinction between GM and non-GM products less clear-cut. Such factors could influence public attitudes towards GM foods and crops within the EU in an unforeseeable way.

Whatever happens, the future development of the debate on how best to regulate GM crops and foods in the EU is undetermined and the current regulatory system may face new challenges.

I. FACTORS INFLUENCING THE FUTURE OF GM PLANTS IN EUROPE

I.1 GENERAL ASSESSMENT

Question 1:

a) Many factors will influence the future of GM plants and food in Europe. Below is a list of frequently cited major factors. Please indicate for each factor whether you think it will encourage or discourage the demand for GM plants and foods.

Please feel free to add other important factors not listed.

major factors	Encour-age demand	Discour-age demand	Neither	Don't know
World food demand				
Attitudes to health				
Attitudes to the environment				
Use of bio-energy and biomass				
Global trade of food products				
Structures and power relations in the food chain (for instance increasing retailer power)				
Differentiation of food products (consider developments such as food label-ling and use of processed foods)				
International trade regulation				
Increased use of for pharmaceuticals				
Pest pressure				
Trend towards more efficient agricultural production methods				
.....				
.....				

b) Overall, would you think that the demand to introduce new GM plants in the

European agriculture will increase or decrease?
(Please select one possibility)

Increase	
Decrease	
No net effect	
Don't know	

Question 2:

Do you think that the "first generation" of GM plants (as insect resistant (IR), herbicide resistant (HR) and virus resistant (VR) plants) will be grown in Europe to a noticeable extent (say more than 5 % of the available agricultural crop land) in the next 15 years?

Time scale of introduction	in Europe	in your country
Within the next 5 years		
Within 6 – 10 years		
Within 11 - 15 years		
Not within the next 15 years		
Don't know		

I.2 NEW GM PLANTS, NEW APPLICATIONS

Question 3:

a) Currently there are several classes of new GM plants in development. Please check if you believe the following statements are valid for the different classes of crops.

Please feel free to add other classes of new gm plants not listed.

Statement: "Such crops will become available within the coming 10 years."	Valid	Not valid	Don't know
GM plants with new agricultural input traits (e.g. reduced need for fertilizer, water)			
GM plants with consumer benefits (e.g. improved nutritional value, taste, less allergens)			
GM plants for bioenergy (e.g. higher biomass yield, new plants)			
GM plants for plant made industrials (e.g. starch, fibre, plastics)			
GM trees designed for industrial/energy purposes			
GM plants for plant made pharmaceuticals (e.g. haemo-proteins, vaccines)			
GM plants for phytoremediation (e.g. plants for extracting toxics from the soil)			
New GM flowers etc. (e.g. new flower colours, grasses for lawns and golf courses)			
.....			
.....			
.....			

Statement: "Such crops will be authorised for cultivation in Europe."	Valid	Not valid	Don't know
GM plants with new agricultural input traits (e.g. reduced need for fertilizer, water)			
GM plants with consumer benefits (e.g. improved nutritional value, taste, less allergens)			
GM plants for bioenergy (e.g. higher biomass yield, new plants)			
GM plants for plant made industrials (e.g. starch, fibre, plastics)			
GM trees designed for industrial/energy purposes			
GM plants for plant made pharmaceuticals (e.g. haemo-proteins, vaccines)			
GM plants for phytoremediation (e.g. plants for extracting toxics from the soil)			
New GM flowers etc. (e.g. new flower colours, grasses for lawns and golf courses)			
.....			
.....			
.....			

Statement: "Such crops will find significant demand from farmers."	Valid	Not valid	Don't know
GM plants with new agricultural input traits (e.g. reduced need for fertilizer, water)			
GM plants with consumer benefits (e.g. improved nutritional value, taste, less allergens)			
GM plants for bioenergy (e.g. higher biomass yield, new plants)			
GM plants for plant made industrials (e.g. starch, fibre, plastics)			
GM trees designed for industrial/energy purposes			
GM plants for plant made pharmaceuticals (e.g. haemo-proteins, vaccines)			
GM plants for phytoremediation (e.g. plants for extracting toxics from the soil)			
New GM flowers etc. (e.g. new flower colours, grasses for lawns and golf courses)			
.....			
.....			
.....			

Statement: "Products from such crops will find acceptance with consumers."	Valid	Not valid	Don't know
GM plants with new agricultural input traits (e.g. reduced need for fertilizer, water)			
GM plants with consumer benefits (e.g. improved nutritional value, taste, less allergens)			
GM plants for bioenergy (e.g. higher biomass yield, new plants)			
GM plants for plant made industrials (e.g. starch, fibre, plastics)			
GM trees designed for industrial/energy purposes			
GM plants for plant made pharmaceuticals (e.g. haemo-proteins, vaccines)			
GM plants for phytoremediation (e.g. plants for extracting toxics from the soil)			
New GM flowers etc. (e.g. new flower colours, grasses for lawns and golf courses)			
.....			
.....			
.....			

Please feel free to give explanations or comments concerning your answers to these questions.

……
……
……
……
……
……

Question 4:

a) In future, technical developments such as "cisgenic" GM technology may become more important. While traditional "transgenic" plants result from gene transfers which use recombined DNA from other species, "cisgenic" plants result from gene transfers which use only recombined DNA from the same species. Please indicate if you agree or disagree with the following statements.

Statement	Agree	Disagree	Don't know
"Cisgenic" GM technology will gain high importance in the future.			
Such technologies will lead to blurring the boundaries between GM and non-GM plants in the future.			
Products derived from such technologies will be regarded as "less hazardous" by the public.			
"Cisgenic" GM technology will undermine the demand for transgenic GM technology.			
In the light of these developments, existing regulation will have to be adapted.			

b) “Smart breeding” is another new technical development. "Smart breeding" derives from traditional methods of plant breeding but includes tools on the basis of modern recombinant DNA technology such as molecular markers. Please indicate if you agree or disagree with the following statements.

Statement	Agree	Disagree	Don’t know
“Smart breeding” will gain high importance in the future.			
"Smart breeding" will have a good public image.			
"Smart breeding" will overcome the demand for currently regulated GM technologies.			
"Smart breeding" will overcome the current need to regulate GM technologies.			

Please feel free to give explanations or comments concerning your answer on these questions.

……
……
……
……
……
……

I.3 Public Attitude and Acceptance

Question 5:

Currently the consumer acceptance of gm plants and food varies across Europe. Many factors have been associated with public acceptance. Please rank the factors in the list below in their importance for consumer acceptance over the next 10 to 15 years.

Please feel free to add other factors not listed.

Factors	Not important	Little important	Important	Very important	Don't know
Risk issues related to environment					
Environmental upsides (e.g. reduced need for fertilizer, pesticides or tillage)					
Risk issues related to health					
Price benefits for consumers					
Consumer benefits related to food quality and health					
functioning risk management					
Perspectives on global food security					
Quality of information to citizens					
Getting accustomed to GM products					
Opportunity for public participation in decision making					
Efficient and transparent labelling and free consumer choice					
Global distribution of risks and benefits					
.....					
.....					

.....					

Question 6:

Will public attitudes to GM crops and food change in the next 10 to 15 years?

Issues	More negative	No change	More positive
Acceptance of GM technology in general			
Acceptance of new GM food products			
Acceptance of new GM non-food products			

Please feel free to give explanations or comments concerning your answer on this question.

……
……
……
……
……
……

II. CHALLENGES FOR EUROPEAN POLICY

II.1 CHALLENGES LINKED TO FREEDOM OF CHOICE, LABELLING AND CO-EXISTENCE

Question 7:

Co-existence measures are a central part of risk management under GM-cultivation. Co-existence is also a central prerequisite for freedom of choice. Co-existence may be a challenge, depending on type of crop and location. Do you think that co-existence will work for the "first generation" of gm plants (e.g. insect resistant, herbicide resistant and virus resistant (VR) plants) in the next 15 years?
(Please tick one possibility)

Yes, for the cultivation of GM plants on a large scale for almost every crop	
Yes, for the cultivation of GM plants on a large scale for some specific crops	
Yes, but only for the cultivation of GM plants on a small scale for almost every crop	
Yes, but only for the cultivation of GM plants on a small scale for some specific crops	
No, not at all	
Don't know	

Please feel free to give explanations or comments concerning your answer on this question.

……
……
……

……
……

Question 8:

a) For the cultivation of GM crops some experts have discussed whether there could be relevant environmental or economic risks (e.g. to farmers not applying gm crops) that would not be contained by current risk assessment and co-existence schemes. Please tick the statement that comes closest to your opinion.

Relevant risks do not exist at all	
Relevant risks exist for a few particular GM crops	
Relevant risks exist for all GM crops	
Don't know	

If you think that relevant risks do not exist at all, or if you don't know, proceed to Question 9.

b) If you think that relevant risks might exist, please tick those statements that come closest to your opinion (multiple answers possible).

In general, risks are negligible	
Environmental risks are balanced by benefits to society and acceptable	
Economic risks to other farmers can be negotiated between parties involved	
Such risks are unacceptable and need regulatory intervention	
Don't know	

c) Do you think that current regulatory provisions are sufficient to deal with such risks, today or for the foreseeable future?

Yes, in the current situation and in the foreseeable future	
Yes in the current situation, but not in the foreseeable future	
No, not at all	
Don't know	

d) If you ticked "No, not at all" or "not in the foreseeable future", how do you think these risks should be addressed? Please indicate the measure you consider most appropriate to address such risks (multiple answers possible).

New criteria for risk assessment	
More stringent litigation schemes	
Stronger liability of gm producer and user	
New regulation	
.....	
.....	
Don't know	

Question 9:

Co-existence and labelling of GM food are closely connected. There are different opinions over how well the current EU regulations would cope with the extended use and growing of gm plants in Europe. Please indicate which scenario in your opinion is most likely.
(Please tick one scenario)

Scenario	
Successful coexistence: The labelling of GM food is generally correct (including occasional mishap), non GM food is also available.	
Misapplication of labelling: All food is labelled as "may contain GM", also non GM food.	
Failure of labelling regime: GM food is on the market, but not labelled correctly.	
Failure of coexistence: More or less all food is GM or contains GM components, and is labelled as GM food.	
Blockade of GM food: Very little GM food on the market so that labelling is of little relevance.	
Don't know	

Please feel free to give explanations or comments concerning your answer on this question.

……
……
……
……
……
……

II.2 CHALLENGES LINKED TO NEW GENERATION GM CROPS

Question 10:

a) Newly developed GM plants for the non-food sector (e.g. gm plants for plant made pharmaceuticals, for industrial raw materials, and for bio-energy) are sometimes said to have new properties compared to gm plants for food and therefore pose new regulatory challenges. Do you or don't you agree with the following statement?

	Yes	No	Don't know
New GM plants for the non-food sector will pose new regulatory challenges			

If you ticked "No" or "Don't know", proceed to question 11.

b) If you ticked "Yes", please assess which regulatory challenges non-food GM plants will raise in the next 10-15 years, and whether this will be very likely, likely, unlikely or highly unlikely.

Please feel free to add other regulatory challenges not listed.

Type of regulatory challenge	Very likely	Likely	Unlikely	Highly unlikely	Don't know
New parameters for risk assessment and manage-ment					
Confinement / containment measures					
Regulation of coexistence					
Labelling					
Liability					
.....					
.....					
.....					

Please feel free to give explanations or comments concerning your answer on this question.

……
……
……
……
……
……

Question 11:

So far, the assessment procedures for GM plants and food only takes into account potential risks. Some actors have advocated that also potential benefits should be taken into consideration as applied in areas such as pharmaceuticals.
Below is a list of potential benefits that could be included in such considerations. Please assess how likely it is that in future different benefits will be considered for GM approvals.

Please feel free to add other groups not listed.

Aspect	Very likely	Likely	Unlikely	Highly unlikely	Don't know
Environmental benefit					
Economic return					
Food safety					
Food quality					
Nutritional benefit					
.....					
.....					
.....					

Please feel free to give explanations or comments concerning your answer on this question.

.....
.....
.....
.....
.....
.....

Question 12:

In order to assess risks and benefits of GM cultivation, it must be compared to established practices in agriculture. In Europe, these practices vary according to climate or soil, but also to the tasks assigned to agriculture. For example, and apart from efficiently producing crops or providing jobs, agriculture should also protect the traditional landscape and the natural environment, among others. Thus, agriculture must pursue different aims, against which the performance of GM cultivation will be measured. Please rank the aims in the list below in their importance over the next 10 to 15 years.

Aims in agriculture	Not important	Little important	Important	Very important	Don't know
Achieving high yields in crop production					
Reducing inputs in crop production					
Efficient crop production under difficult agricultural conditions (erosion, pest pressure etc.)					
Staying competitive in times of market liberalisation and reduced subsidies					
Crop production with least possible environmental impact					
Producing high quality food in great variety					
Providing jobs for the rural population					
Protecting the traditional cultivated landscape					
Promoting organic farming					

II.3 GLOBAL ASPECTS OF GM REGULATION

Question 13:

a) It is probable that more types of GM crops will be released both in export countries and in Europe. The current EU regulation, based on the precautionary principle and case-by-case risk assessment and authorisation, might be challenged by the US and other countries also in the future. Please give your judgement on how robust the EU regulatory system will turn out to be to challenges for example at the WTO in the next 10 to 15 years.
(Please tick one possibility)

Robustness of the current EU regulatory system	
The general principles and approaches of the EU regulation and the varying implementation of the EU Member States can withstand challenges through the WTO.	
The general principles and approaches of the EU regulation can be maintained. However, the most restrictive practices of individual EU Member States will have to be changed.	
The general principles and approaches of the EU regulation can be maintained, but a more substantial harmonisation among the EU Member States will be necessary.	
The EU regulatory system can not be maintained due to challenges through the WTO.	
Don't know	

b) The EU legalisation has been a model for regulations in some other countries. Will the EU regulation continue to be influential in the future?
(Please tick one possibility)

Yes	
No	
Don't know	

Please feel free to give explanations or comments concerning your answer on this question.

……
……
……
……
……
……

III. CHALLENGES FOR RESEARCH POLICY

Question 14:

In view of new developments in the research on GM plants, what will be the objectives of publicly-funded research in your country in the coming years?

Please feel free to add other objectives not listed.

Objectives of R&D	Very likely	Likely	Unlikely	Highly unlikely	Don't know
Risk assessment and management					
Development of products/solutions responding to agronomic problems not covered by private research					
Development of innovative products with the intent to improve economic competitiveness					
.....					

IV. AREAS OF ACTION

Question 15:

In order to meet challenges that have been explored in this questionnaire, it could be necessary for government institutions to take further action. Please prioritise the areas below in which you consider action needs to be taken.

Please feel free to add areas of action not listed.

Area of action	Very low priority	Low priority	High priority	Very high priority	Don't know
Research funding					
Better implementation of existing regulation					
Amendment of existing regulation					
Adaptation to international ruling (e.g. WTO)					
Reform of competent authorities/institutions					
Subsidiarity / change in the level of decision making					
Expert involvement in decision making					
Stakeholder involvement in decision making					
Public involvement in decision making					
None, let the system work as it is					
.....					
.....					

.....					

Question 16:

In order to further explore new challenges, within which areas do you consider further investigations (for example technology assessment projects) to be most relevant.
(Please give key words)

……
……
……
……
……
……

ANNEX 5: TABLES OF RESULTS

FIGURE 1: INFLUENCING FACTORS FOR THE FUTURE OF GM PLANTS AND FOOD IN EUROPE (*Question 1A; n = 71)*

Question: Many factors will influence the future of GM plants and food in Europe. Below is a list of frequently cited major factors. Please indicate for each factor whether you think it will encourage or discourage the demand for GM plants and foods. Please feel free to add other important factors not listed.

	Encourage demand	Discourage demand	Neither	Don't know	Total	
	%	%	%	%	%	n
World food demand	50.7%	8.5%	33.8%	7.0%	100.0%	71
Attitudes to health	31.0%	43.7%	15.5%	9.9%	100.0%	71
Attitudes to the environment	28.2%	54.9%	12.7%	4.2%	100.0%	71
Use of bio-energy and biomass	74.6%	1.4%	19.7%	4.2%	100.0%	71
Global trade of food products	50.7%	8.5%	29.6%	11.3%	100.0%	71
Structures and power relations in the food chain (for instance increasing retailer power)	9.9%	49.3%	23.9%	16.9%	100.0%	71
Differentiation of food products (consider developments such as food labelling and use of processed foods)	22.5%	33.8%	31.0%	12.7%	100.0%	71
International trade regulation	52.1%	8.5%	25.4%	14.1%	100.0%	71
Increased use of for pharmaceuticals	52.1%	5.6%	31.0%	11.3%	100.0%	71
Pest pressure	53.5%	11.3%	28.2%	7.0%	100.0%	71
Trend towards more efficient agricultural production methods	66.2%	8.5%	19.7%	5.6%	100.0%	71

FIGURE 2: FUTURE DEMAND FOR NEW GM PLANTS IN EUROPEAN AGRICULTURE (*Question 1B; n = 71)*

Question: Overall, would you think that the demand to introduce new GM plants in the European agriculture will increase or decrease?

ABB. 2

	Column %	Count
Increase	62.0%	44
Decrease	14.1%	10
No net effect	18.3%	13
Don't know	5.6%	4
Total	100.0%	71

FIGURE 3: FUTURE CULTIVATION OF FIRST GENERATION GM PLANTS IN EUROPE

(*Question 2; n = 71)*

Question: Do you think that the "first generation" of GM plants (as insect resistant (IR), herbicide resistant (HR) and virus resistant (VR) plants) will be grown in Europe to a noticeable extent (say more than 5 % of the available agricultural crop land) in the next 15 years)?

	Within the next 5 years	Within 6 – 10 years	Within 11 - 15 years	Not within the next 15 years	Don't know	Total	
	%	%	%	%	%	%	n
in Europe	21.1%	35.2%	15.5%	19.7%	8.5%	100.0%	71
in your country	1.4%	23.9%	21.1%	40.8%	12.7%	100.0%	71

FIGURE 4: AVAILABILITY OF NOVEL GM PLANTS

(*Question 3A; n = 71)*

Question: Currently there are several classes of new GM plants in development. Please check if you believe the statement: "Such crops will become available within the coming 10 years."

	Valid	Not valid	Don't know	Total	
	%	%	%	%	n
GM plants with new agricultural input traits (e.g. reduced need for fertiliser, water)	54,9%	22,5%	22,5%	100,0%	71
GM plants with consumer benefits (e.g. improved nutritional value, taste, less allergens)	50,7%	32,4%	16,9%	100,0%	71
GM plants for bioenergy (e.g. higher biomass yield, new plants)	60,6%	15,5%	23,9%	100,0%	71
GM plants for plant made industrials (e.g. starch, fibre, plastics)	78,9%	4,2%	16,9%	100,0%	71
GM trees designed for industrial/energy purposes	25,4%	46,5%	28,2%	100,0%	71
GM plants for plant made pharmaceuticals (e.g. haemo-proteins, vaccines)	64,8%	14,1%	21,1%	100,0%	71
GM plants for phytoremediation (e.g. plants for extracting toxins from the soil)	23,9%	39,4%	36,6%	100,0%	71
New GM flowers etc. (e.g. new flower colours, grasses for lawns and golf courses)	60,6%	14,1%	25,4%	100,0%	71

FIGURE 5: AUTHORISATION OF NOVEL GM PLANTS (*Question 3B; n = 71)*

Question: Currently there are several classes of new GM plants in development. Please check if you believe the statement: "Such crops will be authorised for cultivation in Europe."

	Valid	Not valid	Don't know	Total	
	%	%	%	%	n
GM plants with new agricultural input traits (e.g. reduced need for fertiliser, water)	57,7%	22,5%	19,7%	100,0%	71
GM plants with consumer benefits (e.g. improved nutritional value, taste, less allergens)	53,5%	26,8%	19,7%	100,0%	71
GM plants for bioenergy (e.g. higher biomass yield, new plants)	62,0%	18,3%	19,7%	100,0%	71
GM plants for plant made industrials (e.g. starch, fibre, plastics)	70,4%	14,1%	15,5%	100,0%	71
GM trees designed for industrial/energy purposes	32,4%	38,0%	29,6%	100,0%	71
GM plants for plant made pharmaceuticals (e.g. haemo-proteins, vaccines)	43,7%	29,6%	26,8%	100,0%	71
GM plants for phytoremediation (e.g. plants for extracting toxins from the soil)	32,4%	31,0%	36,6%	100,0%	71
New GM flowers etc. (e.g. new flower colours, grasses for lawns and golf courses)	50,7%	16,9%	32,4%	100,0%	71

FIGURE 6: DEMAND FROM FARMERS FOR NOVEL GM PLANTS (*Question 3C; n = 71)*

Question: Currently there are several classes of new GM plants in development. Please check if you believe the statement: "Such crops will find significant demand from farmers."

	Valid	Not valid	Don't know	Total	
	%	%	%	%	n
GM plants with new agricultural input traits (e.g. reduced need for fertiliser, water)	66,2%	19,7%	14,1%	100,0%	71
GM plants with consumer benefits (e.g. improved nutritional value, taste, less allergens)	39,4%	36,6%	23,9%	100,0%	71
GM plants for bioenergy (e.g. higher biomass yield, new plants)	64,8%	16,9%	18,3%	100,0%	71
GM plants for plant made industrials (e.g. starch, fibre, plastics)	57,7%	23,9%	18,3%	100,0%	71
GM trees designed for industrial/energy purposes	26,8%	43,7%	29,6%	100,0%	71
GM plants for plant made pharmaceuti-cals (e.g. haemo-proteins, vaccines)	22,5%	45,1%	32,4%	100,0%	71
GM plants for phytoremediation (e.g. plants for extracting toxins from the soil)	16,9%	53,5%	29,6%	100,0%	71
New GM flowers etc. (e.g. new flower colours, grasses for lawns and golf courses)	32,4%	38,0%	29,6%	100,0%	71

FIGURE 7: ACCEPTANCE WITH CONSUMERS OF NOVEL GM PLANTS (*Question 3D; n = 71)*

Question: Currently there are several classes of new GM plants in development. Please check if you believe the statement: "Products from such crops will find acceptance with consumers."

	Valid	Not valid	Don't know	Total	
	%	%	%	%	n
GM plants with new agricultural input traits (e.g. reduced need for fertiliser, water)	31,0%	43,7%	25,4%	100,0%	71
GM plants with consumer benefits (e.g. improved nutritional value, taste, less allergens)	56,3%	29,6%	14,1%	100,0%	71
GM plants for bioenergy (e.g. higher biomass yield, new plants)	50,7%	29,6%	19,7%	100,0%	71
GM plants for plant made industrials (e.g. starch, fibre, plastics)	50,7%	26,8%	22,5%	100,0%	71
GM trees designed for industrial/energy purposes	35,2%	38,0%	26,8%	100,0%	71
GM plants for plant made pharmaceuticals (e.g. haemo-proteins, vaccines)	47,9%	26,8%	25,4%	100,0%	71
GM plants for phytoremediation (e.g. plants for extracting toxins from the soil)	47,9%	25,4%	26,8%	100,0%	71
New GM flowers etc. (e.g. new flower colours, grasses for lawns and golf courses)	39,4%	28,2%	32,4%	100,0%	71

FIGURE 8: FUTURE IMPORTANCE OF "CISGENIC" GM TECHNOLOGY (*Question 4A; n = 71)*

Question: In the future, technical developments such as "cisgenic" GM technology may become more important. While traditional "transgenic" plants result from gene transfers which use recombined DNA from other species, "cisgenic" plants result from gene transfers which use only recombined DNA from the same species. Please indicate if you agree or disagree with the following statements.

	Agree	Disagree	Don't know	Total	
	%	%	%	%	n
"Cisgenic" GM technology will gain high importance in the future.	33,8%	14,1%	52,1%	100,0%	71
Such technologies will lead to blurring the boundaries between GM and non-GM plants in the future.	50,7%	31,0%	18,3%	100,0%	71
Products derived from such technologies will be regarded as "less hazardous" by the public.	35,2%	39,4%	25,4%	100,0%	71
"Cisgenic" GM technology will undermine the demand for transgenic GM technology.	16,9%	50,7%	32,4%	100,0%	71
In the light of these developments, existing regulation will have to be adapted.	57,7%	22,5%	19,7%	100,0%	71

FIGURE 9: FUTURE IMPORTANCE OF "SMART BREEDING" (*Question 4B; n = 71)*

Question: "Smart breeding" is another new technical development. "Smart breeding" derives from traditional methods of plant breeding but includes tools on the basis of modern recombinant DNA technology such as molecular markers. Please indicate if you agree or disagree with the following statements.

	Agree	Disagree	Don't know	Total	
	%	%	%	%	n
"Smart breeding" will gain high importance in the future.	69,0%	7,0%	23,9%	100,0%	71
"Smart breeding" will have a good public image.	56,3%	14,1%	29,6%	100,0%	71
"Smart breeding" will overcome the demand for currently regulated GM technologies.	15,5%	54,9%	29,6%	100,0%	71
"Smart breeding" will overcome the current need to regulate GM technolo-	9,9%	74,6%	15,5%	100,0%	71

gies.					

FIGURE 10: NEW REGULATORY CHALLENGES CAUSED BY NOVEL GM PLANTS?
(*Question 10A; n = 71)*

Question: Newly developed GM plants for the non-food sector (e.g. gm plants for plant made pharmaceuticals, for industrial raw materials, and for bio-energy) are sometimes said to have new properties compared to gm plants for food and therefore pose new regulatory challenges. Do you or don't you agree with the following statement?

		Column %	Count
New GM plants for the non-food sector will pose new regulatory challenges	Yes	62,0%	44
	No	35,2%	25
	Don't know	2,8%	2
	Total	100,0%	71

FIGURE 11: AREAS OF NEW REGULATORY CHALLENGES OF NOVEL GM PLANTS
(*Question 10B; n = 44)*

Question: If you ticked "Yes" *[in question 10B]*, please assess which regulatory challenges non-food GM plants will raise in the next 10-15 years, and whether this will be very likely, likely, unlikely or highly unlikely. Please feel free to add other regulatory challenges not listed.

Type of regulatory challenge	Very likely	Likely	Unlikely	Highly unlikely	Don't know	Total	
	%	%	%	%	%	%	n
New parameters for risk assessment and management	45,5%	45,5%	6,8%	0,0%	2,3%	100,0%	44
Confinement/containment measures	52,3%	36,4%	6,8%	0,0%	4,6%	100,0%	44
Regulation of coexistence	56,8%	36,4%	4,5%	0,0%	2,3%	100,0%	44
Labelling	25,0%	43,2%	29,5%	0,0%	2,3%	100,0%	44
Liability	34,1%	54,5%	2,3%	0,0%	9,1%	100,0%	44

FIGURE 12: **PUBLIC ATTITUDES (*Question 6; n = 71)***

Question: Will public attitudes to GM crops and food change in the next 10 to 15 years?

	More negative	No change	More positive	Total	
	%	%	%	%	n
Acceptance of GM technology in general	5,6%	36,6%	57,7%	100,0%	71
Acceptance of new GM food products	9,9%	52,1%	38,0%	100,0%	71
Acceptance of new GM non-food products	2,8%	22,5%	74,6%	100,0%	71

FIGURE 13: FACTORS INFLUENCING PUBLIC ATTITUDES (*Question 5; n = 71)*

Question: Currently the consumer acceptance of gm plants and food varies across Europe. Many factors have been associated with public acceptance. Please rank the factors in the list below in their importance for consumer acceptance over the next 10 to 15 years. Please feel free to add other factors not listed.

Factors

	Not important	Little important	Important	Very important	Don't know	Total	
	%	%	%	%	%	%	n
Risk issues related to environment	4,2%	12,7%	45,1%	35,2%	2,8%	100,0%	71
Environmental upsides (e.g. reduced need for fertiliser, pesticides or tillage)	4,2%	47,9%	28,2%	16,9%	2,8%	100,0%	71
Risk issues related to health	1,4%	5,6%	35,2%	54,9%	2,8%	100,0%	71
Price benefits for consumers	8,5%	23,9%	31,0%	35,2%	1,4%	100,0%	71
Consumer benefits related to food quality and health	2,8%	12,7%	33,8%	49,3%	1,4%	100,0%	71
Performance of risk management systems	2,8%	23,9%	43,7%	25,4%	4,2%	100,0%	71
Perspectives on global food security	16,9%	38,0%	25,4%	15,5%	4,2%	100,0%	71
Quality of information to citizens	2,8%	18,3%	42,3%	35,2%	1,4%	100,0%	71
Getting accustomed to GM products	8,5%	15,5%	42,3%	29,6%	4,2%	100,0%	71
Opportunity for public participation in decision making	8,5%	40,8%	36,6%	11,3%	2,8%	100,0%	71
Efficient and transparent labelling and free consumer choice	2,8%	9,9%	43,7%	42,3%	1,4%	100,0%	71
Global distribution of risks and benefits	8,5%	45,1%	32,4%	8,5%	5,6%	100,0%	71

FIGURE 14: WILL COEXISTENCE WORK FOR FIRST GENERATION GM PLANTS?
(*Question 7; n = 71)*

Question: Co-existence measures are a central part of risk management under GM-cultivation. Co-existence is also a central prerequisite for freedom of choice. Co-existence may be a challenge, depending on type of crop and location. Do you think that co-existence will work for the "first generation" of gm plants (e.g. insect resistant, herbicide resistant and virus resistant (VR) plants) in the next 15 years? (Please tick one possibility).

	Percentage	Count
Yes, for the cultivation of GM plants on a large scale for almost every crop	15,5%	11
Yes, for the cultivation of GM plants on a large scale for some specific crops	31,0%	22
Yes, but only for the cultivation of GM plants on a small scale for almost every crop	5,6%	4
Yes, but only for the cultivation of GM plants on a small scale for some specific crops	25,4%	18
No, not at all	15,5%	11
Don't know	7,0%	5
Total	100,0%	71

FIGURE 15: CAN CONSUMERS' CHOICE BE MAINTAINED? (*Question 9; n = 71)*

Question: Co-existence and labelling of GM food are closely connected. There are different opinions over how well the current EU regulations would cope with the extended use and growing of gm plants in Europe. Please indicate which scenario in your opinion is most likely. (Please tick one scenario)

	Percentage	Count
Successful coexistence: The labelling of GM food is generally correct (including occasional mishap), non GM food is also available.	52,1%	37
Misapplication of labelling: All food is labelled as "may contain GM", also non GM food.	5,6%	4
Failure of labelling regime: GM food is on the market, but not labelled correctly.	14,1%	10
Failure of coexistence: More or less all food is GM or contains GM components, and must be labelled as GM food.	7,0%	5
Blockade of GM food: Very little GM food on the market so that labelling is of little relevance.	16,9%	12
Don't know	4,2%	3
Total	100,0%	71

FIGURE 16: DO COEXISTENCE SCHEMES ADDRESS RISKS? (*Question 8A; n = 71)*

Question: For the cultivation of GM crops some experts have discussed whether there could be relevant environmental or economic risks (e.g. to farmers not applying gm crops) that would not be contained by current risk assessment and co-existence schemes. Please tick the statement that comes closest to your opinion.

	Percentage	Count
Relevant risks do not exist at all	15,5%	11
Relevant risks exist for a few particular GM crops	29,6%	21
Relevant risks exist for all GM crops	49,3%	35
Don't know	5,6%	4
Total	100,0%	71

FIGURE 17: HOW TO MEET RISKS? (*Question 8B; n = 56)*

Question: If you think that relevant risks might exist [*in question 8A*], please tick those statements that come closest to your opinion (multiple answers possible).

	Respondents	Responses	Percentage (n=71)
In general, risks are negligible		9	13 %
Environmental risks are balanced by benefits to society and acceptable		17	24 %
Economic risks to other farmers can be negotiated between parties involved		23	32 %
Such risks are unacceptable and need regulatory intervention		26	37 %
Don't know		2	3 %
Total	56	78	

FIGURE 18: ARE REGULATORY PROVISIONS SUFFICIENT? (*Question 8C; n = 56)*

Question: Do you think that current regulatory provisions are sufficient to deal with such risks [*see question 8B*], today or for the foreseeable future?

	Count	Percentage
Yes, in the current situation and in the foreseeable future	19	27 %
Yes in the current situation, but not in the foreseeable future	16	23 %
No, not at all	20	28 %
Don't know	1	1 %
Total	56	

FIGURE 19: **BENEFIT ASSESSMENT (*Question 11; n = 71)***

Question: So far, the assessment procedures for GM plants and food only takes into account potential risks. Some actors have advocated that also potential benefits should be taken into consideration as applied in areas such as pharmaceuticals.
Below is a list of potential benefits that could be included in such considerations. Please assess how likely it is that in future different benefits will be considered for GM approvals. Please feel free to add other groups not listed.

	Highly unlikely	Unlikely	Likely	Very likely	Don't know	Total	
	%	%	%	%	%	%	n
Environmental benefit	15,5%	25,4%	38,0%	16,9%	4,2%	100,0%	71
Economic return	29,6%	28,2%	23,9%	12,7%	5,6%	100,0%	71
Food safety	16,9%	25,4%	33,8%	18,3%	5,6%	100,0%	71
Food quality	16,9%	31,0%	31,0%	15,5%	5,6%	100,0%	71
Nutritional benefit	15,5%	31,0%	35,2%	12,7%	5,6%	100,0%	71

FIGURE 20: **AIMS IN AGRICULTURE (*Question 12; n = 71)***

Question: In order to assess risks and benefits of GM cultivation, it must be compared to established practices in agriculture. In Europe, these practices vary according to climate or soil, but also to the tasks assigned to agriculture. For example, and apart from efficiently producing crops or providing jobs, agriculture should also protect the traditional landscape and the natural environment, among others. Thus, agriculture must pursue different aims, against which the performance of GM cultivation will be measured. Please rank the aims in the list below in their importance over the next 10 to 15 years.

	Not important	Little important	Important	Very important	Don't know	Total	
	%	%	%	%	%	%	n
Achieving high yields in crop production	5,6%	19,7%	36,6%	31,0%	7,0%	100,0%	71
Reducing inputs in crop production	2,8%	5,6%	46,5%	36,6%	8,5%	100,0%	71
Efficient crop production under difficult agricultural conditions (erosion, pest pressure etc.)	2,8%	14,1%	42,3%	33,8%	7,0%	100,0%	71
Staying competitive in times of market liberalisation and reduced subsidies	1,4%	15,5%	39,4%	33,8%	9,9%	100,0%	71
Crop production with least possible environmental impact	0,0%	4,2%	39,4%	52,1%	4,2%	100,0%	71
Producing high quality food in great variety	1,4%	7,0%	35,2%	50,7%	5,6%	100,0%	71
Providing jobs for the rural population	7,0%	21,1%	45,1%	19,7%	7,0%	100,0%	71
Protecting the traditional cultivated landscape	7,0%	12,7%	40,8%	33,8%	5,6%	100,0%	71
Promoting organic farming	8,5%	32,4%	23,9%	26,8%	8,5%	100,0%	71

FIGURE 21: ROBUSTNESS OF THE EU REGULATORY SYSTEM (*Question 13A; n = 71)*

Question: It is probable that more types of GM crops will be released both in export countries and in Europe. The current EU regulation, based on the precautionary principle and case-by-case risk assessment and authorisation, might be challenged by the US and other countries also in the future. Please give your judgement on how robust the EU regulatory system will turn out to be to challenges for example at the WTO in the next 10 to 15 years. (Please tick one possibility)

Answers	% of answers	Number of answers
The general principles and approaches of the EU regulation and the varying implementation of the EU Member States can withstand challenges through the WTO.	22,5	16
The general principles and approaches of the EU regulation can be maintained. However, the most restrictive practices of individual EU Member States will have to be changed.	32,4	23
The general principles and approaches of the EU regulation can be maintained, but a more substantial harmonisation among the EU Member States will be necessary.	23,9	17
The EU regulatory system can not be maintained due to challenges through the WTO.	14,1	10
Don't know	7,0	5
Total	100,0	71

FIGURE 22: THE FUTURE ROLE OF THE EU LEGISLATION (*Question 13B; n = 71)*

Question: The EU legalisation has been a model for regulations in some other countries. Will the EU regulation continue to be influential in the future? (Please tick one possibility)

Answers	% of answers	Number of answers
Yes	69,0	49
No	12,7	9
Don't know	18,3	13
Total	100,0	71

FIGURE 23: PRIORITISATION OF POLICY FIELDS (*Question 15; n = 71)*

Question: In order to meet challenges that have been explored in this questionnaire, it could be necessary for government institutions to take further action. Please prioritise the areas below in which you consider action needs to be taken. Please feel free to add areas of action not listed

	Very low priority	Low priority	High priority	Very high priority	Don't know	Total	
	%	%	%	%	%	%	n
Research funding	0,0%	9,9%	46,5%	38,0%	5,6%	100,0%	71
Better implementation of existing regulation	5,6%	29,6%	39,4%	16,9%	8,5%	100,0%	71
Amendment of existing regulation	2,8%	33,8%	32,4%	21,1%	9,9%	100,0%	71
Adaptation to international ruling (e.g. WTO)	9,9%	33,8%	28,2%	16,9%	11,3%	100,0%	71
Reform of competent authorities/institutions	12,7%	25,4%	33,8%	21,1%	7,0%	100,0%	71
Subsidiarity/change in the level of decision making	4,2%	39,4%	35,2%	7,0%	14,1%	100,0%	71
Expert involvement in decision making	2,8%	19,7%	36,6%	35,2%	5,6%	100,0%	71
Stakeholder involvement in decision making	8,5%	26,8%	42,3%	16,9%	5,6%	100,0%	71
Public involvement in decision making	11,3%	31,0%	33,8%	19,7%	4,2%	100,0%	71
None, let the system work as it is	56,3%	15,5%	5,6%	1,4%	21,1%	100,0%	71

FIGURE 24: OBJECTIVES OF PUBLICLY FUNDED RESEARCH (*Question 14; n = 71)*

Question: In view of new developments in the research on GM plants, what will be the objectives of publicly-funded research in your country in the coming years? Please feel free to add other objectives not listed.

	Highly unlikely	Unlikely	Likely	Very likely	Don't know	Total	
	%	%	%	%	%	%	n
Risk assessment and management	2,8%	23,9%	35,2%	31,0%	7,0%	100,0%	71
Development of products/solutions responding to agronomic problems not covered by private research	5,6%	28,2%	39,4%	16,9%	9,9%	100,0%	71
Development of innovative products with the intent to improve economic competitiveness	7,0%	31,0%	32,4%	18,3%	11,3%	100,0%	71