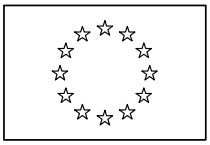

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COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE

REGULATORY ASPECTS OF NANOMATERIALS

[SEC(2008) 2036]

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REGULATORY ASPECTS OF NANOMATERIALS

(text with EEA relevance)

1. INTRODUCTION

In its Communication "Towards a European Strategy for Nanotechnology",[1] the Commission states that R&D and technological progress need to be accompanied by scientific investigation and assessment of possible health or environmental risks associated with nanotechnology. The "Integrated, safe and responsible approach" has become the core of the EU policy for nanotechnology. The Communication "Nanosciences and nanotechnologies: an action plan for Europe 2005 – 2009"[2], specified that all applications and use of nanosciences and nanotechnologies must comply with the high level of public health, safety, consumers and workers protection, and environmental protection chosen by the Community. The Commission therefore announced a regulatory review of EU legislation in relevant sectors. The present Communication reflects this commitment. It covers nanomaterials currently in production and/or placed on the market. In the absence of generally accepted definitions, the term nanomaterials is used in this Communication to cover commonly used terminology such as manufactured (or engineered) nano-sized and nanostructured nanomaterials. The Communication does not address nanomaterials or nanoparticles that occur naturally or are unintentionally produced, e.g. in combustion.

2. REVIEW OF LEGISLATION APPLICABLE TO NANOMATERIALS

Nanotechnologies are enabling technologies, with a high potential benefits for consumers, workers, patients, and the environment, as well as the creation of jobs. On the other hand, nanotechnologies and nanomaterials may expose humans and the environment to new risks, possibly involving quite different mechanisms of interference with the physiology of human and environmental species.

The regulatory challenge is therefore to ensure that society can benefit from novel applications of nanotechnology, whilst a high level of protection of health, safety and the environment is maintained.

Legislation relevant for health, safety and environment aspects of nanomaterials can be grouped under chemicals, worker protection, products and environmental protection, simultaneously applicable. Main elements in relation to risks associated with nanomaterials are described in the annexed Commission Staff Working Document.

Overall, it can be concluded that current legislation covers to a large extent risks in relation to nanomaterials and that risks can be dealt with under the current legislative framework. However, current legislation may have to be modified in the light of new information becoming available, for example as regards thresholds used in some legislation.

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[1] COM(2004) 338 final of 12 5 2004,

[2] COM(2005) 243 final of 7 6 2005

Implementation of legislation and use of regulatory instruments created by legislation remains a particular challenge. Documents that support implementation, particularly in relation to risk assessment, adopted within the context of current legislation will have to be reviewed in order to ensure that they effectively address risks associated with nanomaterials and make best use of the information becoming available. Similarly, authorities and agencies will have to pay special attention to risks in relation to nanomaterials where production and marketing are subject to pre-market control.

In order to properly develop, modify or in particular to implement legislation, the scientific knowledge base needs to be improved. This Communication therefore pays attention both to legislation, implementation and bridging the knowledge gap.

In this context, attention is also drawn to the Code of Conduct for responsible nanosciences and nanotechnologies research.[3] This Code is complementary to legislation and provides Member States, employers, research funders, researchers and more generally all individuals and civil society organisations involved or interested in nanosciences and nanotechnologies research with guidelines favouring a responsible and open approach to N&N research in the Community.

2.1. Chemicals

REACH[4] provides an over-arching legislation applying to the manufacture, placing on the market and use of substances on their own, in preparations or in articles. REACH is based on the principle that manufacturers, importers and downstream users have to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle.

There are no provisions in REACH referring explicitly to nanomaterials. However, nanomaterials are covered by the "substance" definition in REACH.

Under REACH, manufacturers and importers will have to submit a registration dossier for substances that they manufacture or import at or above 1 tonne per year. At or above 10 tonnes/year, the registrant will be obliged to produce a chemical safety report. Furthermore, if deemed necessary for the evaluation of the substance the European Chemicals Agency can require *any* information on the substance, independent of the minimum information requirements of REACH

When an existing chemical substance, already placed on the market as bulk substance, is introduced on the market in a nanomaterial form (nanoform), the registration dossier will have to be updated to include specific properties of the nanoform of that substance. The additional information, including different classification and labelling of the nanoform and additional risk management measures, will need to be included in the registration dossier. The risk management measures and operational conditions will have to be communicated to the supply chain.

In order to address the specific properties, hazards and risks associated with nanomaterials, additional testing or information may be required. To determine specific hazards associated with nanomaterials, current test guidelines may need to be modified. Until specific test guidelines for nanomaterials exist, testing will have to be carried out according to already existing guidelines.

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[3] C(2008) 424 final of 7 2 2008

[4] Regulation (EC) No 1907/2006; OJ L 396 of 30.12.2006

For substances of very high concern[5], an authorisation will be required for their use and their placing on the market. The restrictions procedure allows to take measures with respect to nanomaterials where there is a risk arising from the manufacture, use or placing on the market. Authorisation and restriction schemes apply regardless of quantities manufactured or placed on the market.

The Commission will carefully monitor the implementation of REACH with respect to nanomaterials. Based on information regarding production and marketing, or new knowledge, for instance regarding toxicological or physical-chemical properties, current provisions, including quantitative triggers and information requirements may have to be modified.

Data generated under REACH will serve as input to other regulation, such as worker protection, cosmetics and environmental protection. It complements product legislation (e.g. general product safety) to the extent that this does not cover environmental aspects.

2.2. Worker Protection

Framework Directive 89/391/EEC[6] places a number of obligations on employers to take measures necessary for the safety and health protection of workers. It applies to all substances and work activities including manufacturing and use of chemicals at all levels of the production process, regardless of the number of workers involved and quantities of materials produced or technologies used.

This Directive fully applies to nanomaterials. Employers, therefore, must carry out a risk assessment and, where a risk is identified, take measures to eliminate this risk.

The planning and introduction of new technologies must be subject to consultation with the workers or their representatives, as regards the working conditions and the working environment in accordance with Articles 11 and 12 of the Framework Directive 89/391/EEC.

The Directive foresees the possibility to adopt individual directives laying down more specific provisions with respect to particular aspects of safety and health. Relevant directives thus adopted relate to risks related to exposure to carcinogens or mutagens at work[7], risks related to chemical agents at work[8], the use of work equipment by workers at work[9], the use of personal protective equipment at the workplace[10] and safety and health protection of workers potentially at risk from explosive atmospheres.[11]

As these Directives introduce minimum requirements, national authorities have the possibility to introduce more stringent rules.

2.3. Products

Product legislation lays down requirements regarding specific products, such as medicinal products, plant protection products (PPP), cosmetics, food and feed additives, etc. Consumer products that are not governed by specific legislation have to meet the requirements of the

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5 Carcinogenic, mutagenic or toxic to reproduction (CMR), persistent, bioaccumulating and toxic (PBT) or very persistent and very bioaccumulating (vPvB) or substances giving rise to an equivalent level of concern.

6 OJ L 183, 29.6.1989

7 Directive 2004/37/EC of 29 4 2004; OJ L 158, 30.4.2004

8 Directive 98/24/EC of 7 4 1998; OJ L 131, 5.5.1998

9 Directive 89/655/EEC of 30 11 1989; OJ L 393, 30.12.1989

10 Directive 89/656/EEC of 30 11 1989; OJ L 393, 30.12.1989

11 Directive 1999/92/EC of 16 12 1999; OJ L 23, 28.1.2000

General Product Safety Directive.[12]

Community regulation in these areas contains provisions in relation to health and safety of consumers, workers, patients and users, but not necessarily in relation to environmental protection. To the extent that nanomaterials contained in such products qualify as substances under REACH, they are subject under REACH to an assessment on their environmental impact.

Virtually all product legislation imposes a risk assessment and the adoption of risk management measures. Nanomaterials are not excluded from this obligation.

Where products are subject to a pre-market control or pre-market notification, e.g. medicinal products, novel foods, plant protection products, the assessment and management of risks in relation to nanomaterials can be verified by authorities (or Notified Bodies under the New Approach) before placing on the market. Implementation of these procedures will lead either to implementing legislation (e.g. listing of new substances on a positive or a negative list) or to binding administrative decisions (e.g. market authorisations), that will also specify marketing conditions.

Particularly relevant is the obligation to review, modify or cancel authorisations if there are indications that any of the relevant requirements are not longer satisfied, or if developments in scientific and technical knowledge require such action. Similarly, the holder of an authorisation or certificate must immediately notify the relevant authority or body of all new information on risks.

Where products can be placed on the market without specific pre-market procedural requirements (e.g. cosmetics, consumer products subject to the general product safety directive, various products regulated under the New Approach), compliance with legal requirements must be verified at the level of market surveillance. This does not exclude the possibility to undertake action restricting the placing on the market, or requiring advice from the various EU Scientific Committees. At all times authorities can verify the risk assessment and risk management strategy at the premises of the manufacturer.

In order to increase the level of protection, regulatory change has been proposed with respect to cosmetic products, placed on the market without pre-market control. The requirements regarding the risk assessment will be clarified. Further, manufacturers will be obliged to indicate whether their products contain nanomaterials when notifying their placing on the market and to set up a mechanism in order to monitor the health effects on cosmetic products placed on the market.[13]

As regards medical devices, Commission services will examine the possibility to make the placing on the market of devices presenting risks associated with nanomaterials subject to a systematic pre-market intervention.

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12 Directive 2001/95/EC; OJ L 11, 15.1.2002

13 COM(2008)49 final 2008/0025 (COD); 5.2.2008

2.4. Environmental protection

Environmental regulation relevant in this context relates in particular to integrated pollution prevention and control (IPPC), the control of major accident hazards involving dangerous substances (Seveso II), the water framework directive and a number of waste directives.

The IPPC Directive[14] covers approximately 52,000 industrial installations across the EU and requires installations falling under its scope to operate in accordance with permits including emission limit values based on the application of best available techniques (BAT). In principle, the IPPC Directive could be used to control environmental impacts of nanomaterials and nanomaterials issues at IPPC installations through the inclusion of such considerations into the Commission's BAT Reference Document (BREFs) process should the need arise.

The Seveso II Directive[15] applies to establishments where named dangerous substances (or substances falling within certain classification categories) are present above specific quantities (or thresholds). It imposes a general obligation on operators to take all measures necessary to prevent major accidents and to limit their consequences for man and the environment. If certain nanomaterials are found to demonstrate a major accident hazard, they may be categorised, together with appropriate thresholds, in the context of the Directive.

The Water Framework Directive (2000/60)[16] sets common principles and an overall framework for action to improve the aquatic environment and to progressively reduce the pollution from priority substances and phasing out emissions, discharges and losses of priority hazardous substances to water. A list of 33 priority substances has been established in 2001.[17] Nanomaterials could be included among the Priority Substances depending on their hazardous properties. Environment Quality Standards would in these cases be proposed by the Commission. For groundwater[18], Member States will have to establish quality standards for pollutants representing a risk, in which case nanomaterials may also be included.

Directive 2006/12/EC on waste[19] sets the general framework and imposes an obligation on Member States to ensure that waste treatment does not adversely affect health and the environment. The hazardous waste Directive[20] defines which wastes are hazardous and lays down stricter provisions regarding such waste. Hazardous waste must display certain properties set out in an Annex to the Directive and feature on the European Waste List as hazardous. Wastes containing nanomaterials could be classified as hazardous, if the nanomaterial displays relevant properties which render the waste hazardous.

Specific legislation has been adopted to deal with particular waste streams[21] or specific waste treatment processes, such as incineration[22] and landfill.[23]. Current EU waste legislation covers general requirements for the protection of health and the environment during waste management. It also includes requirements for the management of specific waste materials

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14 Council Directive 2008/1/EC concerning integrated pollution prevention and control; OJ L 24 29.01.2008

15 Directive 96/82 on the control of major-accident hazards involving dangerous substances; OJ L10 of 14.1.1997

16 Directive 2000/60/EC ,OJ L 327, 22.12.2000

17 Decision No 2455/2001/EC, OJ L 331, 15.12.2001

18 Directive 2006/118/EC; OJ L 372, 27.12.2006

19 Directive 2006/12/EC; OJ L 114, 27 4 2006

20 Directive 91/689/EEC; OJ L 377, 31.12.1991

21 E.g. electrical and electronic equipment, end of life vehicles, packaging and packaging materials, batteries, titanium dioxide

22 Directive 2001/80/EC; OJ L 309, 27.11.2001

23 Directive 1999/31/EC; OJ L 182 , 16.07.1999

that may contain nanomaterials whilst not explicitly addressing the risks of nanomaterials. If the need for more specific provisions is established, appropriate action can be proposed or implemented under the current legislative framework. Similarly, action can be taken by Member States in implementing current provisions in the framework of national policies

3. IMPLEMENTATION OF LEGISLATION

Whilst the Community legislative framework generally covers nanomaterials, *implementation* of legislation needs further elaboration. Important elements are the *test methods* and the *risk assessment methods* that serve as a basis for implementing legislation, administrative decisions, manufacturer's obligations or employer's obligations. The scientific basis to fully understand all properties and risks of nanomaterials is not sufficiently available at this point in time.

A number of reviews identifying "knowledge gaps" have been published[24]. The EU Scientific Committee on Emerging and Newly-Identified Health Risks (SCENIHR)[25] and the Scientific Committee for Consumer Products (SCCP)[26] have pointed to the need to improve the knowledge base, in particular regarding test methods and risk assessment (hazards and exposure) methods. In general, there is a consensus in Member States and at the international level that further research is necessary. An indication is given in the annexed Commission Staff Working Document

Where the full extent of a risk is unknown, but concerns are so high that risk management measures are considered necessary, as is currently the case for nanomaterials, measures must be based on the precautionary principle.

As specified in the Commission Communication of 2 February 2000[27] on the Precautionary Principle, recourse to the precautionary principle does not necessarily mean adopting final instruments designed to produce legal effects. A wide range of activities or measures can be used, like legally binding measures, initiation of research projects or recommendations. Measures adopted under the precautionary principle must be based on general principles of risk management and must therefore *inter alia* be proportionate, non-discriminatory, consistent, on an examination of benefits and costs of action or lack of action, and on an examination of scientific developments.

Against this background, Community action in relation to managing the risks in order to meet regulatory requirements should mainly focus on the following activities.

3.1. Improving the knowledge base

There is a need for a rapid improvement of the scientific knowledge basis to support the regulatory work. Research activities are ongoing under the Research Framework Programmes and in the Joint Research Centre, as well as in EU Member States and internationally. In particular, research is needed in areas underpinning risk assessments and risk management like

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24 E.g. 1st Meeting of OECD's Working Party on Manufactured Nanomaterials (WPMN). http://www.oecd.org/department/0,3355,en_2649_37015404_1_1_1_1_1,00.html and subsequent updates

25 modified Opinion (after public consultation) on The appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies; 10 March 2006;http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_003b.pdf

26 http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_099.pdf

27 Com(2000) 1 final

- Data on toxic and eco-toxic effects as well as test methods to generate such data.
- Data on uses and exposures throughout the lifecycle of nanomaterials or products containing nanomaterials, as well as exposure assessment approaches.
- Characterisation of nanomaterials, development of uniform standards and nomenclature, as well as analytical measurement techniques.
- For occupational health aspects, the effectiveness of a range of risk management measures including process enclosure, ventilation, personal protective equipment like respiratory protective equipment and gloves.

The development of standards and test methods requires close international collaboration to ensure that scientific data can be compared globally and that scientific methods used for regulatory purposes are harmonised. A main forum for the coordination of activities at the international level has been provided by the OECD Working Party on Manufactured Nanomaterials. Work is also carried out in the framework of the International Organisation for Standardisation, ISO.

A wide range of activities has been initiated to improve the knowledge base (see the annexed Commission Staff Working Document. and the Commission Communication "Nanosciences and Nanotechnologies: An action plan for Europe 2005-2009. First Implementation Report 2005-2007.[28]

3.2. Improving the implementation of legislation

Commission working groups, meetings of Competent Authorities and Agencies in charge of coordinating the implementation of regulation will have to examine on an ongoing basis whether and what type of further action is needed. These activities will mainly be reflected in documents that support implementation of existing legislation.

Examples are the setting of thresholds, authorisation of substances and ingredients, qualifying waste as hazardous, reinforcing conformity assessment by reclassification, introducing restrictions on the marketing and use of chemical substances and preparations, etc. In most cases, implementing legislation can be adopted through "Comitology" procedures.

Work is also needed on documents for voluntary use, such as regulatory guidance[29], European or international standards[30], advice from Scientific Committees[31] etc. Similarly, ethical issues have to be dealt with, as indicated by the European Group on Ethics in Science and New Technologies (EGE).[32]

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28 COM(2007) 505 final ; http://ec.europa.eu/nanotechnology/pdf/comm_2007_0505_en.pdf

29 E.g. Technical Guidance Document in support of Commission Directive 93/67/EEC on risk assessment for new notified substances and Commission regulation 1488/94 on risk assessment for existing substances; http://ecb.jrc.it/tgd

30 E.g. EN ISO 14971:2000 Medical devices - Application of risk management to medical devices (ISO 14971:2000) EN ISO 14971:2000/A1:2003

31 E.g. Notes of guidance of the Scientific Committee for Consumer Products for the testing of cosmetics ingredients and their safety evaluation; 6th revision http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_03j.pdf

32 http://ec.europa.eu/european_group_ethics/activities/docs/opinion_21_nano_en.pdf

Similarly, input is required from the relevant Agencies such as the European Medicines Agency[33], the European Food Safety Authority, the European Chemicals Agency or the European Agency for Safety and Health at Work (OSHA).

The annexed Commission Staff Working Document indicates action already undertaken in a number of sectors. The need for further action relates in particular to the implementation of risk assessment. Relevant Commission working groups are therefore requested to give a follow-up to the opinions of the European Scientific Committees on risk assessment. Similarly, the European Standards Bodies have been given a formal mandate to verify existing standards on whether they cover in an appropriate way risks in relation to nanomaterials.

Particular attention will have to be given to those products that are not subject to any pre-market verification. Concerted actions between authorities will have to be promoted to ensure optimal market surveillance. A dialogue has to be organised with stakeholders in specific sectors to ensure transparency on what is expected to meet regulatory requirements and how relevant information can be exchanged.

At international level, risks in relation to nanotechnologies have become a priority for international collaboration in the field of cosmetics, pharmaceuticals, chemicals, food safety and medical devices

Awaiting the adoption of more specific implementing legislation, standards or guidance, existing documents that support implementation will continue to be used on a case by case basis.

3.3. Information to users

There are no provisions in Community legislation dealing specifically with nanomaterials. However, without excluding the possibility that a need would be identified for specific labelling requirements, nanomaterials have to comply with the existing provisions of Community law addressing the labelling of products, warnings to consumers and users based on the properties of products, instructions for use, or any other information requirements.

Also relevant are the provisions in REACH with obligations of data dissemination about environment, safety and health risks via Safety Data Sheets up and down the supply chain, to industrial users and via the Internet to the public at large. Chemical safety reports will be produced for substances placed on the market in quantities at or above 10 tonnes[34] and a data base with the purpose to make publicly available non confidential data about chemical substances will be kept by the European Chemicals Agency.

Attention is also drawn to provisions in Community law creating a right of access to information in relation to programmes mainly implementing legislation on environmental protection.

The obligation to provide information in relation to the use of nanomaterials and nano-technologies should be distinguished from manufacturers' claims regarding the presence of particular characteristics associated with the use of nanomaterials and nano technologies.

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[33] E.g. EMEA Reflection paper on nanotechnology-based medicinal products for Human Use, http://www.emea.europa.eu/pdfs/human/genetherapy/7976906en.pdf

[34] See also Article 14(4) and Annex III of the REACH Regulation (EC) No 1907/2006.

Community provisions on false or misleading advertising could be evoked if such claims are not justified.[35]

3.4. Market surveillance and intervention mechanisms

Special attention will be given to the various instruments in Community legislation that oblige national authorities to exchange information or to intervene when products present or are likely to present a risk, even where they conform with legal requirements. Such instruments take the form of safeguard clauses, health monitoring measures, food, feed and pesticide market controls, formal objections to standards, precautionary measures, vigilance procedures, measures based on new evidence or re-assessment of existing data, mutual exchange of information, alert/early warning systems, etc. At all stages, authorities can therefore intervene in the case that particular risks would be identified with respect to products containing nanomaterials already on the market.

4. CONCLUSIONS

Current legislation covers in principle the potential health, safety and environmental risks in relation to nanomaterials. The protection of health, safety and the environment needs mostly to be enhanced by improving implementation of current legislation. The Commission and EU Agencies will therefore in the first place review current documents that support implementation, such as implementing legislation, standards and technical guidance with regard to their applicability and appropriateness to nanomaterials.

Knowledge on essential questions such as characterisation of nanomaterials, their hazards, exposure, risk assessment and risk management should be improved. As knowledge becomes the critical factor for implementation and, eventually, legislation, targeted actions in a number of areas and at different levels, particularly in the field of research and development, were launched as a matter of priority, particularly through FP 6 and 7, and the European Commission's Joint Research Centre. Activities are coordinated with international partners and stakeholders in the appropriate fora, such as the OECD and ISO.

Commission working groups in charge of coordinating implementation of legislation are examining on an ongoing basis whether regulatory change on specific aspects is necessary, taking into account the continuously generated information linked with the identified knowledge gaps. They will take into consideration work that has been carried out in this respect at national and international level.

Authorities and Agencies in charge of implementing legislation should continue to carefully monitor the market, and use Community market intervention mechanisms in case risks are identified for products already on the market.

The Commission intends to report on progress in these areas 3 years after presentation of this Communication.

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[35] Directive 84/450/EEC of 10 9 1984 relating to the approximation of the laws, regulations and administrative provisions of the Member States concerning misleading advertising