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Nano Regulation in Austria (I): Chemical and Product Safety

Summary

Compared to international standards, an Austrian debate on regulation of nanotechnologies was only initiated in 2006. A first parliamentary inquiry was made in 2007. The same year, the Bioethics Commission at the Federal Chancellery adopted a recommendation on nanotechnology. The regulation of nanotechnology is also mentioned in the Program of the Austrian federal government for the (current) 24th legislative period. A legal inquiry into this topic has just begun with only preliminary conclusions. Initially the complexity of the matter, the experience with public communication about genetic engineering and in particular the strong influence of EU law served as justification for the restraint concerning an independent positioning of Austria. Since 2008 the debate gained momentum with several conferences and the enactment of the Austrian Nanotechnology Action Plan (NAP) in 2010. This dossier concentrates on chemicals, biocidal products, pesticides, medicinal products, medical devices, cosmetics and food as well as on general product safety.

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Introduction

The dossier contains a chronology of regulatory policies in Austria and introduces selected legal areas relevant to nano-products. The portrayal of regulatory policies includes scientific debates, parliamentary activities and the Austrian Nanotechnology Action Plan (NAP). The main part of this dossier concerns chemical and product safety, especially focusing on those provisions which are already applicable to nanomaterials (further legal areas, such as workplace safety, industrial law and environmental law, are dealt with in dossier 019).

Chronology of regulatory strategies in Austria

Scientific debate on regulation

In Austria, questions with regard to regulatory efforts concerning nanotechnology were first mentioned in an ITA report from 2006 on Nanotechnology Accompanying Measures[1]. Its focus was put on the international dimension. It proceeded from the general presumption of applicability of existing regulations, while characterizing the level of knowledge as insufficient. Especially for the chemical sector deficits were identified. The report recommended an enhanced dialogue in the areas of governance and regulation with regard to voluntary agreements and best-practice-measures, the adaptation of existing regulation (especially in the sectors of chemical and product safety, insurance and consumer protection), and where applicable, new regulation.

One of the tasks of NanoTrust – which since 2007 is running on a mandate by the Federal Ministry for Transport, Innovation and Technology – is to show up possible regulatory deficits. Thus, several of the NanoTrust Dossiers drafted under the project deal with regulatory aspects[2]. Especially the 2nd NanoTrust autumn workshop 2008[3] as well as an event organized by ITA and the Federal Ministry of Health in February 2010[4] focused on the debate concerning the status of nano-regulation.

In 2008, alongside of political and social aspects, the protection of workers and consumers, the environment as well as chemicals were at the center of the workshop. While representatives of the industry held the regulatory framework to be sufficient and thus propagated a system of voluntary approaches, other participants saw a need for further regulatory efforts. Gaps in the existing legal framework were especially identified with regard to threshold values, conceptualities, definitions and insufficient knowledge. In February 2010, the conference focused on consumer-oriented products and on the debate concerning the status of nano-regulation on the European as well as national level.

Although a legal discussion on regulation had commenced at the international level already in the 1990s[5], Austrian contributions have remained rare. The existence of nanotechnology has been mentioned in few scientific articles[6], and since 2008 a research project on "Governance of emerging technologies, particularly in the field of nanotechnologies" has been ongoing which deals with the regulation of nanotechnology from a legal theory point of view[7].

Nano regulation in the Parliament

Nanotechnology in general, and their regulation in particular, have repeatedly been the topic of requests and resolution motions in the Austrian parliament.

The first steps were taken in 2007 by the Social Democratic Party in the Federal Council with requests directed at the Federal Ministers of Health and of Economy[8] concerning "responsible handling of nanotechnology", *inter alia* requesting information on the need for legislative adaptations as well as labeling and reporting obligations. While the Minister of Health replied[9] with regard to her area of implementation by referring to the activities at the European level, the Minister of Economy elaborated on the different measures taken in his area[10]. According to the Minister of Economy, nanomaterials are covered by the Protection of Workers Act. In addition, the responsibility of employers with regard to the evaluation of working materials as well as guarantee of security, specific protection measures and work inspection was emphasized and added that within the framework of existing regulations there was sufficient protection provided for. Thus, there was no necessity for legal measures in the area of workplace safety.

In 2008, again via the Federal Council, requests were made to the Federal Ministers of Environment and of Infrastructure[11], with a focus on the need of legal adaptions in the area of chemicals as well as their registration and labeling. Both ministers[12] referred to the relevant reports by the EU Commission[5] as well as to working groups which exist at the EU as well as the OECD level. The question of labeling would be asked at the European level and national single-handed actions in this regard would be hard to imagine. In the same year, a request was raised by Green parliamentarians to the Minister of Health concerning foods and cosmetics[13], as well as questions asked with regard to regulatory measures in the sector of public safety and mandatory labeling. In her response[14], the Minister of Health again referred to the relevant EU regulatory measures and their pending amendments and that she thought separate Austrian action therefore not to be necessary. However, she did argue for an authorization-procedure for nano-foods, for a mandatory labeling of consumer-oriented products and even spoke about the possibility of a – preferably European-wide consented – moratorium. A request by the Social Democratic Party[15] in the same year concerning possible labeling of sun protection products containing nanomaterials was answered *inter alia* with reference to the revision of the Cosmetics Directive[16]. Requests by the Greens in 2009 directed towards the Federal Ministers of Health and of Environment[17] asked about the relevant legal provisions in the EU and Austria, as well as whether surveys in the relevant areas (e.g. chemical safety, product liability, insurance, consumer protection) were being conducted, whether authorization-procedures and controls existed, and whether possible liability questions, public registers or even a moratorium had been debated. The Minister of Health[18] again referred to EU law, but explicitly denied the need for a moratorium. The Minister of Environment referred *inter alia* to the actions taken within the framework of the Action Plan (see below)[19].

As far as discernable, the most recent requests – in October 2009[20] and January 2010[21] – to the same ministers originated from the Freedom Party and dealt *inter alia* with labeling, registration as well as potential environmental or health effects of nanomaterials. In their responses[22], both ministers again referred to the relevant development in EU law as well as to the Action Plan (see below).

In addition, several different resolution motions[23] have been initiated by the Greens, calling upon the government to take action in several areas. However, due to early elections in 2008, these motions were not dealt with. On the other hand, a joint motion for a resolution[24] regarding cosmetics was adopted in the National Council. Therein the government was *inter alia* called upon to take a stand for mandatory notification of nano-scale materials.

Chart 1: Parliamentary requests concerning nanotechnology

Year	Chamber	Party	Addressed Minister	Topic of the request
2007	Federal Council	Social Democratic Party	Health, Economy	Regulation, protection of workers, labeling, health and environment
2008	Federal Council	Social Democratic Party	Environment, Infrastructure	Regulation, chemicals, labeling, registers, health and environment
2008	National Council	The Green Party	Health	Regulation, foods, cosmetics, labeling, controls, precautionary measures
2008	National Council	Social Democratic Party	Health	Sun protection products, labeling, health
2009	National Council	The Green Party	Health, Environment	Regulation, chemicals, product liability, consumer protection, authorization, controls, labeling, registers, moratorium
2009	National Council	Freedom Party	Health	Labeling, registers, health, environment
2010	National Council	Freedom Party	Environment	Environment

Nano regulation in the Austrian Action Plan

To best deal with the chances and risks of nanotechnology, the Austrian government committed itself in the government program 2008-2013[25] to develop an Austrian Nanotechnology Action Plan. Four working groups (environment, research, economy, health) developed the Action Plan throughout 2009 and after a consultation procedure on March 3rd, 2010, it was adopted by the government.[26] Within the framework of NAP, it is envisioned to identify the Austrian need for action and to explicitly make concrete recommendations. In the sectors of health and worker protection as well as environment, the Austrian and European legal situation is briefly elaborated on. Among the proposed recommendations one can especially find one on the examination, respectively securing, of the legal framework, in particular concerning worker and consumer protection. *Inter alia* it is recommended to examine whether a nano-labeling and/or a nano-register are necessary and, if necessary, to initiate such an initiative at EU level. Other recommendations range from the reconciliation with international legal developments (REACH, definition, standardization), to the promotion of voluntary measures and the strengthening of the precautionary and the polluter pays principle.

Material and product specific regulation in Austria

Nanomaterials, as chemical material, in general fall under provisions dealing with chemicals. In addition, products which contain nanomaterials or are produced through nanotechnology also fall within the numerous existing legal special rules[27] (for example, Medicinal Products Act, Medical Devices Act or Cosmetics Law). Products which do not fall within specific categories must meet certain security standards derived from product safety law.

Chemicals

At the core of chemical law is the so-called REACH regulation, which regulates the registration, evaluation, authorization and restriction of chemical substances at the European level. As an EU regulation, it is directly applicable in Austria, just as national law.[28] The necessary domestic implementation measures (for example provisions with regard to official monitoring) are contained in the Chemical Substances Act 1996[29].

Biocides

Biocidal products "are active substances and preparations which contain one or more active substances in the form in which they reach the user, and which are destined to destroy, deter or to render harmless, in a chemical or biological way, harmful organisms or to fight them in another way" (§ 2 para. 1(2) Biocidal Products Act[30]). The Biocidal Products Act, which was adopted to implement the Biocidal Products directive, together with the Biocidal Products Act – Existing Active Substances Ordinance[31] serve as the central Austrian provisions concerning the introduction of biocidal products and their monitoring.

The Biocidal Products Act provides the conditions for the introduction of biocidal products not harmful to health (of persons and animals) and not harmful to the environment (§ 1). The Act foresees in this matter extensive notification, registration or authorization procedures.[32]

More and more often, nanomaterial-substances are also being used in biocidal products[5]. How many of these products actually are already on the market is currently hard to tell, especially in light of missing labeling and notification obligations. Nevertheless, nanoscale active substances fall under the active substances terminology of relevant EU law and of the national Biocidal Products Act[33]. As the current biocidal products law does not explicitly recognize nanomaterials, nanoscale active substances are not treated as own active substances. The consequence is that due to the lack of proper data collection methods as well as suitable testing strategies and methods, the specific characteristics and risks of nanomaterials in the assessment of active substances are sometimes not recognized, not correctly assessed and consequently also not considered[30]. This leads to the danger of improper risk management.

Pesticides

In Austria, pesticides are regulated by the Pesticides Act[34]. It foresees an authorization procedure (§§ 4 ff.) which shall guarantee a "risk-minimized usage" as well as a high level of protection for persons, animals and the environment (§ 1). So far, according to the Action Plan, no pesticides containing nanomaterials have been admitted to the Austrian market by Austrian authorities. However, due to the lack of mandatory notifications with regard to used nanomaterials, this contention is of limited significance. Nano-Argentum 10 is a nano-pesticide which has already been admitted in Germany, thus, automatically also being authorized for the Austrian market.[35]

General product safety

Consumers in Austria, aside from sector-specific product safety provisions as highlighted below, are protected by the general Product Safety Act[36]. The Act applies either if no specific product safety regulations exist or if these have gaps. It does not apply where the specification of safety requirement to be met by products falls under the jurisdiction of the Austrian states. The act aims at protecting human life and health. Consumers shall be protected from danger by any hazardous products, hence, the Product Safety Act serves the averting of danger.[37] Within the scope of application of the Product Safety Act, manufacturers, importers as well as vendors are responsible for product safety. According to the Product Safety Act, before the product enters the market, there is no official authorization, control or notification procedure. Thus, ensuring compliance with safety requirements and risk assessments as well as with conformity evaluations lays with the industry: manufacturers and importers are only allowed to introduce products to the market which are safe. Obligations relating to vendors are less stringent, however, they are not allowed to supply products of which they know or should know, due to information accessible to them when exercising reasonable care, that they do not meet such requirements. According to § 4 para. 1 Product Safety Act, a product is deemed safe "when, provided that it is put to its proper of any reasonably foreseeable use, it harbours no dangers or dangers of such a low level as is acceptable for human safety with a view to its use and to safeguarding a high level of protection." Compliance with the provisions is ensured through state market monitoring by the provincial governors and product safety supervisory bodies responsible to them. However, the competent federal minister may also take measures if the safety requirements are not complied with or if the safety of human life and health cannot be ensured.[38]

Within the scope of application of the Product Safety Act, various techniques of information are applied. For one, the law obliges to inform the public of dangers relating to the product. In addition, standards related to the EU's RAPEX system for the rapid exchange of information are implemented. According to this, the competent Minister is obliged to notify the EU Commission if for example a dangerous product is taken off the market or if special obligations are imposed.

In general, the Product Safety Act covers all products, also ones which contain nanomaterials. The envisioned safety provisions shall guarantee that products which pose a danger do not enter the market in the first place, or, in the course of market monitoring (see above), are taken off the market or other suitable official measures are taken. Dangers which follow from nanomaterials must be considered alongside the general safety requirements and risk assessments. The techniques of information are relatively sophisticated; if a safety risk is revealed, the safety requirements can rapidly be increased.

While the Product Safety Act has developed a system for already known dangers to human life and health which protects adequately from danger and is open to innovations, in certain areas the Act falls short. For example, that the Act does not apply to products for which the federal provinces are competent to regulate the safety requirements (e.g. agricultural products). This might complicate the coordination and information efforts, respectively inflate them unnecessarily, however, due to the federal division of

competences, it cannot be avoided. More serious is the fact that the Product Safety Act protects from dangers to human life and health, however other dangers, for example relating to the environment, do not fall within the protective ambit of the Act. Nevertheless, if the nanomaterials which endanger the environment fall within the scope of application of REACH, the environmental compatibility is examined under REACH. A significant problem, however not only with regard to the Product Safety Act, is the problem of lacking knowledge in relation to dangers and risks of nanomaterials.

Medicinal products

With regard to medicinal products, there are already numerous nano-applications[39]. In this connection, various medicinal product usages shall be mentioned, for example "drug-delivery"-systems, where nanoparticles are used as transport systems. Nanoparticles shall also break through certain barriers, to deliver agents targeted to a special place in the body[40]. Different nano-medicinal products in the sector of diagnostics have already been authorized for the European market[41].

The manufacturing and marketing of medicinal products fall under the Medicinal Product Act[42] as well as EU law[43]. Medicinal products in general fall under an official authorization process. Thereby the manufacturer must present to the administrative authority *inter alia* proof on quality and harmlessness. Dangers which can derive from medicinal products containing nanotechnology are to be assessed within the authorization procedure. In comparison to other products, with regard to medicinal products environmental aspects are to be considered as well and in general, eco-toxicological tests are to be conducted[44].

Medical devices

With regard to human medicine, nanomaterials are playing an increasing role as well: e.g. the coating of implants with nanomaterials for a better bio-compatibility and biostability; in tumor diagnostics, with the help of specific fluorescent dyes; or in relation to surgical instruments which, by altering the surface, for example develops an antiseptic effect[37]. Manufacturing, marketing as well as the use of medical devices are covered by the scope of application of the Medical Devices Act[45], which implements relevant EU law.

One of the main tasks in this sector is to ensure the safety and quality of medical devices to protect the life and health of persons which are in contact which such products. The law on medical devices utilizes a differentiated regulatory framework, against the background of a broad European regulatory approach (see box). In addition, there is an Austrian register for medical devices.

The safety and performance requirements applicable to medical devices range from electrical safety to bio-compatibility as well as toxicological and hygienic harmlessness, up to risk/benefit analysis and labeling requirements[47]. Dangers and risks which derive from nanomaterials are also comprised by the fundamental safety requirements. Whether the safety and quality requirements as well as their specifications by standards institutes are sufficient for nanospecific dangers and risks, depends mainly on the level of knowledge. Possible needs of amendment exist in the area of risk assessment, risk management and monitoring.

Due to the complex regulatory framework, which when assessing and managing the risk takes into consideration several diverse actors (manufacturers, private corporations, public authorities and standards institutes at the European and national level), an appropriate and functioning information management system is of special relevance.

Additional questions can appear concerning products which for example due to their use of nanotechnology fall out of the established framework of product limits and therefore are not clearly within one legal framework[48]. With regard to medical devices, legal amendments could be called for to avoid so-called "dual(/multi)-use-products" being brought on the market under less strict provisions.[49]

It remains to be stated that in relation to the protective ambit of medical devices law, environmental concerns are not taken into consideration and also ethical questions are not in the focus of the regulatory efforts.

Cosmetics

Nano-cosmetics, *e.g.* sun protection or skin care products, – until the EU cosmetics regulation enters into force – primarily fall under the regulatory framework of the EU cosmetics directive[5], the Food and Consumer Protection Act (LMSVG)[50] as well as a range of domestic provisions (especially the ordinances on means of control[51], cosmetics[52], cosmetics-dyes[53] as well as cosmetics labeling[54]).

In principle, the marketing of cosmetics which are hazardous to health is prohibited in Austria. However, the current legal framework does not foresee an official pre-examination for marketing – unlike with regard to medicinal products –, a circumstance which has been criticized also with regard to the EU cosmetics directive[55]. Thus, it falls to the manufacturer or importers to assess and document the safety of the product. There are also materials which are not allowed to be used in cosmetics. The examination of materials occurs with regard to the chemical substance, not to the particle size, and consequently, concerning nanomaterials certain gaps can exist in relation to risk

Product harmonization in the EU[46]

In order to realize the European internal market, the EU has been harmonizing the manufacturing, marketing and use of various products since the 1980s. The diverse product groups which are regulated by the new and global concept and where nanotechnology or nanomaterials might play a role in one way or another range from toys over printers, building products, explosive materials up to medical devices. The legal framework for the manufacturing of these harmonized product groups thereby are guided by the same basic structures: determination of general safety and quality requirements by directives: non-binding specification of these requirements through European standards institutes (CEN, CENELEC); only products which comply with the general safety and quality requirements are allowed to enter the market; products which comply with the requirements are marked with a CE symbol; the CE symbol serves as a "goods passport", and the product can circulate freely on the EU market with it; if a product is produced according to the norms and standards of the standards institutes, it is assumed that they comply with the fundamental EU requirements (assumption of conformity). In addition, depending on the danger of the product or product group, the manufacturing and marketing is monitored by a specially accredited corporation (so-called "notified body") and if necessary the conformity of the products with the fundamental requirements is confirmed (certified) by them. Alongside of this accompanying manufacturing and marketing monitoring procedure by private bodies, the market is also monitored by public authorities.

assessment and risk management[56]. Currently applicable labeling requirements do not foresee an obligation to explicitly disclose the usage of nanomaterials – an according provision in this regard will not take effect until 2013 when the EU cosmetics regulation enters into force.

Regardless of missing nanospecific examination standards, the framework of the general safety assessment also entails taking into consideration dangers and risks deriving from nanomaterials. However, lacking knowledge is also a factor in this sector. The existing safety testing methods are aimed at common components of cosmetics and are not necessarily suitable for nanomaterials[57].

Food

A wide field of application of nanotechnology exists in the food industry[58]. In the center of relevant regulatory efforts are several EU-provisions[5]. On a domestic level, especially the Food and Consumer Protection Act (LMSVG)[50] is mention worthy. It contains requirements with regard to the composition of foods. The provisions mainly serve consumer and health protection. Unsafe foods are prohibited from entering the market. This encompasses nanotechnology-containing foods. The responsibility for the safety of food remains with the food business and they are obliged to control compliance with legal requirements and if necessary, to take appropriate measures. In addition, official monitoring takes place. In general, it is possible to state also with regard to food industry that the existing regulations cover dangers stemming from nanomaterials as well. Amendments might be called for e.g. with regard to maximum quantity limits, purity standards and labeling obligations.[59]

For an overview with regard to workplace safety, Austrian industrial law and environmental law as well as a joint conclusion, see NanoTrust Dossier 019.

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