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REGULATORY ASPECTS OF NANOMATERIALS

Summary of legislation in relation to health, safety and environment aspects of nanomaterials, regulatory research needs and related measures

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TABLE OF CONTENTS

Introduction

This Commission staff working document provides a description of elements of selected EU legislation that seems most relevant and likely to apply to nanotechnologies and nanomaterials. It served as a basis for the conclusions presented in the Commission Communication on Regulatory Aspects of Nanotechnologies.

It is not intended to provide a detailed and full description of all directives and regulations that might be applicable, but to highlight some main features, illustrating how provisions apply to nanomaterials. In further work based on the Commission's Communication, it can be used in addition to detailed analyses of potential regulatory gaps have been or will be made available by various Member States.

Consolidated versions of Directives or Regulations referred to in this document can be found through Eur–lex on http://eur-lex.europa.eu/en/index.htm

This document also indicates research needs in the field of environment, health and safety, referred to in the Commission Communication.

Finally, this document summarizes main action undertaken to bridge the knowledge gap in relation to legislation and implementation, reference to which is made in the Communication.

Summary of elements of EU Regulation relevant for health, safety and environment aspects of nanomaterials

1. CHEMICALS.

As chemicals regulation, and in particular REACH, constitutes a cornerstone for addressing health, safety and environmental risks in relation with nanomaterials, this overview starts with regulation on chemicals. REACH will repeal existing regulation at different points in time[1], and therefore attention is still drawn to the current provisions, dealing respectively with (i) classification/labelling, notification/risk assessment of new substances and preparations, (ii) information, risk assessment and management of existing substances, and (iii) market restrictions.

1.1. REACH

REACH[2] introduces fundamental changes to the current regulatory system, inter alia by allocating the responsibility for the safe use of substances to manufacturers, importers and users of substances instead of authorities, by widening the scope for registration of substances, by introducing - for specific aspects of implementation - a centralised European system, which will contribute to ensuring consistency in implementation, by replacing a set of rules historically grown by one single regulatory system, etc.

REACH 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 and to the placing on the market of preparations. REACH also complements current product regulations (e.g. cosmetics, general product safety).

REACH does not cover explicitly nano materials. However, as REACH applies to substances on their own, in preparations or in articles, it covers areas in which nanomaterials are being used. Furthermore, REACH provides the input necessary for a proper implementation of regulation in other areas.

For the sake of this report, attention is drawn to the following elements:

Registration.

For substances produced or imported in quantities of one tonne or more per year, the manufacturers and importers must elaborate and submit a technical dossier and, for substances in quantities of 10 tonnes or more, a chemical safety report, based on a chemical safety assessment.

REACH contains detailed requirements as regards the composition of the Technical Dossier and the Chemical Safety Report. Information required varies according to the tonnage manufactured or imported per year per manufacturer/importer and to the needs of the chemical safety assessment.

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1 Article 139, REACH

2 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, OJ L 396 of 30.12.2006

The Technical Dossier and the Chemical Safety Report must be submitted to the European Chemicals Agency.

Where substances that are already on the market as bulk substance, are produced or imported at the nano scale without modifications, they will, for registration purposes, not be considered as different from the bulk material. Manufacturers and importers would therefore have to cover the nano form in the same registration as the bulk substance. The following information about the nano form would be required in cases where properties or uses differ between the nano and the bulk: (1) the information about the properties and uses, (2) safety assessment for the nano form, (3) any different or additional classification with regard to hazardous properties of the nano form, and (4) any risk management measure and operational conditions required. In order to address the specific hazards associated with the nanoform, additional testing or information may be required. To determine specific hazards associated with the nanoform, current test guidelines may need to be modified. Until revised and/or specific test guidelines for nanomaterials exist, testing will have to be carried out according to already existing guidelines.

Substances in articles have to be registered if they are intended to be released from the article during normal and foreseeable conditions of use. Substances of very high concern are subject to a notification if they are present in the produced or imported article above a concentration of 0.1% (w/w).

Downstream users (e.g. producers of paints, tyres) are required to consider the safety of the use of substances, based on information of their suppliers, and to apply appropriate risk management measures. They must therefore communicate with the supplier of the substance, obtain the information needed through the data sheet, possibly communicate their “intended“ use to the supplier in order to have this qualified as intended use and included in an exposure scenario , or develop his own safety assessment. Downstream users are responsible for assessing the risks from of substances if such use is not covered by the provided safety data sheet.

Registrants have an obligation to update and register new information in relation to issues such as changes in quantities produced or imported, new uses or new knowledge of risks to human health or the environment of which they may be reasonably be expected to have become aware. This may lead to changes in the safety data sheet or the chemical safety report, or changes in the classification and labelling. Furthermore (e.g. with higher quantities of production or import) more information may have to be submitted to the Agency to fulfil the REACH requirements.

Evaluation.

Evaluation provides a means for the authorities to require registrants, and in very limited cases downstream users, to provide further information. There are two types of evaluation: dossier evaluation and substance evaluation.

- Dossier evaluation is conducted by the Agency to examine proposals for testing to ensure that unnecessary animal tests and costs are avoided, and to check the compliance of the registration dossier with the registration requirements.
- Substance evaluation is performed by Member States Competent Authorities when there is a reason to suspect that a substance presents a risk to human health or the environment.

On the basis of the evaluation, the European Chemicals Agency can require further information, even information not required in Annexes VII to X of REACH.

Authorisation.

For substances of very high concern included in Annex XIV of REACH, an authorisation at Community level is required for their use and their placing on the market. Substances subject to authorisation are

- CMRs (carcinogenic, mutagenic or toxic for reproduction) category 1 and 2
- PBTs (persistent, bioaccumulating and toxic) and vPvBs (very persistent and very bioaccumulating)
- substances with probable serious effects to humans or the environment which give rise to an equivalent level of concern as CMRs and PBTs/vPvBs. This is for instance the case for substances with endocrine disrupting properties.

REACH specifies in detail the conditions in which a substance may be authorised, in accordance with the regulatory Comitology procedure, based on criteria relating to the control of risks, (taking into account all discharges, emissions and losses, including risks from diffuse or dispersive uses), risk management measures, socio-economic benefits, availability of alternatives and available knowledge on risks in relation to alternatives. The European Chemicals Agency (Committee for Risk Assessment and Committee for Socio-Economic Analysis) is requested to provide an opinion. Authorisations are time-limited and can be subject to conditions, such as monitoring arrangements.

Specific provisions are foreseen dealing with the review of authorisations, for instance when the circumstances of the original authorisation have changed so as to affect the risk to human health or the environment, or the update of information.

REACH also contains provisions regarding **restrictions on the manufacturing, placing on the market and use of certain dangerous substances, preparations and articles**. When there is a risk to human health or the environment arising from the manufacture, use or placing on the market of a substance, which needs to be addressed at Community-wide basis, restrictive measures shall be laid down by the Commission, based upon an opinion of the European Chemicals Agency (Committee for Risk Assessment and Committee for Socio-Economic Analysis) and in agreement with Member States. This procedure can be initiated by the Commission or a Member State.

REACH maintains the obligation to notify, for reasons of **classification and labelling**, to the European Chemicals Agency substances (on their own, in preparations or in articles) subject to registration and substances within the scope of Directive 67/548/EEC which qualify as dangerous in terms of that directive . On the basis of registration and notification, the Agency will maintain a classification and labelling inventory.

Particularly relevant are the provisions contained in REACH dealing with the **supply of information:**

- Regardless of quantities produced, suppliers of a dangerous substance or a preparation must provide a safety data sheet, containing the data required by REACH. REACH introduces a “safety net” for cases where a safety data sheet would not be obligatory, but where the substance is subject to authorisation, to restrictions or where information is required to enable appropriate risk management measures to be identified and applied.
- Throughout the supply chain, suppliers of articles containing substances subject to authorisation in a concentration above 0.1% weight by weight must provide the recipient with sufficient information available to allow safe use of the article. On request, such information must be given also to consumers.

- Any new information on hazardous properties, regardless of the uses concerned and any other information that might call into question the appropriateness of the risk management measures identified in the safety data sheet must be passed on from any actor in the supply chain to the next actor or distributor.
- Workers have the right of access to information in relation to substances or preparations that they use or may be exposed to.
- Regulation No 1049/2001 on access to documents applies to documents held by the European Chemicals Agency. Information kept by the European Chemicals Agency must be made available over the Internet to the public at large: the name in the IUPAC Nomenclature of dangerous substances (within the meaning of Directive 67/548/EEC); if applicable, the name of the substance as given in EINECS; the classification and labelling of the substance; physicochemical data concerning the substance and on pathways and environmental fate; the result of each toxicological and ecotoxicological study; any derived no-effect levels (DNEL) or predicted no-effect concentrations (PNEC); guidance on safe use; analytical methods which make it possible to detect a dangerous substance when discharged into the environment as well as to determine the direct exposure of humans.

The Commission, in close co-operation with Member States, industry and other stakeholders, is preparing technical guidance documents for industry and authorities to facilitate the implementation of the REACH regulation. The work is done in the framework of so called REACH implementation projects (RIPs) covering the main processes and requirements of REACH. RIP 3 relates to technical guidance for industry and RIP 4 to technical guidance for authorities.[3] The guidance is published by the European Chemicals Agency.

Overall, substances on the nano-scale, either as a substance, a preparation or contained in an article, fall under the scope of REACH and their health and environment properties must accordingly be assessed. All REACH provisions apply to nanomaterials, including the mechanisms put in place by REACH that allow controlling risks (registration, evaluation, authorisation, and restrictions).

1.2. Existing Regulation.

REACH progressively replaces a number of directives and regulations applicable hitherto to chemicals:

Directive 67/548/EEC[4] concerns the classification and labelling of chemical substances according to their intrinsic dangerous properties. Any chemical that is (or is suspected to be) dangerous, must be classified and to be placed into one or several classes of danger defined by the directive. Classification as dangerous requires appropriate labelling, as defined by the directive.[5]

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3 More information on these projects is available at http://ecb.jrc.it/REACH/RIP_PROJECTS/

4 Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, OJ 196, 16.8.1967

5 Classification and labelling will become subject to the UN Global Harmonised System. A proposal for a Regulation to this extent was presented by the Commission on 27 June 2007; http://ec.europa.eu/enterprise/reach/ghs_en.htm

Since 1981, "new" substances have to be notified to the national Competent Authority[6]. Notification requires detailed information about e.g. production and uses, intrinsic properties, including a proposal for classification and labelling, to be accepted by the Competent Authority. The amount of information to be provided depends on quantities marketed.

Since 1992, a competent authority receiving a notification of a "new" substance has to carry out an assessment of the risks to human health and the environment[7] in accordance with principles that have been laid down in Directive 93/67/EEC[8]. The conclusions of the risk assessment may provide the basis for subsequent risk management decisions that have an impact on production, handling, classification, labelling, marketing or use of the substance or include other protective measures.

Notifiers of a substance are obliged to provide follow-up information regarding quantities placed on the market, new knowledge on effects, new uses or changes in the composition.

The Directive foresees a safeguard clause for cases where a substance constitutes a danger for man or the environment that may lead to measures applicable at Community level.

A "comitology" procedure is foreseen for adaptation to technical progress, or for measures following a safeguard clause.

Regulatory guidance has been elaborated by the Commission and Competent Authorities according to which the decisive criterion whether a nanomaterial is a new or existing substance is the same as for all other substances, i.e. whether or not the substance is on the EINECS.[9] The authorities also decided that nanomaterials having specific properties may require a different classification and labelling compared to the bulk material.

Detailed guidance has also been adopted on the risk assessment process.[10]

By virtue of **Directive 1999/45**, similar rules apply for dangerous preparations as regards classification, labelling and packaging[11].

In addition, both Directives require producers of dangerous chemicals to provide industrial and professional users with health, safety and environmental information and advice about their products in the form of safety data sheets. Directive 91/155/EEC[12], as amended by

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6 Council Directive 79/831/EEC of 18 September 1979 amending for the sixth time Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances; OJ L 259 , 15/10/1

7 Council Directive 92/32/EEC of 30 April 1992 amending for the seventh time Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labeling of dangerous substances; OJ L 154 , 05/06/1992

8 Commission Directive 93/67/EEC of 20 July 1993 laying down the principles for assessment of risks to man and the environment of substances notified in accordance with Council Directive 67/548/EEC; OJ L 227 ,8.9.1993

9 Competent Authorities for the Implementation of Directive 67/548 (New Substances) and Council regulation 793/93/EEC (existing substances), Vienna, May 2006; http://ecb.jrc.it/DOCUMENTS/New-Chemicals/Manual_of_decisions.pdf page 64

10 http://ecb.jrc.it/tgd

11 Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations; OJ L 200, 30.7.1999 ; will be replaced by the Global Harmonised System, see Directive 67/548

12 Commission Directive 91/155/EEC of 5 March 1991 defining and laying down the detailed arrangements for the system of specific information relating to dangerous preparations in implementation of Article 10 of Directive 88/379/EEC; OJ L 76, 22.3.1991

Directives 93/112/EEC and Directive 2001/158/EC[13], sets out the requirements for the information which should be included in a safety data sheet. The main purpose of safety data sheets is to enable employers to determine whether any hazardous chemicals are present in the workplace, and to assess whether there is any risk to the health and safety of workers and/or to the environment arising from their use.[14]

Regulation (EEC) No 793/93 deals with the evaluation and control of the risks of "existing" substances**.**[15] It has provisions for data reporting, priority setting, risk assessment and strategies for limiting the risks of existing substances.

Manufacturers or importers are required to provide specific information on existing[16] substances produced or imported into the Community in excess of 10 tonnes per year.

In accordance with priorities set by Commission regulations, the risks of each priority substance are assessed by a Member State. If the conclusion of the risk assessment is that risks are not adequately managed, the regulation requires the determination of a strategy to reduce those risks including control measures.

Since 1994, 4 priority lists have been published with a total of 141 substances. [17]

Rules for risk assessment were laid down in Commission Regulation 1488/94[18] and a 1996 Technical Guidance Document (http://ecb.jrc.it/tgd/).

When, on the basis of the evaluation of a substance, risk reduction measures are deemed necessary, a risk reduction strategy is developed. The recommended measures are then implemented in the relevant Community and/or national frameworks. A Technical Guidance Document (TGD) and minimum requirements have been defined to support the development of Risk Reduction Strategies as referred to in Article 10(3) of Council Regulation (EEC) 793/93. The document outlines possible risk reduction measures, implementing instruments and criteria for selecting the most appropriate approach. [19]

The Existing Substances Regulation contains provisions for updating of reported information (that also apply to the nano-form of existing substances). Manufacturers and importers who have submitted information are required to update information. This concerns inter alia new uses of the substance, and new data obtained on the physico-chemical properties, toxicological or ecotoxicological effects likely to be relevant to the evaluation of the potential risks presented by the substance.

Manufacturers or importers of an existing substance, who acquire knowledge suggesting that the substance may present a serious risk to man or the environment, are required to report

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13 Commission Directive 2001/58/EC of 27 July 2001 amending for the second time Directive 91/155/EEC defining and laying down the detailed arrangements for the system of specific information relating to dangerous preparations in implementation of Article 14 of European Parliament and Council Directive 1999/45/EC and relating to dangerous substances in implementation of Article 27 of Council Directive 67/548/EEC (safety data sheets); OJ L 212, 7.8.2001

14 See also, hereunder, Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work worker protection

15 Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances; OJ L 84, 5.4.1993

16 Substances on the EU market before 18 September 1981, reported in the European Inventory of Existing Commercial Substances

17 http://ecb.jrc.it/esis/esis.php

18 Commission Regulation (EC) No 1488/94 of 28 June 1994 laying down the principles for the assessment of risks to man and the environment of existing substances in accordance with Council Regulation (EEC) No 793/93 (Text with EEA relevance); OJ L 161, 29.6.1994

19 http://ec.europa.eu/environment/chemicals/exist_subst/pdf/tg_risk_reduction.pdf

such information. There are limitations to this provision, i.e. it applies only to substances manufactured/imported in quantities at or above 10 tonnes, industry and use categories are quite broad and may not "sufficiently" catch specific new applications of nanomaterials. Similarly, the effectiveness may be limited in view of the limited information generally available on nanomaterials.

Finally, **Directive 76/769/EEC**[20] creates a harmonised framework by which the use of chemicals are banned, or, in most cases, i.e. restricted for particular uses, only. If need be, restrictions on the marketing or use of nanomaterials could be introduced under this Directive.

2. WORKER PROTECTION

The most important piece of legislation in the area of health and safety at work is the Framework Directive 89/391/EEC "on the introduction of measures to encourage improvements in the safety and health of workers"[21], which fully applies to risks associated with nanoparticles.

This Directive places a number of obligations on employers to take measures necessary for the safety and health protection of workers. Employers must carry out a risk assessment and, where risks are identified, introduce measures to eliminate the risk. , When it is not possible to eliminate the risks then risks should be, minimised, preferably at the source. Prevention and protection principles are listed in the Directive. The planning and introduction of new technologies must be subject to consultation with the workers or their representatives, as regards the consequences of the choice of equipment, the working conditions and the working environment. The employer must be in possession of an assessment of the risks to safety and health of workers at work, including those facing groups of workers exposed to particular risks. The Directive furthermore contains various provisions regarding worker information and consultation and participation of workers in discussions on all questions relating to safety and health at work, and relevant training of workers.

The Framework Directive on Health and Safety foresees the possibility to adopt individual directives laying down more specific provisions with respect to particular aspects of safety and health. "Daughter directives" which are relevant to risks that may result from possible exposure to nanomaterials include:

- Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC)[22] and
- Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive)[23]and

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20 Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations; OJ L 262, 27.9.1976

21 Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work; OJ L 183, 29.6.1989

22 OJ L 158, 30.4.2004

23 Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC); OJ L 131, 5.5.1998

- Council Directive 89/655/EEC of 30 November 1989 concerning the minimum safety and health requirements for the use of work equipment by workers at work (second individual Directive)[24] and
- Council Directive 89/656/EEC of 30 November 1989 on the minimum health and safety requirements for the use of personal protective equipment at the workplace (third individual Directive)[25] and
- Directive 1999/92/EC of the European Parliament and of the Council of 16 December 1999 on minimum requirements for improving the safety and health protection of workers potentially at risk from explosive atmospheres (fifteenth individual Directive)[26].

The Framework Directive and the above-mentioned daughter Directives present a comprehensive package of legal requirements aiming at ensuring a high level of protection of workers health and safety. These requirements, whilst they do not make explicit mention of nanomaterials and nanotechnologies, define a legislative framework that applies to most occupational risks including those arising from the presence of nanomaterials.

In implementing the EU occupational safety and health directives the Member States may introduce more strict requirements at national level.

3. PRODUCTS

Many groups of products are covered by specific Community legislation laying down product requirements for safety and health of workers, consumers and protection of the environment; e.g. cosmetics, pharmaceuticals, cars or chemicals. New Approach legislation deals with categories of risks applicable to product families, (e.g. medical devices, pressure equipment, personal protective equipment), containing sometimes also general safety requirements (e.g. Low Voltage Directive). Consumer products not covered by specific regulation are covered by the Directive on General Safety of Consumer Products. In many cases more than one piece of legislation applies to the same product.

Where regulation contains requirements of a general nature, they will cover also risks related to nanotechnology, even if they have been adopted without specifically intending to address risks associated with nanomaterials and nanotechnologies.

Legislation will determine not only under what conditions products can be placed on the market, but also establish mechanisms to verify compliance with regulatory requirements, oblige manufacturers to monitor their products and authorities to intervene in case safety and health issues are at stake.

3.1. Plant Protection Products

Directive 91/414/EEC concerning the placing of plant protection products on the market[27], lays down rules and procedures for approval of the active substances at EU-level (i.e.

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[24] Council Directive 89/655/EEC of 30 November 1989 concerning the minimum safety and health requirements for the use of work equipment by workers at work (second individual Directive); OJ L 393, 30.12.1989

[25] Council Directive 89/656/EEC of 30 November 1989 on the minimum health and safety requirements for the use of personal protective equipment at the workplace (third individual Directive); OJ L 393, 30.12.1989

[26] Directive 1999/92/EC of the European Parliament and of the Council of 16 December 1999 on minimum requirements for improving the safety and health protection of workers potentially at risk from explosive atmospheres (fifteenth individual Directive); OJ L 23, 28.1.2000

inclusion in Annex I to Dir. 91/414/EEC) and for the authorisation at Member State level of plant protection products (PPPs) containing these substances.

A PPP can only be authorized if it fulfils, among others, the following requirements:

- It is effective;
- It has no unacceptable effects on plants or plant products;
- It does not cause unnecessary suffering and pain to vertebrates to be controlled
- It has no harmful effect on human or animal health directly or indirectly or on groundwater;
- It has no unacceptable influence on the environment.

Furthermore, it must be possible to determine by appropriate methods the nature and quantity of its active substances and any toxicologically or ecotoxicologically significant impurities and co-formulants, its residues which are of toxicological or environmental significance, and its physical and chemical properties deemed acceptable for the purpose of the appropriate use and storage of the product.

Inclusion of an active substance in the Annex I to the Directive can only be granted when it is demonstrated that PPPs containing that active substance fulfil the following conditions:

- their residues do not have any harmful effects on human or animal health or on groundwater or any unacceptable influence on the environment;
- the use does not have any harmful effects on human or animal health or any unacceptable influence on the environment.

One essential element in the rules and procedures laid down by Directive 91/414/EEC is *harmonised data requirements*, i.e. minimum requirements for the *dossier* that has to be submitted by an applicant in order to have an active substance authorised at EU level and a PPP containing the same substance marketed and used at Member State level.

Data requirements are specified in Annexes II (active substance) and III (PPP) to Directive 91/414/EEC and are divided into six sections:

- Physical and chemical properties
- Analytical methods
- Toxicological and metabolism studies
- Residues in treated products, food and feed
- Fate and behaviour in the environment
- Ecotoxicology

The *dossier* shall be in accordance with data requirements referred to in Annexes II and III and shall provide information to evaluate immediate or delayed risks for human, animal and environment, which can derive from the active substance proposed to be included in Annex I (i.e. to become an approved active ingredient in the EU) as well as from the plant protection product proposed for authorisation.

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[27] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market; OJ L 230, 19.8.1991

Data requirements are comprehensive and detailed. Overall, however, the applicant must provide all the information necessary for evaluating the foreseeable risks, whether immediate or delayed, which the substance may entail for humans, animals and the environment. Where relevant, authorities can always require additional information and studies. Consequently, under this rule, also information regarding the use of nanotechnologies and nanomaterials could be requested if necessary.

Authorizations may be reviewed at any time on the basis of developments in scientific and technical knowledge.

The holders of authorizations are obliged to immediately notify the competent authority of all new information on the potentially dangerous effects of any plant protection product, or of residues of an active substance on human or animal health or on groundwater, or their potentially dangerous effects on the environment.

Where a Member State has valid reasons to consider that a product authorized constitutes a risk to human or animal health or the environment, it may provisionally restrict or prohibit the use and/or sale of that product on its territory. National measures will need to be confirmed at Community level.

Nanomaterials could be used as co-formulants in plant protection products. Full composition of the plant protection product needs to be presented when applying for authorisations. The proposal for a Regulation amending Directive 91/414/EEC (COM (2006) 388) foresees that certain co-formulants can be prohibited in case of concern for human, animal health or the environment.

Based on the above, Directive 91/414/EEC does cover nanomaterials adequately in its current form. However, current guidance documents (on data requirements, risk assessment and decision making) could need to be amended in order to properly address risks to nanomaterials.

3.2. Biocides

Directive 98/8/EC on Biocidal Products[28] aims to harmonise the European market for biocidal products and their active substances. At the same time it aims to provide a high level of protection for humans, animals and the environment. The scope of the Directive covers 23 different product types, varying from disinfectants to antifouling agents and rodenticides.

The Directive follows closely Directive 91/414/EEC on placing on the market of Plant Protection Products. It lays down a two tier approach: active substances are evaluated at Community level (Annex I inclusion) whereas biocidal products are authorised or registered at national level. Risk assessment on active substances based on the dossier submitted by the industry (applicant) is done by the Rapporteur Member State. Data requirements for active substances and biocidal products are laid down in the Annexes of the Directive. It is important to note that there are no tonnage triggers for the data requirements. However, studies can be waived in case there are sufficient scientific or technical justifications provided by the applicant.

The final decision on the inclusion of an active substance to the Directive is made by the Commission via a regulatory committee procedure. Member States can then authorise biocidal products containing the approved active substances, provided that the criteria laid down in the Directive and in Annex VI (Common Principles) are fulfilled.

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[28] Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market; OJ L 123, 24.4.1998

The Directive also establishes rules concerning a 10-years transitional period (until May 2010). During this period, all existing active substances need to be evaluated.

The definitions of a biocidal product (Article 2(1)(a) and of an active substance (Article 2(1)(d) cover also nanomaterials and these latter, therefore, fall under the scope of the Directive if used for biocidal purposes. Data requirements are comprehensive and detailed. As no reference is made to any specific test guidelines, the requirements as such are applicable to nanomaterials as well.

Nanomaterials can also be used as co-formulants in biocidal products. Full composition of the biocidal product needs to be presented when applying for authorisation. When necessary, Competent Authorities can request additional data on 'substances of concern'.

Based on the above, the Biocides Directive does cover nanomaterials adequately in its current form. However, current technical notes for guidance (on data requirements, risk assessment and decision making) would need to be amended in order to properly address risks of nanomaterials.

3.3. New Approach Legislation

A number of products relevant for nanotechnology related risks are covered by the so-called New Approach on Technical Harmonisation and Standardisation[29]. These are in particular machinery, personal protective equipment, low-voltage, medical devices, etc.

New Approach Directives deal with particular risks, defined in each Directive. As a general rule, manufacturers are obliged to carry out an assessment of the risks defined in each directive and to adopt a risk management strategy. This implies to adopt measures to eliminate risks, or to reduce risks as far as possible (inherent safe design, construction and use), take the necessary protection measures in relation to risks that cannot be eliminated, and as a last resort, inform users of the residual risks due to any shortcomings of the protection measures adopted, and advice any other protective measure regarding risks that cannot be eliminated. The Directive on medical devices complements these rules by a risk-benefit analysis.

New Approach Directives do not specify the technology that manufacturers must adopt to meet the mandatory regulatory requirements. Whilst they leave in this way flexibility to manufacturers, at the same time they create an obligation to adapt design and production processes in the light of the evolving technology and knowledge. Many Directives introduce concepts such as “the generally acknowledged state of art”, “the state of art” and “generally acknowledged rules of technology”.

In order to assist manufacturers and authorities in complying with Directives, each Directive will have a body of supporting documents.

- Tailor-made European standards can be developed to meet the Directives’ requirements, compliance with which provides a presumption of conformity.
- Stakeholders and authorities adopt guidance documents containing consensus based views on the interpretation of the Directives’ requirements
- In many cases, also the Notified Bodies will adopt guidelines in order to achieve a consistent interpretation of requirements and to achieve equivalent verification of conformity assessment.

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[29] For a list of New Approach Directives and relevant harmonised standards, see http://ec.europa.eu/enterprise/newapproach/standardization/harmstds/reflist.html

Under the New Approach, placing on the market is not subject to a prior market approval by public authorities. Various methods are open to manufacturers to demonstrate compliance with the Directive's requirements. Depending on the risks involved or availability of European standards, this will involve the intervention of a third party, the so-called Notified Body, designated and monitored by national authorities.

The risk assessment and risk management approached must be documented in a technical dossier. Any change to the design or construction process must be documented and, where third party intervention is required, be communicated to the Notified Body who approved originally the design and production process.

New Approach Directives all contain intervention mechanisms, under which Member States can intervene on the market with regard to products likely to present a danger for man or the environment. Similarly, harmonised standards adopted by the European standards bodies in support of the directives can be challenged. The Directives on medical devices also contain provisions on health monitoring.

New Approach Directives have mechanisms to introduce regulatory change with respect to the definition of essential requirements, or, as the case may be, reclassification of products in order to submit them to more or less stringent conformity assessment procedures.

Thus, the Medical Devices Experts Group has set up a working group on New and Emerging Technologies in Medical Devices, with nanotechnology as first priority. Apart from the reclassification of devices, the group also recommended the development of regulatory guidance on the nature of the risks that should be taken into consideration, possible solutions to manage these risks, identification of appropriate regulatory pathways, necessary actions during the post-marketing phase and mechanism for a Voluntary Reporting Scheme. Furthermore, the Group has recommended guidance with regard to the conduct of clinical investigations with nanotechnology products

Given the way New Approach Directives have been written, they allow in principle risks associated with nanomaterials to be covered. More specific guidance can be made available, if need be, through European standards, or guidance documents adopted either by Commission working groups or the relevant Notified Bodies.

3.4. Cosmetic Products

Directive 76/768/EEC[30] contains prescriptive elements through positive (substances that can be used) and negative lists (substances that can not be used) of ingredients, obligation for a manufacturer is to carry out a risk assessment.

A cosmetic product put on the market within the Community must not cause damage to human health when applied under normal or reasonably foreseeable conditions of use, taking account, in particular, of the product's presentation, its labelling, any instructions for its use and disposal as well as any other indication or information provided by the manufacturer or his authorized agent or by any other person responsible for placing the product on the Community market.

The Directive contains detailed rules concerning substances that can not be used, or used only within certain limits and conditions, colouring agents, preservatives and UV filters.

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[30] Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products; OJ L 262, 27.9.1976

The use in cosmetic products of substances classified as carcinogenic, mutagenic or toxic for reproduction, of category 1, 2 and 3, under Annex I to Directive 67/548/EEC is prohibited. A substance classified in category 3 may be used in cosmetics only if the substance has been evaluated by the Scientific Committee for Consumer Products and found acceptable for use in cosmetic products.

The manufacturer must have available an assessment of the safety for human health of the finished product. To that end, he must take into consideration the general toxicological profile of the ingredients, their chemical structure and their level of exposure. The risk assessment must take particular account of the special exposure characteristics of the areas on which the product will be applied or of the population for which it is intended. There must be inter alia a special assessment for cosmetic products intended for use on children under the age of three and for cosmetic products intended exclusively for use in external intimate hygiene.

Also, the Cosmetics Directive contains a provision according to which a Member State may, awaiting measures at Community level, provisionally prohibit the marketing of a product in its territory or subject it to special conditions notes, when a cosmetic product represents a hazard to health.

In accordance with Comitology procedures, detailed rules can be laid down regarding the composition of cosmetic products: substances that cannot form part of the composition of cosmetic products and substances the use of which is subject to restrictions and conditions, substances; similarly, through Comitology procedures the lists can be adapted for colorants, preservatives and UV filters that can be used. The Commission, in agreement with Member States, can specify substances that cannot be part of the composition of cosmetics.

On the basis of the obligation to carry out a risk assessment and the possibility to lay down through implementing legislation detailed conditions of use for certain ingredients, risks in relation to nanomaterials and nanotechnologies can, therefore, in principle be dealt with in an appropriate way.

However, based on a web consultation, the Commission has proposed a revision of the Cosmetic Products Directive, which is directly relevant for products using nanomaterials.[31] Its main elements are:

- clear minimum requirements for the cosmetics safety assessment
- a system of administrative cooperation of competent authorities: this entails a system of coordination of Member States in the assessment of products and their supporting information, including rules for product withdrawal;
- an obligation of industry to actively report serious undesirable effects to competent authorities as part of an early detection mechanism for risks for human health caused by cosmetic products; and
- a notification requirement which provides information to all competent authorities of the internal market through one single notification portal.

3.5. Aerosol Dispensers

According to the aerosol dispenser directive[32], aerosol dispensers must meet a number of specific requirements before they can be placed on the market. Compliance with these requirements means that in principle the product is safe.

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[31] Proposal for a regulation of the European Parliament and of the Council on cosmetic products; COM(2008)49 final 2008/0025 (COD) 5.2.2008

However, the Directive itself accepts that it is possible that some aerosol dispensers placed on the market may represent a hazard to safety or health, even though they comply with the requirements of the Directive and of the Annex thereto. The Directive therefore contains a safeguard procedure allowing Member States to provisionally, i.e. subject to verification at Community level, prohibit the sale of the dispenser or dispensers in their territory or subject it or them to special conditions.

This Directive has been modified in April 2008 to introduce an obligation for manufacturers to carry out a hazard analysis.[33] Discussions in relation to health and safety problems with aerosols placed on the Community market[34] have shown that risks may result from the physical and chemical nature of nano-particles in conjunction with their distribution in the form of an aerosol, i.e. within very small liquid droplets that can easily pass the human lung tissue. Therefore, the revised directive specifies that where appropriate, this analysis shall include a consideration of the risks resulting from the inhalation of the spray ejected by the aerosol dispenser under normal and reasonably foreseeable conditions of use, taking into account droplet size distribution in conjunction with physical and chemical properties of the contents. The manufacturer must then design, construct and test the dispenser, and, if applicable, draft special statements concerning its use, taking account of his analysis.

3.6. Medicinal Products

The European regulatory system for **medicinal products** offers the following routes for authorising medicinal products:

- a "centralised" procedure, with applications made directly to the European Medicines Agency, leading to the grant of a Community marketing authorisation by the Commission. Use of this procedure is compulsory for products listed in the Annex to Regulation (EC) No 726/2004, and optional for other medicinal products under conditions laid down in Article 3 paragraph 2 of that Regulation;
- a "mutual recognition" procedure with applications submitted simultaneously in different Members States. One Member State is selected by the applicant as the reference Member State, other Member State(s) act as concerned Member State(s). Following the evaluation carried out by the reference Member State, the concerned Member State(s) have to approve the assessment report, summary of product characteristic, labelling and package leaflet proposed by the reference Member State. At the end of the procedure, a national marketing authorisation is issued by the reference Member State as well as by each concerned Member State(s).
- a "decentralised" procedure based on the recognition by the concerned Member State(s) of a marketing authorisation already granted by another Member State;
- a purely national authorisation procedure for medicinal products to be marketed in only one Member State.

Community procedures are based on a wide range of prescriptions laid down in implementing rules and guidance documents. No specific rules are foreseen for risks related with nanomaterials or nanotechnology. Nevertheless; the EMEA Committee for Medicinal

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[32] Council Directive 75/324 of 20 May 1975 on the approximation of the laws of the Member States relating to aerosol dispensers, OJ L 147 of 9.6.1975, as last amended by Commission Directive 2008/47/EC, OJ L 96, 9.4.2008

[33] http://ec.europa.eu/enterprise/pressure_equipment/aerosol_sector/index_en.html

[34] http://www.bfr.bund.de/cms5w/sixcms/detail.php/7842

Products for Human Use (CHMP) has produced a reflection paper on nanotechnology-based medicinal products for human use.

As outlined in this reflection paper, the evaluation and prevention of potential hazards related to the use of any given 'nanomedicinal' product is already foreseen under the existing EU pharmaceutical legislation. As for any medicinal product, the EU competent authorities will evaluate any application to place a nanomedicinal product on the market, utilising established principles of benefit/risk analysis, rather than solely on the basis of the technology per se. These considerations of principle equally apply in the field of veterinary medicinal products. .

According to the CHMP, it is likely that many novel applications of nanotechnology will span the regulatory boundaries between medicinal products and medical devices. Under the current legislation, the mechanism of action is key to decide whether a product should be regulated as a medicinal product or a medical device ((Directive 2001/83/EC, as amended, Article 1, 2. Nanomedicinal products, however, may exhibit a complex mechanism of action combining mechanical, chemical, pharmacological and immunological properties and combining diagnostic and therapeutic functions. Furthermore, additional specialised expertise may be required for the evaluation of the quality, safety, efficacy and risk management of such nanomedicinal products.

For the CHMP, it is likely that the evaluation of products of such novel technology will require special consideration. The accumulation of experience, in particular from informal discussion in Briefing meetings, Scientific Advice or Marketing Authorisation applications evaluation procedures, will allow, on an ongoing basis, to assess the need for the development of guidance specific to nanomedicinal products or for the update of existing ones to accommodate for the specific aspects of these products.

In order to deal with the above issues, the EMEA has created the Innovation Task Force (ITF) to ensure EMEA-wide coordination of scientific and regulatory competence in the field of emerging therapies and technologies, including nanotechnologies, and to provide a forum for early dialogue with applicants on regulatory, scientific or other issues that may arise from the development. In the absence of specific guidance, applicants are encouraged to contact the EMEA from the early stages of the development of their products.[35]

3.7. Cars

Passenger cars, motorcycles and tractors are subject to the EC Whole Vehicle Type-Approval (WVTA) system, which implies that these categories of vehicles must comply with the relevant EC legislation on type-approval in order to be placed on the market. Partial harmonisation exists for the remaining vehicle categories, like heavy-duty commercial vehicles, buses and coaches. A new framework Directive[36] adopted in 2007 makes EC WVTA mandatory for all the remaining categories of vehicles in stages from 2009 to 2014.

Manufacturers must obtain a type approval for vehicles and their components, indicating that the type conforms to the technical requirements laid down in the EC legislation. On the basis of the type-approval certificate, the manufacturer will issue a certificate of conformity for each vehicle produced, i.e. a statement that the vehicle to be placed on the market, based on adequate arrangements for ensuring conformity of production, conforms to the relevant EC type-approval.

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35 http://www.emea.eu.int/htms/human/itf/itfintro.htm

36 Directive 2007/46/EC of the European Parliament and of the Council of 5 September 2007 establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles; OJ L 263 of 9.10.2007

To date, about 100 specific regulatory acts have been adopted. They prescribe technical requirements to be met by the vehicles and components concerned in order to comply with a certain safety level or ensure a certain environmental performance, but in principle are not design-restrictive since they do not prescribe a certain technology or material to be used in order to fulfil those requirements. Accordingly, they do not cover risks related to nanomaterials or nanotechnology. Only to the extent that other regulations apply to components or materials or other aspects, risks associated with nanomaterials or nanotechnology are adequately covered. Such aspects would however not be subject to approval by Member States under the WVTA.

Consequently, the use of nanomaterials in articles such as paintings or tyres is to be assessed exclusively under REACH and its provisions on substances contained in articles and downstream-users.

3.8. Food Legislation

3.8.1. General Food Law

Regulation 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority (EFSA) and laying down procedures in matters of food safety[37], applies horizontally to all foods and feed. Within the context of food law, also the general requirements for feed, including its production and use where that feed is intended for food-producing animals, are included.

The General Food Law aims at ensuring a high level of protection of human life and health, taking into account the protection of animal health and welfare, plant health and the environment. The Regulation provides for e.g. general food safety requirements, sets the responsibility of safe food on food business operators and defines the principles of risk analysis in relation to food. It also establishes the structures and mechanisms for the scientific and technical evaluations which are undertaken by EFSA as well as safeguard measures for emergency situations.

Following the rules on access to documents, applications for authorisation, supplementary information from applicants and opinions from the Authority, excluding confidential information, shall be made accessible to the public in accordance with Articles 38, 39 and 41 of Regulation (EC) No 178/2002.

More particularly relevant in relation to risks associated with nanomaterials are the following.

3.8.2. Novel Food

Regulation 258/97 concerning novel foods and novel food ingredients[38] regulates the placing on the market of foods and food ingredients which have not been used for 15 May 1997 for human consumption to a significant degree within the Community, and which fall under particular categories laid down in Article 1 paragraph 2 of Regulation, including e.g.

- foods and food ingredients with a new or intentionally modified primary molecular structure;

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[37] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31, 1.2.2002

[38] Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients, OJ L 43, 14.2.199

- foods and food ingredients to which has been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances

Foods and food ingredients falling within the scope of this Regulation must not present a danger for the consumer, mislead the consumer and differ from foods or food ingredients which they are intended to replace to such an extent that their normal consumption would be nutritionally disadvantageous for the consumer.

Food and food ingredients can only be placed on the market if they have been subject of an initial assessment arranged for by a Member State. The results of this initial assessment are distributed to the other Member States and the Commission. If no objections are raised, the Member State to which the application was submitted, informs the applicant that he may place the food on the market. If objections are raised, a Commission's decision by comitology procedure is required. In such case the safety assessment is often duplicated by EFSA. A simplified procedure (notification to the Commission) is foreseen for foods that are substantially equivalent to already existing or authorised foods.

Special labelling rules are foreseen. Without prejudice to other requirements of Community law, information must be given in order to ensure that the final consumer is informed of

- Any characteristic of the food, which renders a novel food or food ingredient no longer equivalent to an existing food or ingredient. In this case, the labelling must indicate the characteristics or properties modified, together with the method by which that characteristic or property was obtained.
- The presence of a materials which is not present in an existing equivalent foodstuff and which may have implications for the health of certain sectors of the population
- The presence of a materials which is not present in an existing equivalent foodstuff and which gives rise to ethical concerns

Detailed rules for implementing these requirements are to be adopted by the Commission in agreement with the Member States and proper information to the European Parliament.

Where as a result of new information or a reassessment of existing information, there are detailed grounds for considering that the use of a food or a food ingredient complying with this Regulation endangers human health or the environment, Member State may take restrictive measures, to be confirmed or withdrawn subsequently after a procedure at Community level.

In order to facilitate implementation of the Regulation, the Commission has published a series of recommendations on the scientific aspects and the presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients and the preparation of initial assessment reports.[39]

Consequently, Regulation 258/97 allows assessing possible risks associated with the use of nanomaterials and nanotechnologies (novel food ingredients) and nanotechnologies (novel

[39] Commission Recommendation of 29 July 1997 concerning the scientific aspects and the presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients and the preparation of initial assessment reports under Regulation (EC) No 258/97 of the European Parliament and of the Council; OJ L 253, 16.9.1997

technology with impact on food) in relation with food and food ingredients.[40] Similarly, provisions in relation to labelling allow to take, if need be, further risk management measures by setting conditions of use or by informing about the use of the food.

3.8.3. Food contact materials

Regulation (EC) 1935/2004 relating to materials and articles intended to come into contact with food[41] applies to materials and articles which are already in contact with food or which, are intended for food contact or which can be reasonably expected to come into contact with food. It covers also articles for contact with water intended for human consumption.

As a basic rule, materials and articles must be manufactured in compliance with good manufacturing practice so that, under their normal or foreseeable conditions of use, they do not transfer their constituents to foodstuffs in quantities which could:

- endanger human health,
- bring about an unacceptable change in the composition of the food or
- a deterioration in the organoleptic characteristics of the food.

The Regulation allows for the adoption of specific measures setting out specific requirements for certain materials and articles.[42] These groups of materials and articles and, where appropriate, combinations thereof as well as recyled materials used in these articles may be subject to specific measures that regulate issues such as:

- authorisation of substances to be used, including specific limits on their migration into food;
- purity criteria and specifications for such substances;
- special conditions of use for these substances and/or the materials and articles in which they are used;
- the basic rules necessary for checking compliance: sample taking and the methods of analysis.
  If need be, special provisions can be adopted for new types of materials and articles designed to actively maintain or improve the condition of the food (active food contact materials and articles) or designed to monitor the condition of the food (intelligent food contact materials and articles).

Prior to authorisation for their use in food contact materials substances need to undergo a safety assessment carried out by EFSA. EFSA has issued guidelines on how to present an application for evaluation of a substance. These guidelines would need to be adapted to require identifications of possible compounds present in "nano form". The risk assessment would need to be adapted to take into account specific risk arising from the use of substances in "nano-form", if any.

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40 Under the novel food regime only the food produced by nanotechnology is assessed, not nanotechnology as such

41 Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC, OJ L 338, 13.11.2004

42 For a list of specific directives on materials in contact with food, see http://ec.europa.eu/food/food/chemicalsafety/foodcontact/legisl_list_en.htm

The applicant or any business operator using the authorised substance or materials or articles containing the authorised substance shall immediately inform the Commission of any new scientific or technical information, which might affect the safety assessment of the authorised substance in relation to human health. If necessary, the Authority shall then review the assessment.

When a Member State, as a result of new information or a reassessment of existing information has detailed grounds for concluding that the use of a material or article endangers human health, although it complies with the relevant specific measures, it may temporarily suspend or restrict application of the provisions in question within its territory.

Consequently, the requirements and mechanisms contained in Framework Regulation (EC) No 1935/2004 allow risks associated with nanomaterials to be dealt with in an appropriate way.

3.8.4. Food additives

Directive 89/107/EEC on food additives authorized for use in foodstuffs intended for human consumption[43] covers substances added to food for a "technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food". A food additive is not normally consumed as a food itself and not normally used as a characteristic ingredient of food; however, its intentional addition to food may result in it or its by-products becoming directly or indirectly a component of such food.

The only substances which may be used as food additives are those included in the Community lists and then only under the conditions of use mentioned in those lists.

Inclusion of additives on the Community lists occurs after an opinion of the European Food Safety Authority and is based on criteria indicated in the Directive. Thus, additives can be approved only provided that:

- they present no hazard to the health of the consumer at the level of use proposed, so far as can be judged on the scientific evidence available,
- there is a reasonable technological need and
- they do not mislead the consumer

In order to assess the possible harmful effects, a food additive or derivatives thereof, will have been subject of appropriate toxicological testing and evaluation, which must also take into account, for example, any cumulative, synergistic or potentiating effect of its use and the phenomenon of human intolerance to substances foreign to the body.

All food additives must be kept under continuous observation and must be re-evaluated whenever necessary in the light of changing conditions of use and new scientific information. For example if they are prepared by production methods or starting materials significantly different from those included in the safety assessment they should be submitted for a further evaluation with emphasis on the new process or starting materials. Approval of food additives must take into account any acceptable daily intake, or equivalent assessment, established for the food additive and the probable daily intake of it from all sources.

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[43] Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption; OJ L 40, 11.2.1989

The Directives thus contains the necessary provisions to take into consideration the potential benefits and safety issues related to the use of nanomaterials or nanotechnologies.

3.8.5. Food supplements

Directive 2002/46/EC on food supplements provides with a definition of food supplements, provides for appropriate specific rules on labelling, presentation and advertising of these products and regulates their compositions in vitamins and minerals.

Positive lists of vitamins and minerals and of their sources that can be used in food supplements are given in the Annexes of the Directive. These sources have been evaluated for their safety and bioavailability.

Prior to the authorisation and inclusion in the positive lists every vitamin and mineral and/or every source need to undergo a safety assessment carried out by the European Food Safety Authority (EFSA). EFSA has issued guidelines on how to present an application for evaluation of vitamins and minerals and of their sources. These guidelines could need to be adapted to require identifications of possible compounds present in “nano form”. The risk assessment would need to be adapted to take into account specific risk arising from the use of substances in “nano-form”, if any

When a Member State, as a result of new information or a reassessment of existing information has detailed grounds for concluding that a product ,although it complies with the Directive, endangers human health, it may temporarily suspend or restrict application of the provisions in question within its territory. On this basis the Commission may consider the necessary amendment to the Directive.

Consequently, the requirements and mechanisms contained in Framework Directive 2002/46/EC allow risks associated with the use of vitamins and minerals in "nano" forms to be dealt with in an appropriate way.

However, explicit information on the particle form/production process of vitamins and minerals could be envisaged to be explicitly requested and scrutinised to in a future revision of Directive 2002/46/EC.

Regulation (EC) 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods lists in Annex I the vitamins and minerals that may be added and in Annex II the sources of vitamins and minerals that may be used and provides for certain restrictions regarding the foods to which vitamins and minerals may be added. Furthermore, it also provides the basis for scrutinising and, where necessary, regulating the addition of substances with nutritional or physiological effect, other than vitamins and minerals, to foods.

Prior to the authorisation and inclusion in the positive lists every vitamin and mineral and/or every source need to undergo a safety assessment carried out by the European Food Safety Authority (EFSA). EFSA has issued guidelines on how to present an application for evaluation of vitamins and minerals and of their sources. These guidelines could need to be adapted to require identifications of possible compounds present in “nano form”. The risk assessment would need to be adapted to take into account specific risk arising from the use of substances in “nano-form”, if any.

Furthermore, the Regulation foresees a procedure allowing, under certain conditions, to scrutinize and eventually restrict or forbid the use in foods of substances other than vitamins and minerals with a nutritional or physiological effect.

This procedure can be followed where a substance other than vitamins or minerals, or an ingredient containing a substance other than vitamins or minerals, is added to foods or used in

the manufacture of foods under conditions that would result in the ingestion of amounts of this substance greatly exceeding those reasonably expected to be ingested under normal conditions of consumption of a balanced and varied diet and/or would otherwise represent a potential risk to consumers.

Therefore, it could be envisaged that a substance produced in "nano" form providing with an increased bioavailability, could be subject of this procedure.

The Regulation contains the necessary provisions to take into account the potential safety issues related to the use of nanotechnologies. However, explicit information on the particle form/production process of vitamins and minerals could be envisaged to be explicitly requested and scrutinised to in a future revision of Regulation (EC) 1925/2006.

Dietetic foods are regulated by Council Directive 89/398/EEC on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses (framework Directive).

Directive 89/398/EEC foresees the adoption of specific Commission directives for different groups of foods for particular nutritional uses which are listed in its Annex.

The nutritional substances that can be added to dietetic foods are controlled either through positive lists included in the specific Commission directives or by Commission Directive 2001/15/EC. Directive 2001/15/EC includes a positive list of vitamins preparations, mineral substances, and nitrogen containing substances for use in foods for particular nutritional uses, except products infant formulae, follow-on formulae, processed cereal-based foods and other baby foods intended for infants and young children which have their own lists in the specific legislation.

Prior to the authorisation and inclusion in the positive lists every new substance need to undergo a safety assessment carried out by the European Food Safety Authority (EFSA). EFSA has issued guidelines on how to present an application for evaluation of these substances. These guidelines could need to be updated to require identifications of possible compounds in "nano form".

Directive 89/398/EEC provides for the following: when a Member State, as a result of new information or a reassessment of existing information has detailed grounds for concluding that a foodstuff intended for particular nutritional use, although it complies with the Directive 89/398/EEC and/or the specific directives, endangers human health, it may temporarily suspend or restrict application of the provisions in question within its territory. On this basis the Commission may consider the necessary amendment to the Directive(s).

Directive 89/398/EEC contains the necessary provisions to take into account the potential safety issues related to the use of nanotechnologies. However, explicit information on the particle form/production process of the substances could be envisaged in the revision of Directive 89/398/EEC (ongoing).

3.8.6. Feed legislation

As mentioned above, within the context of food law, also the general requirements for feed, including its production and use where that feed is intended for food-producing animals, are included. Specific requirements in relation to feedingstuffs have been laid down in a series of directives or regulations, such as

- Directive 96/25/EC on feed materials, i.e. raw or processed materials intended for use as animal feed or for manufacturing compound feedingstuffs.[44] The Annex to Directive 96/25/EC gives a non-exhaustive list of the feed materials that need to be identified on the label. This Annex has been entirely replaced and updated to technical and scientific progress by Commission Directive 98/67/EC
- Directive 79/373/EC on the marketing of compound feedingstuffs, i.e. mixtures of feed materials, which may contain additives for use as animal feed in the form of complete or complementary feedingstuffs.[45]

Directives 96/25/EC and 79/373/EC contain provisions of a rather general nature. Feed materials and feedingstuffs must be of sound, genuine and of merchantable quality. They must not represent any danger to animal or human health or to the environment and must not be put into circulation in a manner that is liable to mislead. Relevant is however article 11 of Directive 96/25, according to which the Commission, in agreement with Member States, and with information of the European Parliament, can draw up a list of materials whose circulation or use for animal nutrition purposes is restricted or prohibited in order to ensure their compliance with these generic requirements. On this basis, any risk associated with nanomaterials could be controlled.

Directive 82/471/EEC concerning "bio-proteins" produced by certain technical processes e.g. fermentation, lays down the provisions for the circulation of these technological products.[46] Risk management is done by maintaining a positive list (e.g. what is safe is on the list, all other who are not evaluated are forbidden).

Regulation 1831/2003 on additives for use in animal nutrition establishes more detailed requirements. Additives can only be placed on the marker, processed or used as a feed additive if they have been authorized, conditions for use have been respected and labelling and packaging requirement are being met.

One of the conditions for authorisations is the absence of an adverse effect on animal health, human health or the environment. Applications for authorisation will be assessed by the European Food Safety Authority, on the basis of a technical documentation that contains, amongst others,

- a description of the method of production, manufacturing . and intended uses of the feed additive, of the method of analysis of the additive in feed according to its intended use and, where appropriate, of the method of analysis for the determination of the level of residues of the feed additive, or its metabolites, in food;
- a copy of the studies which have been carried out and any other material which is available to demonstrate that the feed additive satisfies the criteria.

Specific guidelines have to be laid down for the authorisation of additives, if need be for each category of them defined in the regulation.

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44 Council Directive 96/25/EC of 29 April 1996 on the circulation and use of feed materials, amending Directives 70/524/EEC, 7463/EEC, 82/471/ EEC and 93/74/EEC and repealing Directive 77/101/EEC; OJ L 125, 23.5.1996

45 Council Directive 79/373/EEC of 2 April 1979 on the circulation of compound feedingstuffs; OJ L 86, 6.4.1979

46 Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition; OJ L 213, 21.7.1982

A decision on authorisation is taken by the European Commission under the regulatory committee procedure defined by Article 5 of Council Decision 1999/468, which includes, a requirement to inform the European Parliament. Authorisations can impose specific conditions or restrictions in relation to handling, post market monitoring and use. Authorisations can be modified, suspended or withdrawn at any stage when the conditions for satisfying the Regulation are not no longer met.

The regulation contains a clause on confidentiality of data submitted by the applicant. However, certain information cannot be confidential, such as physico-chemical and biological characteristics of the feed additive, the conclusions of the study results on effects of the feed additive on human and animal health and on the environment, the conclusions of the study results on effects of the feed additive on the characteristics of animal products and its nutritional properties, or methods for detection and identification of the feed additive and, where applicable, monitoring requirements and a summary of the results of the monitoring.

Regulation 1831/2003 provides that EFSA shall apply the principles of Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents when handling applications for access to documents held by the Authority. As regards data that can be considered as confidential, Member States, the Commission and the Authority will nevertheless provide access where it is appropriate for such information to be made public in order to protect human health, animal health or the environment.

Intervention mechanisms in relation to feedingstuff are established by Regulation 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority (EFSA) and laying down procedures in the Regulation 882/2004/EC on official controls on matters of food safety and feeding Council Directive 95/53/EC .[47]

3.9. Consumer products not covered by specific regulation.

Directive 2001/95/EC on general product safety[48] (GPSD) covers any product – including in the context of providing a service – which is intended for consumers or likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them, and is supplied or made available, whether for consideration on or not, in the course of a commercial activity, and whether new, used or reconditioned.

To the extent that regulatory requirements have been established in product-specific regulation, these latter requirements will apply (e.g. for medicinal products, cosmetics, chemicals…..), complemented by the requirements of the GPSD that are not covered by the product-specific regulation.

According to the Directive, manufacturers can only place on the market "safe" products, i.e. products which under normal or foreseeable conditions of use, do not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level protection for the safety and health of persons, taking into consideration certain points such as the characteristics and presentation of the product.

The assessment whether a product is safe, is based on a number of factors, such as product legislation, standards, Commission recommendations, codes of good practice, state of the art and reasonable consumer expectations. Products will be "deemed safe" when they comply

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47 Council Directive 95/53/EC of 25October 1995 fixing the principles governing the organization of official inspections in the field of animal nutrition ; OJ L 265, 8.11.1995

48 Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety; OJ L 11, 15.1.2002

with non harmonised national regulatory provisions[49] and, under particular conditions, European standards

Attention is also to be drawn to the obligation of producers to provide consumers with the relevant information to enable them to assess the risks inherent in a product where such risks are not immediately obvious without adequate warnings and to take precautions against those risks.

The Directive creates an obligation for producers to monitor their products enabling them to be informed of risks which products might pose and to choose "corrective" action. Where producers know or ought to know that a product poses risks incompatible with the general safety requirements, they must inform so the national competent authorities, and cooperate with these latter.

Within the scope of this Directive, obligations placed on producers are very wide, obliging them "de facto" to carry out a risk assessment commensurate with the potential risks inherent to products and to technologies employed. In this respect, there is no exclusion regarding nano-technologies or nano products.

Where producers place consumer products on the market that may present risks associated with nanotechnologies, they must take care of such risks. Where documents on the basis of which products are "deemed to comply" do not cover nanotechnology related aspects, the producer will remain under an obligation to document and justify the use of technologies, components, etc. that may present nanotechnology related risks.

The mechanisms foreseen in the GPSD allow risks in relation to products containing or consisting of nanomaterials and nanotechnologies to be taken into account. In the absence of documents, in particular European standards, assessment will take place on a case-by-case basis.

4. ENVIRONMENTAL LEGISLATION

4.1. Integrated Pollution Prevention and Control (IPPC)

Council Directive 2008/1/EC concerning integrated pollution prevention and control[50] sets a general framework for integrated pollution prevention and control. Particular industrial activities can only operate if the operator holds a permit that implements certain basic obligations in order to prevent, or where this is not practicable, to reduce emissions in the air, water and land, including measures concerning waste. National competent authorities can only give such a permit if, inter alia, all the appropriate preventive measures are taken against pollution, no significant pollution is caused, and waste production is avoided, and where waste is produced, it is recovered or disposed of while avoiding or reducing any impact on the environment.

In their application for a permit, operators must provide a number of data, including the nature and quantities of foreseeable emissions from the installation in each environmental medium as well as the identification of significant effects of the emissions of the environment, and the technology and other techniques for preventing or reducing emissions from the installation.

In order to implement its provisions, the Directive promotes application of best available techniques. In order to facilitate a consistent implementation of the Directive, the Commission

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[49] In case of harmonisation, Community rules will be applied

[50] Council Directive 2008/1/EC of 15 January 2008 concerning integrated pollution prevention and control; OJ L 24, 29.1.2008

has produced a series of so-called BAT reference (BREF) documents, which constitute the main guidance for implementation.

The IPPC Directive requires that permit conditions include Emission Limit Values (ELVs) based on BAT to control releases of polluting substances. The Directive does not specify what form such ELVs must take – conventionally they are in the form of concentrations (e.g. mg/m3), but in principle they could be established in other ways, and could, therefore, conceivably be written specifically to address any concerns about releases of nanomaterials.

Practical IPPC implementation presently tends to focus mostly on conventional pollutants (sulphur, nitrogen, dust, halogens, heavy metals, etc) emitted in conventional form, reflecting the long-established need to control such emissions and the corresponding expertise of the competent authorities concerned.

Relying on implementation of the IPPC Directive as an effective regulatory tool in relation to nanomaterials would therefore require attention to be given to the assessment of the releases of such materials from IPPC installations (noting that some such releases may be from industrial installations falling outside the scope of the IPPC Directive), their impacts, and control techniques that may be considered as BAT.

The capacity of competent authorities to apply, monitor and enforce compliance with emission limit values or other types of permit conditions relating to nanomaterials would also need to be established.

4.2. Major-accidents, Seveso II Directive

Directive 96/82 on the control of major-accident hazards involving dangerous substances [51] applies to establishments where dangerous substances are present above certain quantities (or thresholds) The dangerous substances are certain named substances or groups of substances, plus all dangerous substances and preparations that are classified under Directives 67/548/EEC or Directive 1999/45/EC as very toxic, toxic, oxidising, explosive, flammable, dangerous for the environment or any other classification in combination with certain risk phrases. The quantity thresholds vary according to the nature and degree of hazard and the level of controls imposed. For example, the thresholds for toxic substances are 50 tons and 200 tons respectively.

The Directive 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. To this end, operators must notify their activities to national authorities. They must draw up and implement a major-accident prevention policy based on principles defined in the Directive. Operators must further present, and regularly review, safety reports showing that the directive's objectives on accident prevention are being met. Similarly, operators must draw up emergency plans. The Directive further contains a number of provisions in relation to provision of information, inspection, information on safety measures, land-use planning and "domino effect", i.e. an obligation for authorities to identify establishments or groups of establishments where the likelihood and the possibility or consequences of a major accident may be increased because of the location and the proximity of such establishments, and to set up an exchange of information and cooperation on public information

The major accident hazard potential of nanomaterials will depend primarily on the magnitude of any potential effects on human health or the environment. Due to the atypical

[51] Council Directive 96/82/EC of 9 December 1996 on the control of major-accident hazards involving dangerous substances; OJ L 10, 14.1.1997, as amended

physicochemical and unknown ecotoxicological properties of nanomaterials, it is possible that small quantities could have a significant impact on human health and the environment due to accidental release. If in the future certain nanomaterials are found to demonstrate a major accident hazard, then it may be possible to categorise these materials, together with appropriate thresholds, in the context of the Seveso II Directive.

4.3. Water

Directive 2000/60 of 23 October 2000 establishes a framework for Community action in the field of water policy[52]. As the provisions of this Directive are or progressively become fully operational, corresponding provisions in existing directives will be phased out.

The Directive sets common principles and an overall framework for action throughout the Community, aiming to improve the aquatic environment and to progressively reduce the emissions of hazardous substances to water. Directive 2000/60 presents an integrated approach, closely related to a wide variety of EU law relevant for the quality of water, particularly as regards the control of emissions.

Member States are obliged to identify individual rivers basins, and to establish programmes of measures for such basins. The Directive specifies the environmental objectives thus to be attained for surface water, ground water and for protected areas. Based on technical specifications set out in the Directive, Member States must carry out for each basin an analysis of its characteristics, a review of the impact of human activity of the status of surface and ground waters, and an economic analysis of water use. Programmes of measures and of quality assessments of water of are subject of regular review and monitoring. Discharges into surface water are to be controlled to the combined approach of controlling emission and achieving quality objectives or quality standards.

At Community level, the Directive foresees the adoption by the European Parliament and the Council of specific measures concerning individual (groups of) pollutants presenting a significant risk to or via the aquatic environment, based on priorities proposed by the Commission.

Priority substances will be subject of a series of measures, to be proposed by the Commission:

- the progressive reduction of discharges, emissions and losses of the substances, and the cessation or phasing out of discharges, emissions and losses.
- quality standards applicable in surface water, sediments or biota
- emission controls for point sources and environmental quality standards

Priorities are based on a risk assessment carried out under chemicals regulation, the plant protection products directive and the directive on biocidal products, or a targeted risk-based assessment focusing solely on aquatic ecotoxicology and on human toxicology via the aquatic environment.

A list of 33 priority substances has been established in 2001.[53]

Quality objectives were proposed at the end of 2006.[54] As regards emission standards, a large number of standards has been proposed, or is available, in related EU legislation, a list of

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52 Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy OJ L 327, 22.12.2000

53 Decision 2455/2001/EC of the European Parliament and of the Council of 20 November 2001 establishing the list of priority substances in the field of water policy and amending Directive 2000/60/EC 15.12.2001; OJ L 331, 15.12.2001

which is given in Annexes 5 and 6 of the Impact Assessment, accompanying the proposal for the Framework Water Directive[55]

As regards groundwater, the Directive foresees the adoption by the European Parliament and the Council of specific measures achieving the objective of good groundwater chemical status. Measures will include criteria for (a) assessing good groundwater chemical status, and (b) the identification of significant and sustained upward trends and for the definition of starting points for trend reversals. Such measures were adopted on 12 December 2006[56]

Depending on their properties, nanomaterials could fall into categories of pollutants identified by the Directive (Annex VIII and list of Priority Substances), because either they possess carcinogenic or mutagenic properties which may affect steriodogenic, thyroid, reproduction or other endocrine-related functions in or via the aquatic environment, or qualify as metals and their compounds, albeit other pollutant categories may also be concerned (e.g. bioaccumulative organic toxic substances).

National monitoring programmes to evaluate deterioration risks of water bodies and their actual chemical status and assessment of the efficiency of measures, monitoring will have to focus on a wide array of pollutants, including those arising from discharges of nanoproducts into the environment.

Future European (Environment) Quality Standards (EQS) are currently proposed by the Commission related to priority substances in the context of a daughter directive expected to be adopted by the end of 2008. These EQS could have an effect on the way emissions of nanoparticles will be tackled. This concerns not only direct emissions to the water environment, but also particles that are absorbed onto suspended matters and/or deposited in sediments, this affecting filter-feeding and other biological organisms. A specific issue would be to investigate how the presence of both bulk chemicals and their nanoforms would be measured together to make up a concentration in media.

In addition, Member States will have to establish groundwater quality standards for pollutants representing a risk to groundwater (this may include nanoparticles) under the new Groundwater Directive developed under the WFD.

4.4. Waste

Community regulation as far as relevant for nanomaterials and nanotechnologies can be presented under the general framework directives on waste and directives on specific waste streams and specific waste treatment techniques.

Directive 2006/12/EC on waste[57] sets the general framework for waste policies. It provides the basic definitions for waste legislation and provides that Member States take the necessary measures to ensure that waste treatment does not adversely affect health and the environment. The Directive furthermore sets rules regarding the setting up of administrative structures, planning, implementation, a system of permits for installations or undertakings treating, storing recovering or disposing waste on their behalf or on behalf of third parties, regular

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54 Proposal for a Directive of the European Parliament and of the Council on environmental quality standards in the field of water policy and amending Directive 2000/60/EC {COM(2006) 398 final} {SEC(2006) 947}

55 http://ec.europa.eu/environment/water/water-dangersub/pdf/sec_2006_947_en.pdf, pp 51-59

56 Directive 2006/118 EC on the protection of groundwater against pollution and deterioration; OJ L 372 of 27 December 2006.

57 Directive 2006/12/EC of the European Parliament and of the European Council of 5 April 2006 on waste; OJ L 114 of 27 4 2006

inspections, etc. It also instructs Member States to adopt policies to encourage the prevention, recovery (including the reuse of waste, its recycling or use as a fuel) and sound disposal.

Directive 91/689/EEC on hazardous waste[58] defines which wastes are hazardous and lays down stricter provisions regarding waste that is to be considered as hazardous. Hazardous waste must have one or more of the properties listed in Annex III to the Directive and feature on the European Waste List as hazardous. The list combining hazardous and non hazardous entries was established by Decision 2000/532/EC. The Directive concerns issues such as records and identification of waste, prohibition to mix different categories of waste, separation of hazardous waste, permitting of facilities treating hazardous waste, packaging and labelling, the establishment of national plans for the management of waste and public access to such plans, emergency measures and reporting to the Commission, Parliament and Council.

The classification procedure and the specific R-numbers laid down in the Waste list Decision 2000/532/EC refers to Directive 67/548/EEC on the classification, packaging and labelling of dangerous substances and its subsequent amendments. Both Annex III to the Hazardous Waste Directive and the Waste List may be amended through the regulatory Comitology procedure, for example to add hazardous properties and/or to add wastes to the list.

On this basis, wastes could be considered as hazardous if they contain relevant quantities of nanomaterials, provided these materials are classified as dangerous under Directive 67/548/EEC. Relevant information allowing qualifying waste as hazardous could be made better available in particular through the implementation of REACH.

It if was to be established that nanomaterials cause adverse effects on the environment or human health that are also listed in Annex III the waste can be classified as hazardous. Even if it was to be concluded that a new criterion is needed, this can be accommodated by amending the list of hazardous properties. On that basis, Member States would have a basis to classify the nanomaterials becoming a waste as hazardous.

Specific legislation has been adopted to deal with **particular waste streams**, such as end-of-life electrical and electronic equipment[59], vehicles[60], packaging and packaging materials[61],

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58 Council Directive 91/689/EEC of 12 December 1991 on hazardous waste; OJ L 377 , 31/12/1991

59 Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment ; OJ L 37, **13/02/2003**

60 Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles; OJ L 269 , 21/10/2000

61 Directive 94/62/EC of the European Parliament and the Council of 20 December 1994 on packaging and packaging waste; OJ L 365, 31.12.1994

batteries[62], titanium dioxide[63] and to deal with **specific waste treatment processes**, such as incineration[64] and landfill.[65]

None of these Directives address specifically nanomaterials and their risks. However, directives dealing with specific end-of-life products lay down (i) requirements in relation to the collection, recycling/re-use, recovery targets, (ii) as minimum mandatory steps for the dismantling of the end-of-life products, and (iii) restrict or prohibit the use of specific substances when alternatives are available. The latter relate mainly to heavy metals and some organic substance. The dismantling requirements and substance restrictions are regularly reviewed through the regulatory committee procedure. It is possible to review the list of exemptions from the substance bans by adding new exemptions or removing the existing ones, depending on the technical and scientific progress in the availability of substitutes. For packaging, it is possible to allow certain packaging types to exceed the maximum concentration values for heavy metals specified in the Directive.

In summary, 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 products that may contain nanomaterials whilst not including specific provisions addressing the risks of nanomaterials contained in these waste products. If the need for more specific provisions were established, the Commission could envisage taking appropriate action. Similarly, action can be taken by Member States in implementing current provisions in the framework of national policies.

The classification of waste from nanomaterials as hazardous waste would trigger a particular set of provisions to reduce the environmental and health risks displayed by the materials at the risk phase. However, the central issue lies in the lack of understanding of the potential risks displayed by nanomaterials at the waste stage. A better understanding of the fate of nanomaterials contained in articles throughout their lifecycle is needed. Currently there is not a full understanding whether nanoparticles are released under use of the article, or if they remain in the waste phase, and if so, in what form. The future implementation of the REACH Regulation should generate useful information.

4.5. Air quality

EU legislation on air quality, comprises the framework Directive 96/62/EC on ambient air quality assessment and management,[66] and the following daughter Directives 1999/30/EC relating to limit values for sulphur dioxide, nitrogen dioxide and oxides of nitrogen,

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62 Directive 2006/66/EC of the European Parliament and the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC; OJ

63 Council Directive 78/176/EEC of 20 February 1978 on waste from the titanium dioxide industry, OJ L 54, 25.2.1978; Council Directive 82/883 of 3 December 1982 on procedures for the surveillance and monitoring of environments concerned by waste from the titanium dioxide industry, OJ L 378 of 31.12.1982, and Council Directive 92/112/EEC of 15 December 1992 on procedures for harmonizing the programmes for the reduction and eventual elimination of pollution caused by waste from the titanium dioxide industry; OJ L409 of 31 12 1992; under review in the context of the better regulation exercise

64 Directive 2001/80/EC of the European Parliament and of the Council of 23 October 2001 on the limitation of emissions of certain pollutants into the air from large combustion plants; OJ L 309, 27.11.2001

65 Council Directive 1999/31/EC of 26 April 1999 on the landfill of waste; OJ L 182 , 16/07/1999

66 Council Directive 96/62/EC of 27 September 1996 on ambient air quality assessment and management; OJ L 296, 21.11.1996

particulate matter and lead in ambient air[67], Directive 2000/69/EC relating to limit values for benzene and carbon monoxide in ambient air, Directive [68], 2002/3/EC relating to ozone in ambient air[69], and ambient air[70]. All those Directives, except Directive 2004/107/EC, have been merged into a new Directive on ambient air and cleaner air for Europe[71] which is due to enter into force in May 2008.

Fuel quality is regulated through Directive 98/70/EC relating to the quality of petrol and diesel fuels and amending Directive 93/12/EC. Directive 2005/33/EC amending Directive 1999/32 as regards the sulphur content of marine fuels Emissions of air pollutants from mobile sources are regulated by means of Directive 98/69/EC[72] and Regulation (EC) 715/2007[73] for light-duty vehicles, Directive 2005/55/EC[74] for heavy-duty vehicles, and Directive 97/68/EC[75] for non-road mobile machinery.

Existing EU air quality legislation does not contain any relevant limit values and/or measurement and control methods suited to control nanoparticles in ambient air. While embedded in the particulate matter PM10 and PM2.5, the metric related to total mass is unsuitable to ultra-fine particles. Review process is set to reconsider the objectives and the appropriate PM metric by 2013. Other regulated pollutants such as heavy metals and PAH may also exhibit quite different toxicity in combined exposure with the ultrafine particles. The legislation on Euro 5 (Regulation (EC) 715/2007) contains provisions to set limit values on the number count of particulate matter emissions. This has been motivated by concerns over the emissions of ultrafine particles (with a size of 100 nanometres or smaller) that are emitted by diesel engines. The proposal on new Euro VI standards for heavy-duty vehicles[76] also contains such provisions.

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67 Council Directive 1999/30/EC of 22 April 1999 relating to limit values for sulphur dioxide, nitrogen dioxide and oxides of nitrogen, particulate matter and lead in ambient air; *OJ L 163, 29.6.1999*.

68 Directive 2000/69/EC of the European Parliament and of the Council of 16 November 2000 relating to limit values for benzene and carbon monoxide in ambient air; *OJ L 313, 13.12.2000*

69 Directive 2002/3/EC of the European Parliament and of the Council of 12 February 2002 relating to ozone in ambient air; *OJ L 67, 9.3.2002*

70 Directive 2004/107/EC of the European Parliament and of the Council of 15 December 2004 relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air; *OJ L 23, 26.1.2005*

71 COM (2005) 447.

72 Directive 98/69/EC of the European Parliament and of the Council of 13 October 1998 relating to measures to be taken against air pollution by emissions from motor vehicles and amending Council Directive 70/220/EEC. OJ L 350, 28.12.1998, p. 1–57

73 Regulation (EC) No 715/2007 of the European Parliament and of the Council of 20 June 2007 on type approval of motor vehicles with respect to emissions from light passenger and commercial vehicles (Euro 5 and Euro 6) and on access to vehicle repair and maintenance information; OJ L 171, 29.6.2007

74 Directive 2005/55/EC of the European Parliament and of the Council of 28 September 2005 on the approximation of the laws of the Member States relating to the measures to be taken against the emission of gaseous and particulate pollutants from compression-ignition engines for use in vehicles, and the emission of gaseous pollutants from positive-ignition engines fuelled with natural gas or liquefied petroleum gas for use in vehicles; OJ L 275, 20.10.2005

75 Directive 97/68/EC of the European Parliament and of the Council of 16 December 1997 on the approximation of the laws of the Member States relating to measures against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery; OJ L 59, 27.2.1998

76 Proposal for a Regulation of the European Parliament and of the Council on type-approval of motor vehicles and engines with respect to emissions from heavy duty vehicles (Euro VI) and on access to vehicle repair and maintenance information; COM(2007)851.

4.6. Soil

In September 2006, the Commission adopted the Thematic Strategy on the protection of soil[77], which includes a proposal for a Directive on soil protection[78]. This legislative proposal aims at establishing a framework for the protection of soil and the preservation of the capacity of soil to perform its environmental, economic and social functions. It addresses, inter alia, the issues of the prevention of soil contamination and the management of contaminated sites.

As regards the prevention of soil contamination, the proposal requires Member States "*to take appropriate and proportionate measures to limit the intentional or unintentional introduction of dangerous substances on or in the soil, excluding those due to air deposition and those due to a natural phenomenon of exceptional, inevitable and irresistible character, in order to avoid accumulation that would hamper soil functions or give rise to significant risks to human health or the environment*." For the purpose of this Directive, dangerous substances mean substances or preparations classified as dangerous within the meaning of Council Directive 67/548/EC[79] and Directive 1999/45/EC[80].

The first reading on the proposal was adopted by the European Parliament in November 2006[81]

4.7. Environmental liability

Directive 2004/35/EC[82] establishes a framework of environmental liability, based on the "polluter-pays" principle, to prevent and remedy environmental damage.

Under the terms of the Directive, environmental damage is defined as:

- direct or indirect damage to the aquatic environment covered by Directive 2000/60 establishing a framework for Community action in the field of water policy ;
- direct or indirect damage to species and natural habitats identified by reference to Directive 79/409 on the conservation of wild birds and Directive 92/43 on the conservation of natural habitats and of wild fauna and flora;
- direct or indirect contamination of the land which creates a significant risk to human health.

The Directive covers environmental damage and imminent threat of damage resulting from occupational activities, where it is possible to establish a causal link between the damage and the activity in question.

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77 COM (2006) 231, 22.9.2006

78 COM(2006) 232, 22.9.2006

79 Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances; OJ 196, 16.8.1967

80 Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations; OJ L 200, 30.7.1999

81 European Parliament legislative resolution of 14 November 2007 on the proposal for a directive of the European Parliament and of the Council establishing a framework for the protection of soil and amending Directive 2004/35/EC (P6_TA(2007)0509).

82 Directive 2004/35/EC of the European Parliament and of the Council of 21 April 2004 on "environmental liability with regard to the prevention and remedying of environmental damage" ; OJ L 143, 30.4.2004

The Directive distinguishes two complementary situations, each one governed by a different liability scheme: occupational activities specifically mentioned in Annex III to the Directive and any other occupational activities.

The first liability scheme applies to the dangerous or potentially dangerous occupational activities listed in Annex III to the Directive. These include activities covered by Directive 96/61 on integrated pollution prevention and control (IPPC), activities which discharge polluting substances into water or the air, installations storing or producing dangerous chemical substances (including those falling under Directive 96/82 on the control of major-accident hazards involving dangerous substances – Seveso II Directive), waste management activities (including landfills and incinerators) and activities concerning genetically modified organisms and micro-organisms. Under this first scheme, the operator may be held responsible even if he is not at fault. There are, however, circumstances in which an operator may not be required to bear costs under the Directive. Of particular relevance here is the circumstance resulting from the demonstration by the operator that his activity was not considered likely to cause environmental damage according to the state of scientific and technical knowledge at the time when the activity took place. It should be noted, however, that this exonerating circumstance is optional in that Member States are allowed – but are not required to – provide it in their national implementing legislation.

The second liability scheme applies to all occupational activities other than those listed in Annex III to the Directive, but only where there is damage, or imminent threat of damage, to protected species or natural habitats. In this case, the operator will be held liable only if he is at fault or negligent.

Operators whose activity involves the use of nanotechnology and/or nanomaterials could be held liable under the Directive as and when the various conditions set out therein are met.

The operator liable under the Directive must bear the cost of the necessary preventive or remedial measures. He will do so either directly or indirectly:

- In the first case, the operator pays for the measures he takes himself or he entrusts a specialised undertaking to take them on his behalf.
- In the second situation, where a competent authority has acted, itself or through a specialised undertaking, in the place of the liable operator, that authority shall recover the costs it has incurred from the operator.

Environmental damage may be remedied in different ways depending on the type of damage irrespective to chemicals or nanomaterials:

- for damage affecting the land, the Directive requires that the land concerned be decontaminated until there is no longer any significant risk of adverse effect on human health;
- for damage affecting waters or protected species and natural habitats, and in addition to the removal of any significant risk for human health, the Directive aims at restoring the environment to its baseline condition. To that effect, measures to restore, rehabilitate or replace damaged natural resources and/or impaired services, or to provide an equivalent alternative to those resources or services should be taken.

Research needed to support legislative work in the field of environment, health and safety

1. MEASUREMENT METHODS, REFERENCE MATERIALS AND MATERIALS CHARACTERISATION,

- Development and validation of reliable methods to assess relevant properties (size, shape, surface area & surface chemistry), particle size distribution and physico-chemical and biological parameters of nanomaterials in various matrices and under various conditions.
- Reference materials and certified reference materials to underpin the development, validation and quality assurance of these characterisation methods and exposure monitoring tests.
- Physicochemical characterization of the nanomaterials (particle size, surface characteristics, substances on particle surface, particle charging, agglomeration & de-agglomeration characteristics including kinetics, solubility, formulation, explosion characteristics etc.).
- Research aiming to support the development of a uniform nomenclature system, for different types of nanomaterials.

2. TEST METHODS FOR HUMAN HEALTH, SAFETY AND ENVIRONMENT AND REFERENCE MATERIALS

- Review, comparison and development of standard and validated test methods and test schemes for nanomaterials. Particular attention should be given to the development of non-animal test methods. Comparison of *in-vitro*, *in-vivo* and *in silico* test methods and models for materials.
- Review of existing test methods and where appropriate development and validation of new test methods to detect adverse effects from nanomaterials to *human health*; including acute and chronic toxicity (oral, inhalation, dermal), toxicokinetics, CMR properties etc.
- Review of existing test methods and where appropriate development and validation of new test methods to detect adverse effects from nanomaterials to the *environment*; including eco-toxicity tests, bioaccumulation, persistence, etc including bioavailability as well as their likely environmental/health impacts.

3. EXPOSURE INFORMATION THROUGHOUT THE LIFE CYCLE OF NANOMATERIALS

- **Uses and markets**. Overview of potential sources of specific nanomaterials where environment or humans may be exposed. Identification of nanomaterials/nanoparticles predicted to be "high volume" or causing high exposure to humans or the environment.
- Sampling, measurement and monitoring for exposure assessment and exposure mitigation verification linked to humans and various environmental species. Robust, harmonised and reliable sampling, detection and monitoring techniques for nanomaterials (also for routine use – here: in-situ, on-line & at-line

approaches). These should also be capable of distinguishing the background from the additionally manufactured nanomaterials.

- Identify employment sectors in which nanomaterials are either manufactured or used together with collecting information on the likely number of persons who work with, or may be exposed, to them. Also, what risk management measures have been identified as necessary and are they successful in practice in controlling any identified risks to workers health and safety

4. RISK ASSESSMENT METHODS

- Review of existing methods for risk assessment and for life cycle analysis and, as appropriate, application, adjustment, development of new and validation of methods applicable to nanomaterials.
- Application, adjustment, development of new and validation of Life Cycle Assessment.
- **Environmental fate** of nanoparticles (air, water, soil, biota) including the application, adjustment and validation of existing models and as appropriate next to the eventual development and validation of new environmental compartment and safety models.

5. RISK MANAGEMENT

- For worker protection purposes - determine the effectiveness of a range of risk management measures including process enclosure, ventilation (general and local exhaust ventilation, filters used in ventilation systems etc), personal protective equipment (PPE) including respiratory protective equipment (RPE) and gloves.

6. NETWORKING AND INFRASTRUCTURE ASPECTS

- Networking of existing and establishment of new networks and infrastructures to ensure a cost-effective and time-efficient examination of health, safety, and environmental aspects of nanomaterials throughout Europe and linking effectively with other international related activities.

Addressing the knowledge gap

A detailed account of various activities is given in the Communication from the Commission to the Council, the European Parliament and the Economic and Social Committee: Nanosciences and Nanotechnologies: An action plan for Europe 2005-2009. First Implementation Report 2005-2007.[83]

This report indicates main actions addressing the knowledge gap directly relevant for addressing the knowledge gap on health, safety and the environment in relation to legislation and regulatory implementation.

1. INTERNATIONAL COOPERATION AT THE LEVEL OF OECD

The OECD Working Party on Manufactured Nanomaterials (WPMN) was established in 2006 under the Chemicals Committee. The objective of the WPMN is to promote international co-operation in human health and environmental safety related aspects of manufactured nanomaterials. The work is being implemented via specific projects dealing with research issues in the health and environment area, the setting up a database, development of test methods, test guidelines, and risk assessment methods, and information exchange on voluntary schemes and regulatory approaches, the role of alternative testing methods, and exposure measurement and exposure mitigation. Some aspects of the OECD work are closely linked with standardisation activities, and the International Organisation for Standardisation (ISO) is taking part in the work.

1.1. Testing Methods and Risk Assessment

Existing OECD test guidelines (used for conventional chemicals) are currently reviewed with respect to their applicability to nanomaterials as part of the WPMN work. The WPMN has also set up a sponsorship programme, under which certain selected nanomaterials will undergo testing. These two activities should lead to better understanding about the specific test requirements for nanomaterials, and the need to modify or develop new OECD test guidelines.

Potential approaches for exposure measurement and detection of nanomaterials in the workplace and the environment are currently being developed. Methods currently examined may extend to those assessing, amongst other things, compartmentalisation properties, monitoring, and measurement of exposure, fate and persistence.

Risk assessment approaches are being reviewed and further developed based on new knowledge with a view to adjust these. This is supplemented by cooperation on the identification of alternative test methods (e.g. in vitro tests) for nanomaterials. An important part of these activities involves sharing of assessment reports, case studies, and reviewing application of risk assessment methodologies.

1.2. Information Sharing, Co-operation and Dissemination

Clear and concise information relevant to the human health and environmental safety of manufactured nanomaterials will be made publicly available.. An inventory and comparison of approaches by different member countries will facilitate harmonisation of regulatory practices in the chemicals regulatory area. Information

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

on current or planned initiatives on risk assessments, voluntary programmes and regulation will be shared. Based on the approaches in member countries, industry and other stakeholders, OECD will specific recommendations on research strategies for the short, medium and longer term, and identify potential opportunities for collaboration. An OECD Database on Human Health and Environmental Safety Research is under construction.

2. STANDARDISATION AT THE INTERNATIONAL AND EUROPEAN LEVEL

The **European Committee for Standardization, CEN,** has started standardisation work on (i) classification, terminology and nomenclature (ii) metrology, measurement and characterization (including procedures for calibration), (iii) health, safety and environmental issues; and (iv) nanotechnology products and processes.

Similarly, the **International Organisation for Standardisation, ISO**, and the **International Electrotechnical Commission, IEC,** have created Technical Committees on nanotechnologies. Work is scheduled on terminology and nomenclature; metrology and instrumentation, including specifications for reference materials; test methodologies; modeling and simulation; and science-based health, safety, and environmental practices. European input is ensured through CEN and the European Committee for Electrotechnical Standardization, **CENELEC**.

As various aspects of standardization work may be relevant for the implementation of regulation, the Commission has, in accordance with Directive 98/34/EC [84] addressed, in April 2007, a formal standardization mandate to the European standards bodies. In this mandate, the Commission invites the European standards bodies in a first stage to:

- take stock of current standardisation relevant to nanotechnologies and nanomaterials (e.g. medical devices, personal protective equipment, etc.) which may need a revision in the light of risks associated with nanotechnologies and nanomaterials;
- Identify the need for new standards;
- Identify the need to develop standardisation documents other than standards in relation to the above mentioned priority areas;

A standardisation programme is expected early 2008.

3. EU SCIENTIFIC COMMITTEES WITH REGARD TO RISK ASSESSMENT

The EU **Scientific Committee on Emerging and Newly Identified health Risks (SCENHIR)** has produced two Opinions in relation to nanomaterials risk assessment, respectively in March 2006[85], and in March 2007[86]. In its first opinion,

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84 Directive 98/34/EC, laying down a procedure for the provision of information in the field of technical standards and regulations; OJ L 204 , 21/07/1998

85 Scientific Committee on Emerging and newly identified risks; 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

86 SCENHIR, Opinion, approved for public consultation, on the appropriateness of the risk assessment methodology in accordance with the technical guidance documents for new and existing substances for

SCENHIR concluded that the existing toxicological and ecotoxicological methods are appropriate to assess many of the hazards associated with the products and processes involving nanoparticles, but that they may not be sufficient to address all the hazards. The assays may need to be supplemented by additional tests, or replaced by modified tests, as it cannot be assumed that current scientific knowledge has elucidated all the potential adverse effects of nanoparticles. Specifically, attention needs to be given to the mode of delivery of the nanoparticle to the test system to ensure that it reflects the relevant exposure scenarios.

For exposure, SCENIHR also expressed that the use of mass concentration data alone to express dose is insufficient, and that the number concentration and/or surface area would need to be used as well. Equipment that enables routine measurements for exposure to free nanoparticles is not yet available. In particular, existing methods used for environmental exposure assessment may not necessarily be appropriate for determining the environmental fate of nanomaterials.

Consequently, current risk assessment procedures may require modification for nanoparticles both regarding test methods for hazard identification and exposure assessment.

The SCENHIR suggested that there is insufficient knowledge and data concerning nanoparticle characterisation, their detection and measurement, the fate (and especially the persistence) of nanoparticles in humans and in the environment, and all aspects of toxicology and environmental toxicology related to nanoparticles, to allow for satisfactory risk assessments for humans and ecosystems to be performed.

In its second opinion, dealing particularly with the appropriateness of the risk assessment methodology in accordance with the Technical Guidance Documents ("TGD") for new and existing (chemical) substances for assessing the risks of nanomaterials, the SCENHIR concluded that current methodologies described in the TGDs are likely to identify certain hazards, but that modifications are required for the assessment of risks to human health and the environment. Furthermore, the opinion highlights needs to determine appropriateness of current test procedures for the prediction of human health hazards and estimation of risks for all types of nanoparticles.[87] In particular, the SCENIHR focussed on the potential of nanomaterials to reach new target organs in the body, when administered in similar ways as bulk chemicals (translocation). This observation would lead to additional requirements of test methods to demonstrate potential new hazards.

In December 2007, the **Scientific Committee for Consumer Products** (SCCP) adopted an Opinion on safety of nanomaterials in cosmetic products.[88] For labile particles, conventional risk assessment methodologies based on mass metrics may be adequate, whereas for the insoluble particles other metrics, such as the number of particles, and their surface area as well as their distribution are also required. It is crucial when assessing possible risks associated with nanoparticles to consider their uptake. It is primarily for the insoluble particles that health concerns related to possible uptake arise. Should they become systemically available, translocation/ transportation and eventual accumulation in secondary target organs may occur. The

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assessing the risks of nanomaterials.
http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_004c.pdf

87 http://ec.europa.eu/health/ph_risk/committees/04_sccp/sccp_opinions_en.htm

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

Committee also identifies a number of knowledge gaps. More particularly as regards the ban on animal testing with respect to cosmetics,[89] the Committee takes note that at present no methodology has been validated for nanomaterials. Finally, the Committee states that review of the safety of the insoluble nanomaterials presently used in sunscreens is required.

4. THE EUROPEAN FOOD SAFETY AUTHORITY

The European Food Safety Authority has identified the risk assessment of nanoparticles as a priority action for its Advisory Forum and Scientific Committee.[90] It will be necessary to investigate how far guidance for evaluation of substances to be used in food or food contact materials has to be adapted to accommodate the use of nanomaterials in these products. In June 2007, the Commission has therefore requested EFSA to provide an initial scientific opinion on the risks arising from nanomaterials and nanotechnologies in the food and feed area.

5. ETHICAL CONSIDERATIONS WITH REGARD TO NANOMEDECINE

Nanomedicine is still a 'new' technology and in an experimental phase (pre-clinical applications), involving a number of ethical issues that should be properly taken into account. In September 2005 the European Group on Ethics in Science and New Technologies (EGE) was requested to issue an opinion on ethics and nanomedicine. The Opinion was adopted on 17 January 2007.[91]

The EGE underlines the vital importance of addressing concern for safety with respect to nanomedical developments (and, in fact, nanotechnology in general) and therefore advocates the need to establish measures to verify the safety of nanomedical products and to ensure that nanomedical devices are properly assessed with regard to public health. Attention is paid to public participation and transparency (including openness about uncertainties and knowledge gaps), essential for public trust in nanotechnology. Additionally, the Group underlines the need for prospective technology assessment, including consideration of social effects (also in developing countries) and interdisciplinary research on the Ethical, Legal and Social Implications (ELSI) of nanomedicine, and enhanced information exchange, on issues such informed consent procedures with regard to safety.

As far as the legal implications of nanomedicine are concerned, the EGE does not propose any new regulatory structures specifically dealing with nanomedicine at this point, and argues that any changes should be made within existing structures (with focus on implementation of existing regulations). The Group proposes, however, that possible regulatory overlaps should be looked at carefully to allow the implementation of existing regulation in an unambiguous manner. In addition, the EGE calls for comparative research on intellectual property rights and nanomedicine and advocate the needs to look further into the balance between knowledge protection and information dissemination

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89 Directive 2003/15/EC of 27 February 2003 ("7th Amendment"); OJ 66, 11.3.2003

90 http://www.efsa.europa.eu/en/mboard/mb_meetings/mb_29th_meeting.html; 2007 management plan.

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

6. JOINT RESEARCH CENTRE OF THE EUROPEAN COMMISSION

The Joint Research Centre of the European Commission (JRC) is currently exploring the needs and requirements in the area of metrology and toxicology related to manufactured nanomaterials. Activities are focused at the moment on the development of

- Reference materials to increase the reliability and hence the confidence in measurements at the nanoscale and of (engineered) nanomaterials in order to enable the validation and comparison of existing and newly proposed measurement methods, and the verification of the proficiency of test laboratories. The JRC cooperates with OECD, CEN and ISO on such topics and also the characterisation and the development of exposure assessment tools of nanomaterials.
- validation and harmonisation of testing methods for evaluating the potential toxicity of nanomaterials. Manufactured nanomaterials are characterised and tested *in vitro* for their toxic potential; their uptake and intracellular distribution is tested by the means of radio-labelled nanoparticles.
- cell and molecular imaging systems in support to the development of non-animal methods in order to get a better insight into the mechanisms underlying different aspects of nanotoxicology,
- computer-based methods supporting the assessment of the distribution and fate of nanoparticles and their effects on human health and the environment. nanomaterials

Other activities include a feasibility study on the development and hosting of a database on the intrinsic properties of nanomaterials for the EU, or work by means of activated nanomaterials on the release of nanomaterials from advanced consumer materials under wear or corrosive conditions and the development and testing of sensor and detection systems corresponding to specific requirements for various applications, such as in the area of environmental monitoring and security.

7. STUDY ON SOCIO-ECONOMIC FACTORS

The JRC is coordinating a study that will identify opportunities and risks for future developments in the European Union by examining the present and future market for nanotech products, the composition of the sectors and industries mainly affected, and the competitiveness of the European industry vis-à-vis its main competitors. These overall objectives of the Euronano study will be pursued along three main lines, i.e.

- a brief technical description on main groups of nanotechnologies and the main technological advantages and an identification of applications of each technology and of the main application sectors
- Identifying appropriate indicators to provide for a comprehensive analysis of EU competitiveness in nanotechnologies and marketable nanomaterials/nano-products; this includes an assessment of the availability, reliability and degree of accurateness of data sources for future more detailed sectoral study(ies)
- Analysing the competitiveness of the European industry vis-à-vis some main competitors, the current status of R&D and the application of nanotechnology in products and processes; Identifying current and future centres/clusters of activities

related to nanotechnology; Characterising the current markets for nanotech products and processes and the already felt effects of this emerging technology on the sectors/industries mainly affected.

This study will find a follow-up on a wider and more permanent basis through a support action under FP7. Under this action, an observatory should be established, appropriate methodology developed, data collected and analysed so as to provide European decision makers with state-of-the-art analyses as well as dynamic assessments of nanotechnology development and use, allowing stakeholders to understand levels of success and critical issues, and to take actions.

8. SIXTH AND SEVENTH FRAMEWORK PROGRAMMES FOR RESEARCH AND TECHNOLOGICAL DEVELOPMENT

Funding for research in relation to nanotechnologies has been steadily increasing. Whilst for Framework Programme 6 (2002 – 2006) 1300 M€ was earmarked to the theme Nanosciences, nanotechnologies, materials & new production technologies (NMP), under Framework Programme 7 (2007 – 2013) 3400 M€ has been allocated. It is difficult to assess what share will eventually be available for nanotechnology. Not all funding available this theme will be made available for nanotechnologies, and inversely, funding for nanotechnology will be made available under other FP7 themes, such as Health or nanoelectronics. Nevertheless, it is estimated that the share of overall spending on nanotechnology will more than double with respect to FP6.

It is expected that past research activities in the area of impact assessment of nanoparticles on the environment and health will continue and be reinforced within the FP7. In the first two years, the EC launched several topics in the area of health, safety and environmental impact of nanoparticles. There were 6 topics in the first call for research proposals (launched on 22 December 2006) and two more in the second call.

Regulatory priorities identified by Commission services and national authorities to be covered by the 7th Framework Programme relate to

- Nanomaterials/particles characterisation and nomenclature
- Hazard characterisation
- Exposure end effects assessment
- Environmental fate, transport and persistence
- Measurement, sampling and monitoring

This work also builds upon and compliments various other activities by several European Technology Platforms (ETPs)[92], COST and national research programmes/activities.

[92] Information on Different Activities Related to Nanotechnologies in European Technology Platforms (ETPs), Version: 1 March 2006, European Commission.