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## The EU code of conduct for nanosciences and nanotechnologies research

### Summary

The code of conduct for responsible nanosciences and nanotechnologies research (code of conduct) is the Annex to the first nanotechnology-specific legal measure by the EU (2008), a Commission recommendation that is legally non-binding. The nanotechnologies code of conduct contains principles and guidelines for integrated, safe and responsible (ethical) nanosciences and nanotechnologies (N&N) research. The central control mechanisms are research prioritisation, technology assessment, ethical and fundamental law clauses/restrictions, defensibility checks and accountability. The EU Commission appeals to the Member States to comply with the voluntary guidelines and principles; encourages funding bodies to only fund research that complies with the code and to implement the code; encourages researchers to commit themselves to compliance with the code and civil society organisations to participate in N&N research. As yet, only a few implementation measures have been adopted. From a legal point of view, the code is controversial, and nevertheless it has an influence on the ongoing discussion on the topic of "responsible research and innovation" at EU level.

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### Introduction

The Commission recommendation for a code of conduct for responsible nanosciences and nanotechnologies research (code of conduct) dates from 2008. Nevertheless, it continues to be a subject of discussion. Thus the 2012 final report on the NanoCode research project, which has been monitoring the development and implementation of the nanotechnology code over two years, recommends inter alia that the principles and guidelines of the code be extended to all new technologies and to science as a whole.<sup>1</sup> The initiative for a Commission recommendation on "Responsible research and innovation", launched by the EU Commission in March 2012 adopts the same approach.<sup>2</sup> The principles and guidelines of the code of conduct should be extended to all technologies and also include production and application. The present dossier sets out the origins of the original code of conduct and its main contents. At the same time, reference is also made to legal problems that would result from national implementation. Finally, the latest developments are summarised.<sup>3</sup>

### The first nano-specific EU legal measure

The code of conduct was the first nano-specific EU legal measure.<sup>4</sup> Thus, contrary to what one might have expected on the basis of the strategy pushed since 2004,<sup>5</sup> the EU did initially not make use of hard-law instruments – such as by adjusting the existing legal framework in material, product or environmental law to developments in nanotechnology – but instead adopted a softer instrument, a legally non-binding Commission recommendation. The original idea was an instrument that would enable the EU to pursue responsible N&N research internationally. However, no consen-

sus was reached on an international control instrument. What remained was the Commission recommendation for a nanotechnology code of conduct adopted at the beginning of 2008. Before adopting the recommendation, the Commission, as usual with EU legal measures, consulted the public for three months. The results of this consultation process were included in the code of conduct. The code is meant to be an essential element of a safe, integrated and responsible European nanotechnology strategy, to contribute to the good governance of nanotechnology, to encourage dialogue, to mobilise stakeholders, and finally to set European standards and act as a model at international level.<sup>6</sup>

### On the contents of the code

The code fits generally into larger European policy programmes and objectives; the implementation of the European research area, compliance with the principle of precaution and sustainability, and the appropriate regulation of risks and the establishment of competitiveness.<sup>7</sup> The core of the code comprises seven principles (see Box 1).

The scope of application extends to research activities "dealing with matter at the nanometric scale (1 to 100 nm). It includes all man-made nano-objects be they engineered or involuntarily generated. Naturally occurring nano-objects are excluded from the scope of the code of conduct. N&N research encompasses research activities from the most fundamental research to applied research, technology development and pre- and co-normative research underpinning scientific advice, standards and regulations" (2.b of the code). For the EU Commission itself, the scope of application of the recommendation is expect-

ed to change, since in 2011 it adopted a Commission recommendation on the definition of nano material<sup>10</sup> which could have self binding effect. According to the definition therein, nano-material means "a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where,

for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm. In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50 % may be replaced by a threshold between 1 and 50 %."

The nanotechnology code of conduct addresses not only Member States but also employers, research (funding) bodies, researchers and all citizens and NGOs engaged, involved or interested in N&N research (2.c of the code). See Box 2.

## The code from a legal point of view

The code is the subject matter of discussions in the legal world. Specifically, the discussion addresses (1) whether the Commission has any jurisdiction to issue such a recommendation; (2) in what manner it could take effect *de facto* and *de jure*; (3) whether the principles of the code are sufficiently specific; and (4) whether individual guidelines are compatible with the fundamental rights of the freedom of science.

(1) *Competence*: The code of conduct is a recommendation by the EU Commission. Given the narrow competences in the EU within the field of research, the code is above all based on the EU legal basis that empowers the Commission to adopt legally non-binding recommendations within the scope of application of the Treaty. The content and scope of the code raised doubts among lawyers as to whether the legal basis was at all sufficient.<sup>11</sup> In particular, its strong *de facto* binding effect gave rise to reservations. However, it was argued that precisely the *de facto* binding effect is one of the essential features of legally non-binding recommendations. Thus, legally non-binding recommendations are intended precisely for cases where the EU lacks competence for harmonisation.<sup>12</sup>

(2) *De facto and de jure validity*: Commission recommendations are by law (Art. 288 of the TFEU) legally non-binding. The primary significance of recommendations, including the nanotechnology code of conduct, is to be found in their political and psychological regulatory effect. As a rule, they are used by the Commission if it wishes to set political impulses or create legal uniformity in subject areas in which it lacks sufficient competence to achieve harmonisation. Although in legal terms recommendations are not binding, they can become (legally) effective in combination with binding legal measures or general legal principles. For this, either European and national regulations or another legal act (for instance a private or public law contract) would have to refer to the code:

### The seven principles

*Principle of public well-being*: Under the heading "Meaning", the Commission requires that N&N research should primarily serve the interest of the well-being of individuals and society and should respect fundamental rights (Paragraph 3.1) and that research funds should only be given to research that is useful to the general public. The code encourages research institutions and member states only to pursue research "with the broadest possible positive impact" (4.1.13) and in particular support research projects "aiming to protect the public and the environment, consumers or workers and aiming to reduce, refine or replace animal experimentation" (4.1.13).

*Principle of sustainability*: Safe and ethical research should contribute to sustainable development (3.2); N&N research should not harm or create a biological, physical or moral threat to people, animals, plants or the environment. The code of conduct encourages the denial of funding to research that could involve a violation of fundamental rights or "fundamental ethical principles" (4.1.15), and human enhancement research (4.1.16). Finally, the Commission requires funding bodies to monitor the potential social, environmental and human health impacts of N&N research. (4.2.4).

*Principle of precaution*: N&N research should anticipate potential environmental health and safety impacts and maintain a high level of protection, avoiding risks without impeding innovation (3.3, 4.1.5). As long as risk assessment studies on long-term safety are not available, nano-objects should not be intruded into the human body, food or other consumer related products (4.1.17). In order to protect workers and researchers against potential hazards and risks (4.2.1), the Commission insists on specific regulations and risk and ELSI research (4.2.5, 4.2.7).

*Principle of democracy*: The code of conduct envisions all stakeholders participating in the decision-making process (3.4, 4.1.8), research being conducted transparently (4.1.6)<sup>8</sup>, the presentation of research results being clear, balanced and comprehensible and made generally accessible (4.1.2, 4.1.4, 4.1.8, 3.1, 3.4). The EU is intended to serve as a forum for discussion to permit an appropriate debate on social concerns and hopes (4.1.1). The corresponding information and communication would be the responsibility of the Member States (4.1.1). All stakeholders are encouraged to participate in the determination of the content of N&N research (4.1.8, 4.1.10). Finally, the code requires the Member States and the research funding bodies to disseminate the code and its principles (4.3.1, 4.3.2).

*Principle of excellence*: N&N research should meet the best scientific standards (3.5), for which in particular the Member States and the research bodies are responsible. The Commission attempts to prevent "dubious practices"<sup>9</sup> and to protect whistleblowers either through the employer or legal regulations (4.1.5). The code requires peers to verify the scientific results before they are widely disseminated (4.1.4).

*Principle of innovation*: N&N research should take place within an innovation-friendly environment (3.6), public authorities and standardising organisations should develop N&N research standards (4.1.11) and the Member States and research funding bodies should devote an appropriate part of research funds to risk assessment, standardisation and the refinement of metrology methods (4.1.12). The grant of funds should be preceded by a cost-benefits analysis (4.1.14) and funds should only be awarded if a risk assessment is presented together with the application for funding (4.2.3).

*Principle of responsibility*: Researchers and research organisations should "remain accountable for the social, environmental and human health impacts that their N&N research may impose on present and future generations" (3.7). To this purpose, researchers should conduct participatory foresight exercises (4.1.9). In order to ensure that the stakeholders actually comply with the principles of the code and other relevant legal regulations, the Commission wants the Member States to provide sufficient resources to monitor and control N&N research (4.1.6, 4.3).

- Thus for instance the EU's Framework Programmes (FP) could refer to the code and only award EU funding if researchers comply with the code. FP 7, however, does not refer to the code (since it was adopted earlier), nor does the follow-up programme, Horizon 2020.<sup>13</sup>
- It is conceivable for a national regulation to refer to the code. In the Netherlands, the national research funding body must oblige its funding recipients by contract to comply with the principles and guidelines of the code in the field of N&N research.<sup>14</sup> In this way, the code of conduct indirectly becomes part of the content of the funding agreement and has legal effects as against the researchers. The ECJ in certain cases relies on recommendations when interpreting binding law.<sup>15</sup> However, Austria has not adopted any such im-

**"Obligations" on the basis of the code**

**Researchers**

- Research in the public interest
- Consideration of fundamental ethical principles and fundamental rights
- Risk research as an element of all applications for funds
- Responsibility for the consequences of research

**Research funding bodies**

- Research priorities with respect to socially useful research, risk assessment, metrology and standardisation
- Uniformity of standardisation and metrology
- Accountability in the light of research priorities
- Publication of the cost-benefits assessment of funded projects

**Member States**

- Collaboration between Member States and the Commission
- Monitoring and control systems
- Dissemination
- Encouragement of research in accordance with the code
- Annual report on application and measures within the framework of the code

**EU Commission**

- Compliance with the code when granting research funding
- Collaboration with the Member States
- Review of the code every two years
- Dissemination

plementation measures, nor as yet does the code play a role, as far as is known, for the relevant Austrian funding bodies.

- University statutes could also refer to the code, but do not; however, a number of universities have set up ethics commissions and these can assess research on the basis of ethical principles, which at some universities can even lead to unethical research being prohibited (for instance at the University of Salzburg). In theory, ethics commissions could use the code in their work.
- (Non-)binding university guidelines could also refer to the code of conduct. However, we are not aware of any Austrian university that refers to the code.
- The code could also be implemented via the Performance Agreement (PA) between the research performing bodies and the Ministry of Science. While the current 2010-12 PA admittedly refers to other research law recommendations (for instance to the "European Charter for Researchers", the Annex to a legally non-binding Commission recommendation dating from 2005),<sup>16</sup> there are no references to the nano code. If the code were to be mentioned in future PAs, this would oblige both universities and the Ministry to comply with or implement these principles and guidelines. For the researchers themselves, according to legal doctrine,<sup>17</sup> the mere reference to the code in a public law contract would not establish any obligations.
- Recommendations can also become legally valid through the application of general legal principles (such as the protection of legitimate expectations or the principle of equal treatment) and in this way the Commission itself could be obliged to comply with the code.<sup>18</sup>

If in the implementation (for instance by the legislature, a university, a research [funding] body) the intention was to prevent the code having indirect binding effect by means of a reference in a binding legal act, the binding legal act would once again have to confirm that it is being implemented purely "voluntarily".

3) *Lack of certainty*: The seven principles at the core of the code (see box) are criticised from a legal point of view<sup>19</sup> because in part they are linguistically vague and their content is difficult to determine. In particular the principles of general well-being, sustainability and defensibility use vague terms and thus allow scope for interpretation. The following is a brief overview:<sup>3</sup>

The code gives priority to research in the general interest or that is generally useful, without specifying what is meant by this. In any event, research is in the general interest if it is devoted to the development of methods and instruments for risk assessment (4.1.12); on the other hand, it is not in the general interest to develop artificial viruses with pathogenic potential (4.1.15) or to pursue research with the sole purpose of the artificial enhancement of human performance (4.1.16); according to the Commission, the former should not be encouraged and the latter should not be researched at all. As far as concerns the remaining research (funding), according to the code, research that could potentially infringe the fundamental rights or fundamental ethical principles should be prohibited or at least not funded (4.1.15). However, it is largely unclear what fundamental rights or fundamental ethical principles are the subject of the code of conduct. It is also difficult to determine the ethicality of specific research. The question arises which "fundamental ethical principles" research must apply.

There is also a need to construe the principal responsibility laid down under accountability. In the German version of the code, it is not clear whether this accountability ("Rechenschaftspflicht") is a legal responsibility or is intended to encourage a "culture of responsibility" (4.1). The term "accountability" in the English version tends not to suggest a legal obligation to render accounts.

(4) *Freedom of science*: If the code is to be implemented in Austrian law with binding effect, account must also be taken of national constitutional law, in particular freedom of science (Art. 17 of the Basic Law): Science and its teaching are free; protection extends to "any intellectual activity that in terms of form, content and objectives constitutes a serious attempt to obtain knowledge in a methodical, systematic and verifiable manner."<sup>20</sup> The Basic Law applies without reservations. However, this does not mean that science cannot be subject to any limits whatsoever. The general limits of the legal system (for instance criminal law provisions) also apply to the exercise of the freedom of science. According to the judicial practice of the Constitutional Court, science must not however be subjected to any specific restrictions deliberately intended to limit this freedom.<sup>21</sup> From a legal point of view, individual guidelines and principles of the code, if implemented in national law, would interfere in the scope of protection of the freedom of science. This concerns in particular the intended priority to be given to certain types of re-

search, the control of the ethicality of research, the obligation to render accounts and prohibitions on research and research funding. Interventions of this kind are not of themselves excluded but must satisfy the requirements of the freedom of science.

## Latest developments

In order to adapt the code to more recent developments, it was proposed to review it every two years<sup>22</sup>. At the beginning of 2010 the Commission conducted a public consultation process but the proposed amendment failed. The prospects for 2012 are not good either. No support was given to the request to the Member States to report to the Commission each year on the measures within the scope of application of the code. However, this lack of reporting activity could be due to the hitherto almost total lack of measures. An amendment of the code is no longer to be expected. As long as the Commission does not itself abandon it, however, it will remain in the *acquis* of the EU. Leaving aside single implementation measures (for instance by the Netherlands), it is not to be expected that the Member States will adopt extensive implementation measures. The plan is to merge the nanotechnology strategy in a broad innovation strategy. The new nano-action plan originally proposed has however been shelved, as has been an amendment of the code of conduct. What is currently being prepared is an extension of the principles and guidelines of the code to the wider field of research and development and to the field of application.<sup>23</sup>

### MASTHEAD:

**Owner:** Austrian Academy of Sciences; legal person under public law (BGBl 569/1921; BGBl I 130/2003); Dr. Ignaz Seipel-Platz 2, A-1010 Vienna

**Editor:** Institute of Technology Assessment (ITA); Strohgasse 45/5, A-1030 Vienna; [www.oew.ac.at/ita](http://www.oew.ac.at/ita)

**Mode of publication:** The NanoTrust Dossiers are published irregularly and contain the research results of the Institute of Technology Assessment in the framework of its research project NanoTrust. The Dossiers are made available to the public exclusively via the Internet portal "epub.oew" : [epub.oew.ac.at/ita/nanotrust-dossiers](http://epub.oew.ac.at/ita/nanotrust-dossiers)

NanoTrust-Dossier No. 036en, December 2012: [epub.oew.ac.at/ita/nanotrust-dossiers/dossier036en.pdf](http://epub.oew.ac.at/ita/nanotrust-dossiers/dossier036en.pdf)

ISSN: 1998-7293



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## Conclusions

The acceptance and dissemination of the code has hitherto remained within limits. This is in part due to the vague wording of the regulations and the lack of control, monitoring and penalty possibilities. In addition, questions remain whether such a code of conduct is at all justified in the field of nanotechnology research.

The Commission's proposal to extend the code to emerging technologies and the entire life cycle ("framework for responsible research and innovation") is, as the legal discussion on the nanotechnology code of conduct shows, faced by legal challenges. Currently, it appears improbable that the generally worded nanotechnology code of conduct will become a practicable general standard.

## Notes and References

- <sup>1</sup> Cf. [nanocode.eu/files/NanoCode-Master-Plan.pdf](http://nanocode.eu/files/NanoCode-Master-Plan.pdf), 1.2.12 (MasterPlan).
- <sup>2</sup> Cf. [ec.europa.eu/governance/impact/planned\\_ia/docs/2010\\_rtd\\_012\\_responsible\\_research\\_innovation\\_en.pdf](http://ec.europa.eu/governance/impact/planned_ia/docs/2010_rtd_012_responsible_research_innovation_en.pdf).
- <sup>3</sup> This dossier is based on a more detailed working paper published in parallel and in part adopted word for word: Eisenberger, EU-Verhaltenskodex Nanotechnologie: Rechtsstaatliche und demokratische Aspekte, ITA-manu: script 12-03, with detailed references; accordingly, for reasons of space, this dossier largely refrains from citing sources.
- <sup>4</sup> Cf. [ec.europa.eu/nanotechnology/pdf/nanocode-rec\\_pe0894c\\_de.pdf](http://ec.europa.eu/nanotechnology/pdf/nanocode-rec_pe0894c_de.pdf).
- <sup>5</sup> Cf. [ec.europa.eu/nanotechnology/pdf/nano\\_com\\_de.pdf](http://ec.europa.eu/nanotechnology/pdf/nano_com_de.pdf); see also NanoTrust-Dossier 017en.
- <sup>6</sup> More extensive references in Eisenberger (EN 3).
- <sup>7</sup> Cf. Bochon, Evaluation of the European Commission Recommendation for a Code of Conduct for Responsible Nanosciences and Nanotechnology Research, *Nanotechnology Law & Business Journal* 2011, 117ff.
- <sup>8</sup> This means in particular that nano researchers must show that they also comply with the relevant regulations.
- <sup>9</sup> What this means remains unclear; however, it must in any event be more than "good scientific practice", since the code itself lays down that it primarily does not mean "plagiarism, falsifications and fabrication of data."

- <sup>10</sup> Cf. [eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:275:0038:0040:DE:PDF](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:275:0038:0040:DE:PDF).
- <sup>11</sup> Cf. Vöneky and von Achenbach, Erste Stellungnahme zu der „Empfehlung der Kommission für einen Verhaltenskodex für verantwortungsvolle Forschung im Bereich der Nanowissenschaften und -technologien“, 2008, [www.mpil.de/shared/data/pdf/eukodex\\_stellungnahmeanmpg\\_23juni08insinternet.pdf](http://www.mpil.de/shared/data/pdf/eukodex_stellungnahmeanmpg_23juni08insinternet.pdf), 4.
- <sup>12</sup> Eisenberger, Kleine Teile, große Wirkung, ITA-manu:script 10-01, especially FN 58.
- <sup>13</sup> Cf. [eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2011:0809:FIN:de:PDF](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2011:0809:FIN:de:PDF).
- <sup>14</sup> Cf. MasterPlan (EN 2) 17.
- <sup>15</sup> For details see Eisenberger (EN 3) with further references
- <sup>16</sup> Cf. [eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:075:0067:0077:DE:PDF](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:075:0067:0077:DE:PDF).
- <sup>17</sup> Cf. Kopetzki, Muss Forschung „ethisch vertretbar“ sein? in: Jabloner et al. (eds.), *Vom praktischen Wert der Methode* (2011) 253; Pöschl, Von der Forschungsethik zum Forschungsrecht: Wie viel Regulierung verträgt die Forschungsfreiheit? in: Körtner et al. (eds.), *Ethik und Recht in der Humanforschung*, 2010, 90.
- <sup>18</sup> Cf. Eisenberger (EN 12) 11f., with further references; additional sources in Eisenberger (EN 3).
- <sup>19</sup> On the following comments cf. in particular Vöneky and von Achenbach (EN 11); Kopetzki (EN 17), Pöschl (EN 17); von Schomberg, Prospects for Technology Assessment in a framework of responsible research and innovation, in: Dusseldorp and Beecroft (eds.), *Technikfolgen abschätzen lehren* (2011) 39; Scherzberg, Grundlagen staatlicher Risikosteuerung, in: Albers (ed.), *Risikoregulierung im Bio-, Gesundheits- und Medizinrecht* (2011) 35; Details and references in Eisenberger (EN 3).
- <sup>20</sup> Cf. Pöschl (EN 16), 114f. citing Rebhan and further references.
- <sup>21</sup> Cf. VfSlg. 8136/1977 and 13.978/1994 with further references.
- <sup>22</sup> Cf. K (2008) 424 Recommendation 5.
- <sup>23</sup> Further discussion in Eisenberger (EN 3) with further references.