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REPORT

on regulatory aspects of nanomaterials
(2008/2208(INI))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Carl Schlyter

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MOTION FOR A EUROPEAN PARLIAMENT RESOLUTION

on regulatory aspects of nanomaterials
(2008/2208(INI))

The European Parliament,

– having regard to the Commission Communication of 17 June 2008 entitled "Regulatory aspects of nanomaterials" (COM(2008)0366) and the accompanying Commission staff working document (SEC(2008)2036),

– having regard to the Commission Communication of 12 May 2004 entitled "Towards a European strategy for nanotechnology" (COM(2004)0338),

– having regard to the Commission Communication of 7 June 2005 entitled "Nanosciences and nanotechnologies: An action plan for Europe 2005-2009" (COM(2005)0243) ("the action plan") and to its resolution of 28 September 2006[1] on the action plan,

– having regard to the Commission Communication "Nanosciences and nanotechnologies: An action plan for Europe 2005-2009. First Implementation Report 2005-2007" (COM(2007)0505),

– having regard to the opinions of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) on definitions and risk assessment of nanomaterials[2],

– having regard to the opinion of the Scientific Committee on Consumer Products (SCCP) on the safety of nanomaterials in cosmetics[3],

– having regard to the Commission Recommendation on a code of conduct for responsible nanosciences and nanotechnologies research (COM(2008)0424) ("Code of Conduct"),

[1] OJ C 306 E, 15.12.2006, p. 426.
[2] Opinion on "The scientific aspects of the existing and proposed definitions relating to products of nanoscience and nanotechnologies; 29 November 2007";
http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_012.pdf
And accompanying Information by Commission services concerning the SCENIHR Opinion on Scientific Aspects of Existing and Proposed Definitions relating to Products of Nanoscience and Nanotechnologies;
http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_oc_012.pdf
Opinion on The Appropriateness of the Risk Assessment methodology in accordance with the technical guidance documents for new and existing substances for assessing the risks of nanomaterials; 21-22 June 2007;
http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_010.pdf
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
Opinion on Risk Assessment of Products of Nanotechnologies; 19 January 2009;
http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_023.pdf
[3] Opinion on Safety of nanomaterials in cosmetic products; 18 December 2007;
http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_123.pdf

– having regard to the opinion from the European Group on Ethics in Science and New Technologies to the European Commission on the ethical aspects of nanomedicine[1],

– having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)[2],

– having regard to 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[3],

– having regard to 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[4] and its daughter directives,

– having regard to Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety[5] as well as specific product legislation, in particular Council Directive 76/768/EEC of 27 July 1976 on approximation of laws of the Member States relating to cosmetic products[6],

– having regard to 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[7], Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives[8], and Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs[9], to Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms[10], and to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients[11],

– having regard to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006[12],

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[1] Opinion No 21, 17 January 2007.
[2] OJ L 396, 30.12.2006, p. 1.
[3] OJ L 123, 24.4.1998, p. 1.
[4] OJ L 183, 29.6.1989, p. 1
[5] OJ L 11, 15.1.2002, p. 4.
[6] OJ L 262, 27.9.1976, p. 169.
[7] OJ L 31, 1.2.2002, p. 1.
[8] OJ L 354, 31.12.2008, p. 16.
[9] OJ L 109, 6.5.2000, p. 29.
[10] OJ L 268, 18.10.2003, p. 24.
[11] OJ L 43, 14.2.1997, p. 1.
[12] OJ L 353, 31.12.2008, p. 1.

– having regard to Community environmental legislation, in particular Directive 2008/1/EC of the European Parliament and of the Council of 15 January 2008 concerning integrated pollution prevention and control[1], 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[2] and Directive 2006/12/EC of the European Parliament and of the Council of 5 April 2006 on waste[3],

– having regard to Directive 2006/114/EC of the European Parliament and of the Council of 12 December 2006 concerning misleading and comparative advertising[4],

– having regard to Rule 45 of its Rules of Procedure,

– having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinion of the Committee on Employment and Social Affairs (A6-0255/2009),

A. whereas the use of nanomaterials and nanotechnologies (hereinafter referred to as "nanomaterials") promises important advances with multiple benefits in innumerable applications for consumers, patients and the environment, as nanomaterials can provide different or new properties compared to the same substance or material in normal form;

B. whereas the advances in nanomaterials are expected to have significant influence on policy decisions in the fields of public health, employment, occupational safety and health, information society, energy, transport, security and space,

C. whereas despite the introduction of a specific European strategy on nanotechnologies and the subsequent allocation of approximately EUR 3 500 000 000 for research in nanosciences for the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013) (FP7), the European Union is lagging behind its current main competitors – the USA, Japan and South Korea – who account for over half of the investment and two-thirds of the patents filed worldwide;

D. whereas nanomaterials on the other hand potentially present significant new risks due to their minute size, such as increased reactivity and mobility, possibly leading to increased toxicity in combination with unrestricted access to the human body, and possibly involving quite different mechanisms of interference with the physiology of human and environmental species,

E. whereas the safe development of nanomaterials can make an important contribution to the competitiveness of the European Union's economy and to the achievement of the Lisbon strategy,

F. whereas the current discussion about nanomaterials is characterised by a significant lack of knowledge and information, leading to disagreement and political struggles, starting at

[1] OJ L 24, 29.01.2008, p. 8.
[2] OJ L 327, 22.12.2000, p. 1.
[3] OJ L 114, 27.4.2006, p. 9.
[4] OJ L 376, 27.12.2006, p. 21.

the level of definitions:

a) concerning the size: approximate indication of the size ("in the order of 100 nm or less") versus a specific size range ("between 1 and 100 nm"),

b) concerning different/new properties: different/new properties due to size effects as an independent criterion versus using such properties as an additional criterion for the definition of nanomaterials,

c) concerning problematic properties: limitation of the definition of nanomaterials to certain properties (e.g. insoluble or persistent), or not making such limitations,

G. whereas a fully developed set of harmonised definitions is not currently available although a number of international standards are either available or in progress, defining "nanoscale" as "having one or more dimensions of the order of 100 nm or less", and often distinguishing between:

– nano-objects, defined as "discrete pieces of materials with one, two or three external dimensions at the nanoscale", i.e. as materials constituted by isolated objects with very small dimensions,

– nano-structured materials, defined as materials "having an internal or surface structure at the nanoscale", e.g. exhibiting cavities of small dimensions,

H. whereas the almost infinite application of nanotechnologies to such diverse sectors as electronics, textiles, biomedicals, personal care products, cleaning products, food or energy makes it impossible to introduce a single regulatory framework at Community level,

I. whereas there is no clear information about the actual use of nanomaterials in consumer products, for instance:

– while inventories by renowned institutions list more than 800 manufacturer-identified nanotechnology-based consumer products currently on the market, trade associations of the same manufacturers question these figures, on the basis that they are overestimations, without providing any concrete figures themselves,

– while companies happily use "nano-claims", as the term "nano" seems to have a positive marketing effect, they are strictly opposed to objective labelling requirements,

J. whereas the lack of clarity about the actual use of nanomaterials in consumer products is unlikely to change, unless there are clear notification requirements on the use of nanomaterials, as well as full enforcement of Directive 2006/114/EC,

K. whereas presentations about the potential benefits of nanotechnologies predict an almost infinite diversity of future applications of nanomaterials**,** but fail to provide reliable information about current uses,

L. whereas there is a major debate about the possibility of assessing the safety of nanomaterials; whereas the scientific committees and Agencies of the European Union point to major deficiencies not only in key data, but even in methods of obtaining such data; whereas the European Union thus needs to invest more into adequate assessment of nanomaterials to close the knowledge gaps and to develop and implement as fast as possible, and, in collaboration with its agencies and international partners, methods of evaluation and an appropriate and harmonised metrology and nomenclature,

M. whereas SCENIHR identified some specific health hazards as well as toxic effects on environmental organisms for some nanomaterials, and considered that these observations indicate potential hazards which should be taken into consideration,

N. whereas SCENIHR furthermore found a general lack of high quality exposure data both for humans and the environment and expects risk assessment procedures to remain under development until there is sufficient scientific information available to characterise the possible harmful effects on humans and the environment, thus concluding that the knowledge on the methodology for both exposure estimates and hazard identification needs to be further developed, validated and standardised,

O. whereas the combination of evidence of hazards for certain nanomaterials and the overall lack of methods to properly assess the risks of nanomaterials is a reason for concern,

P. whereas current funding into the environmental, health and safety aspects of nanomaterials in FP7 is far too low; whereas moreover the evaluation criteria for granting research projects to assess the safety of nanomaterials under FP7 are too restrictive (i.e. they have a narrow innovation bias), and thus do not sufficiently promote the urgent development of scientific methods to assess nanomaterials; whereas it is essential to allocate sufficient resources for research on the safe development and use of nanomaterials,

Q. whereas the knowledge about potential health and environmental impacts lags significantly behind the pace of market developments, thus raising fundamental questions about the ability of the current governance model to deal with emerging technologies in "real time",

R. whereas, in its resolution of 28 September 2006 on nanosciences and nanotechnologies Parliament had called for investigation of the effects of nanoparticles that are not readily soluble or biodegradable, in accordance with the precautionary principle, before such particles are put into production and placed on the market,

S. whereas the value of the Commission Communication on "Regulatory aspects of nanomaterials" is rather limited due to the absence of information about the specific properties of nanomaterials, their actual uses, and potential risks and benefits, which also makes it difficult to judge their specific added value compared to conventional technologies, materials and substances,

T. whereas the Commission presented only a general overview of the relevant Community legislation**,** without considering the specific nature of nanomaterials and the resulting challenges,

U. whereas the Commission's overview shows that there are no nano-specific provisions in Community legislation for the time being,

V. whereas nanomaterials should be covered by a multi-faceted, differentiated and adaptive body of law based on the precautionary principle and on the principle of producer responsibility to ensure the safe production, use and disposal of nanomaterials before the technology is put on the market, while avoiding systematic recourse to general moratoria or undifferentiated treatment of different applications of nanomaterials,

W. whereas, in the context of REACH, it has already been agreed that further guidance and advice on nanomaterials, in particular on substance identification, as well as an adaptation of risk assessment methods is needed,

X. whereas a closer look at REACH reveals several deficiencies to deal with nanomaterials, for example:

– the tonnage thresholds might not be adequate, as the properties and potential risks of nanomaterial are determined to a greater extent by particle number, surface structure and surface activity than by their tonnage,

– an exposure assessment only becomes mandatory for substances produced by a manufacturer above 10 tonnes/year and if they have been found to meet the criteria for classification as dangerous in accordance with Directive 67/548/EEC[1]; however, given the current difficulties with hazard identification, an exposure assessment may well not be provided due to non-identification of hazards on the basis of existing methodology, even though an exposure assessment is crucial for a proper risk assessment of nanomaterials,

– the REACH notification requirements for substances in articles only concern substances of very high concern that are on the candidate list and when they are present in concentrations above 0,1 % by weight in the article and in a total quantity of over one tonne in those articles per producer per year; however, as not a single nanomaterial is currently on the candidate list, such listing will be difficult in light of the problems with hazard identification of nanomaterials, and even if those problems could be overcome, the nanomaterials would most likely not exceed the tonnage and concentration thresholds, so that it is highly unlikely that REACH in its current form will lead to notification of nanomaterials in articles,

Y. whereas waste legislation in the absence of nano-specific provisions may not apply correctly, for example:

– adequate waste treatment depends inter alia on the hazardousness of a waste (e.g. acceptance criteria for different wastes in a landfill), but will not apply for

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[1] 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, p. 1.

nanomaterials as long as there is no agreed method for hazard identification, thus leading to non-specific treatment of nanomaterials depending on the general nature of the waste they end up in (anything from municipal solid waste to hazardous waste),

– emission limit values for waste incineration only apply to certain known pollutants and not for nanomaterials, even though some might have to be classified as pollutants, or might have special requirements (e.g. carbon nanotubes, which can present asbestos-like properties, are stable until very high temperatures),

Z. whereas the significant amendments concerning nanomaterials adopted in a first reading agreement between the Council and the European Parliament in the context of the recast of the cosmetics directive[1], and the significant amendments adopted by the European Parliament in the first reading of the review of the regulation on novel food[2], respectively, highlight the clear need to amend Community legislation to address nanomaterials adequately,

Aa. whereas the current debate about regulatory aspects of nanomaterials is largely limited to expert circles, even though nanomaterials have the potential to bring about far-ranging societal change, which requires wide-ranging public consultation and full public participation in decision-making,

Ab. whereas a broad application of patents to nanomaterials, as well as the excessive cost of patenting and the absence of patent access facilities for very small businesses and small and medium-sized enterprises (SMEs), could stifle further innovation,

Ac. whereas the likely convergence of nanotechnology with biotechnology, biology, cognitive sciences and information technology raises serious questions relating to ethics, safety, security and respect for fundamental rights that need to be analysed by a new opinion of the European Group on Ethics in Science and New Technologies,

Ad. whereas the Code of Conduct is an essential instrument for safe, integrated and responsible research in nanomaterials; whereas the Code of Conduct must be adopted and respected by all producers intending to manufacture or place goods on the market,

Ae. whereas the precautionary principle, the polluter-pays principle and sustainability objectives should form the basis of the regulatory and guidance framework for nanotechnologies and nanomaterials, and these principles and objectives should help steer the development of nanotechnologies and nanomaterials towards uses that are of greatest benefit to society,

1. Is convinced that the use of nanomaterials should respond to the real needs of citizens and that their benefits can only be realised in a safe and responsible manner within a clear regulatory and policy framework (legislative and other provisions) that explicitly addresses existing and expected applications of nanomaterials as well as the very nature of potential health, environmental and safety problems over their life cycle;

[1] Position of the European Parliament of 24 March 2009, Texts adopted, P6_TA(2009)0158.
[2] Position of the European Parliament of 25 March 2009, Texts adopted, P6_TA(2009)0171.

2. Deplores the absence of a proper evaluation of the *de facto* application of the general provisions of Community law in the light of the actual nature of nanomaterials;

3. Does not agree, in the absence of any nano-specific provisions in Community law, with the Commission's conclusion that current legislation covers in principle the relevant risks relating to nanomaterials, when due to the lack of appropriate data and methods to assess the risks relating to nanomaterials it is effectively unable to address their risks;

4. Considers that as long as current legislation does not contain any nano-specific provisions, and as long as data and methods to adequately assess the risks of nanomaterials are missing, better implementation of current law alone cannot bring about the necessary level of protection;

5. Considers that the concept of the "safe, responsible and integrated approach" to nanotechnologies advocated by the European Union, is jeopardised by the lack of information on the use and on the safety of nanomaterials that are already on the market, particularly in sensitive applications with direct exposure of consumers;

6. Draws attention to the fact that different categories of people might be at risk at different stages of the product lifecycle: in the production and handling stages, in packaging, transport and maintenance, during disposal and demolition, and where secondary and end-users, and consumers are concerned; recalls that risk assessment has to be based on normal use and accidents, as well as the fact that the features are inhalation, dermal and other routes of exposure; stresses that the relevant legislation has to take into account the categories of people at risk as well as the risks related to these categories;

7. ¨Calls on the Commission to review all relevant legislation within two years to implement the principle "no data, no market" for all applications of nanomaterials in products with potential health, environmental or safety impacts over their life cycle, and to ensure that legislative provisions and instruments of implementation reflect the particular features of nanomaterials to which workers, consumers and/or the environment may be exposed;

8. Stresses that such review is not only necessary to adequately protect human health and the environment, but also to provide certainty and predictability to economic operators as well as public confidence;

9. Calls for the introduction of a comprehensive science-based definition of nanomaterials in Community legislation as part of nano-specific amendments to relevant horizontal and sectoral legislation;

10. Calls on the Commission to promote the adoption of a harmonised definition of nanomaterials at the international level and to adapt the relevant European legislative framework accordingly,

11. Considers it particularly important to address nanomaterials explicitly within the scope of at least legislation on chemicals (REACH, biocides), food (foodstuffs, food additives, food and feed products from genetically modified organisms), relevant legislation on worker protection, as well as legislation on air quality, water quality and waste;

12. Considers that products containing nanomaterials that present a risk to human health due to exposure of workers or consumers or an unacceptable risk for the environment should not be placed on the market;

13. Calls for the application of a "duty of care" for manufacturers that wish to place nanomaterials onto the market;

14. Calls specifically for amendments to REACH that ensure the following not later than 18 months after entry into force:

    – simplified registration for nanomaterials manufactured or imported (with a threshold based on for instance surface activity instead of tonnage), providing core data on physico-chemical properties as well as toxicological and ecotoxicological effects,

    – a chemical safety report with exposure assessment for all registered nanomaterials irrespective of hazard identification,

    – notification requirements for all nanomaterials placed on the market on their own, in preparations or in articles irrespective of tonnage and concentration thresholds;

15. Asks that when a substance has already been covered by Community legislation and there has been a significant change in the production methods, source materials or particle size through nanotechnology, the substance prepared by those new methods or materials be considered as a different substance, and a new entry in the Community legislation or change in the specifications on how the substance may be used shall be required before it may be placed on the market.

16. Calls specifically for amendments to waste legislation to adequately address nanomaterials, such as:

    – a separate entry for nanomaterials in the list of waste established by Decision 2000/532/EC[1],

    – a revision of the waste acceptance criteria in landfills in Decision 2003/33/EC[2],

    – a revision of relevant emission limit values for waste incineration to supplement the mass-based measurements by metrics based on particle number and/or surface;

17. Calls specifically for a revision of emission limit values and environmental quality standards in air and water legislation to supplement the mass-based measurements by metrics based on particle number and/or surface to adequately address nanomaterials;

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[1] Commission Decision of 3 May 2000 replacing Decision 94/3/EC establishing a list of wastes pursuant to Article 1(a) of Council Directive 75/442/EEC on waste and Council Decision 94/904/EC establishing a list of hazardous waste pursuant to Article 1(4) of Council Directive 91/689/EEC on hazardous waste, OJ L 226, 6.9.2000, p. 3.

[2] Council Decision of 19 December 2002 establishing criteria and procedures for the acceptance of waste at landfills pursuant to Article 16 of and Annex II to Directive 1999/31/EC, OJ L 11, 16.1.2003, p. 27.

18. Furthermore, underlines the fact that nanomaterials, throughout their whole life cycle, raise major challenges for occupational health and safety, as many workers along the production chain are exposed to these materials without knowing whether the safety procedures implemented and the protection measures taken are adequate and efficient; notes that the number and diversity of workers exposed to the effects of nanomaterials is expected to increase in the future;

19. Invites the European Risk Observatory of the European Agency for Safety and Health at Work and the Member States to step up their efforts in awareness-raising and the exchange of good practice;

20. Furthermore points out that, in individual cases, provisions on worker protection and safety concerning nanomaterials should be available in several languages;

21. Emphasises that a clear assignment of liability to producers and employers arising from nanotechnology and from the use of nanomaterials is necessary;

22. Calls specifically for amendments to worker protection legislation to ensure that nanomaterials are only used in closed systems as long as it is not possible to reliably detect and control exposure;

23. Underlines the importance for the Commission and/or Member States to ensure full compliance with, and enforcement of, the principles of Community legislation on the health and safety of workers when dealing with nanomaterials, including adequate training for health and safety specialists, to prevent potentially harmful exposure to nanomaterials;

24. Calls on the Commission to compile before June 2011 an inventory of the different types and uses of nanomaterials on the European market, while respecting justified commercial secrets such as recipes, and to make this inventory publicly available; furthermore calls on the Commission to report on the safety of these nanomaterials at the same time;

25. Reiterates its call for the provision of information to consumers on the use of nanomaterials in consumer products: all ingredients present in the form of nanomaterials in substances, mixtures or articles should be clearly indicated in the labelling of the product (e.g. in the list of ingredients, the name of such ingredients should be followed by the word 'nano' in brackets);

26. Calls for full enforcement of Directive 2006/114/EC to ensure that that there is no misleading advertising with nanomaterials;

27. Recommends the establishment of a feedback portal where nanomaterial researchers from industry, academia and citizen users can share experiences, report and share findings and find out the latest information, and which will regularly review these contributions.

28. Calls for the urgent development of adequate testing protocols and metrology standards to assess the hazard of, and exposure to, nanomaterials over their entire life cycle, using a multi-disciplinary approach;

29. Calls for a major stepping up of the funding of research into the environmental, health and safety aspects of nanomaterials over their life cycle, e.g. via the establishment of a special European Fund within FP7; furthermore calls specifically on the Commission to revise the evaluation criteria under FP7 so that FP7 attracts and funds significantly more research to improve the scientific methodology to assess nanomaterials;

30. Calls on the Commission to promote coordination and exchange between Member States on research and development, risk assessment, guidance development and regulation of nanomaterials by using existing mechanisms (e.g. REACH Competent Authorities Subgroup on Nanomaterials) or by creating additional ones, if appropriate;

31. Calls on the Commission and Member States to propose, as soon as possible, the establishment of a permanent and independent European decision-making platform responsible for monitoring nanotechnologies and nanomaterials, and a basic and applied research programme on the methodology for this monitoring (particularly metrology, detection, toxicity and epidemiology);

32. Calls on the Commission to carry out an impact assessment on the costs and benefits of creating a European institute on nanomaterials;

33. Asks the Commission and the Member States to undertake an EU-wide public debate on nanotechnologies and nanomaterials and on the regulatory aspects of nanomaterials and seek public opinion on which developments are considered acceptable or necessary and under which conditions;

34. Recognises that it is essential to remove the obstacles preventing very small businesses and SMEs in particular from accessing patents and calls at the same time for patent rights to be limited to specific applications or production methods of nanomaterials, and only to be extended to nanomaterials themselves on an exceptional basis, to avoid stifling innovation and to avoid creating a North-South "nano-divide";

35. Considers that stringent ethical guidelines need to be developed in due time, particularly for nanomedicine, such guidelines being the right to privacy, free and informed consent, the limits set on non-therapeutic human enhancement, whilst offering encouragement to this promising interdisciplinary domain with breakthrough technologies such as molecular imaging and diagnostics, which can offer impressive benefits for the early diagnosis and smart and cost-effective treatment of many diseases; asks the European Group on Ethics in Science and New Technologies to draw up an opinion on this issue, building on its Opinion No 21 of 17 January 2007 on "Ethical aspects of nanomedicine" and drawing on the ethical opinion issued by EU national ethics bodies as well as the work undertaken by international organisations such as UNESCO;

36. Calls on the Commission and Member States to pay special attention to the social dimension of the development of nanotechnology, including to the accompanying social science research; underlines the fact that nanotechnology should be judged in terms of its usefulness and its effect on humans and the environment; furthermore considers that the active participation of the social partners concerned has to be ensured from the earliest possible stage.

37. Considers that regulatory action on nanomaterials should also assess possibilities to address nanomaterials that are created as unintended by-products of combustion processes in a cost-effective manner, given that Community legislation on air quality does not yet cover the emission of very fine particles (of under 2,5µm) into ambient air, and given the very high number of air pollution-related deaths every year;

38. Instructs its President to forward this resolution to the Council and Commission, and the governments and parliaments of the Member States.

EXPLANATORY STATEMENT

Nanotechnology is the art of engineering at a new level, where fantastic results can be achieved in energy, manufacturing, consumer products and other sectors. Biomedicine with sensors implanted in the body and medicine which penetrates blood-brain barriers can be developed. Nano-generators can exploit the environment or body movement to create energy. Energy-efficient windows, more durable fishing rods, sun creams with high sun protection factors, crash-resistant bodywork, sensors for various environmental toxins, sterile surfaces etc., the list of what already exists on the market or may do within the near future is endless.

But all these dreams may turn to ashes unless we ensure that products are safe before they appear on the market; the old REACH motto, 'no data, no market', springs to mind. Nanotechnology entails new toxicological risks which are vaguely defined and difficult to test, a field in which our knowledge about immune defence response - if it is able to react at all in any given situation - is poor. Carbon nanotubes have proved to give rise to exactly the same type of damage as asbestos, carbon nanoclusters in low concentrations have caused brain damage in fish and sterilising nano silver from socks has leaked into waste water with unknown risks to treatment plants. When we know that nanoparticles are capable of penetrating the blood-brain barrier, how can we allow sun creams on to the market when we cannot guarantee that they have been tested to explore the possible differences in behaviour they may exhibit compared with previous creams? Moreover, the fact that different tests performed on the same nanomaterial can produce different results in toxicological investigations and that chemically identical nanomaterial produced by different manufacturers or manufacturing processes can have different properties also requires a better understanding. The experience gained with nanoparticles produced by combustion in engines, etc. is discouraging.

Nanotechnology entails entering into areas with a limited amount of knowledge. The old mechanical models used for bigger objects and their behaviour no longer entirely apply. Neither can nanoparticles always behave in accordance with the laws of quantum mechanics. They sometimes fall into a theoretical grey area but, above all, into a legal grey area. It is our role, as politicians, to ensure that nanotechnology is regulated in a way that protects the environment and mankind.

Nanotechnology exploits the fact that nano-size particles have completely different properties from bigger particles of the same substance. The most common definition of nanoparticles is that they are less than 100 nm in dimension. However, nanotechnology also covers a functional change in the properties of a material owing to its small size where the particles are larger than 100nm.

Particles which are so incredibly small are much more reactive than a substance in its original form and may bring about entirely new technological advances. These properties are also the problems faced by nanotechnology.

Technology can help us and harm us. In order to make informed choices whereby we can assess the risks of using a new technology, we have to find out how toxic something is, what risk we run of coming into contact with the chemical and whether it is biodegradable.

At the present time, we have no rules for the labelling of nanomaterials; there is not even an

established warning symbol! Your rapporteur attempted to investigate the Swedish market but, after sending reminders, received specific answers as to exactly which products contained nano in only two of seventeen cases. Without knowledge, consumers cannot make informed choices. We need to reassess the limit values laid down by laws and regulations on chemicals and introduce regulations on nano waste.

The Commission's paper on nanotechnology considers that the current rules are adequate despite the fact that none of them are geared to the specific effects of nanotechnology. The Commission's analysis is based on a one-dimensional, legalistic overview of the current rules but those rules are about as effective in addressing nanotechnology as trying to catch plankton with a cod fishing net. The environment, public health, all of us as consumers and even industry would benefit from regulation. There is a need for specially adapted toxicological tests; there must be regulation of the manner in which products may be placed on the market and the introduction of labelling of consumer products. It is not possible to regard such rules merely as a question of implementation whereby the Commission, with the aid of constant ad hoc letters, seeks new knowledge from companies. There is a need for clear rules to protect human beings and the environment but also so that companies are able to assume their responsibility and assess the potential of investment in nanotechnology.

In this respect, it is also important that we do not repeat the mistakes made in the USA in regard to patent rights. Broad patents on the properties of specific particles will impede developments and create wider global divisions. Patents should be awarded for specific advances such as a particular production process of a nanomaterial or a specific application which constitutes a clear 'inventive step'. Broad patenting of a specific particle would prevent everyone else from developing new or better applications.

In the slightly longer term, IT, biotechnology and micromechanics may converge and coincide at the nano level, at which point it may even be possible to upgrade living creatures, including human beings, through the application of nanotechnology - which creates entirely new ethical dilemmas. What is a human being and what can be done to us?

It would be tragic if nanotechnology acquired a bad reputation for all time because we were in too much of a hurry to get it on to the market without being aware of the risks involved.

3.12.2008

OPINION OF THE COMMITTEE ON EMPLOYMENT AND SOCIAL AFFAIRS

for the Committee on the Environment, Public Health and Food Safety

on regulatory aspects of nanomaterials
(2008/2208(INI))

Rapporteur: Jan Cremers

SUGGESTIONS

The Committee on Employment and Social Affairs calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to incorporate the following suggestions in its motion for a resolution:

1. Welcomes the Commission's Communication, which in general provides a balanced and up-to-date overview of the scientific knowledge and an assessment of the possible health or environmental risks of nanomaterials on the one hand, and a review of the Community legislation, on the other hand;

2. Acknowledges that nanotechnology and the use of nanomaterials have benefits, including in terms of job creation; underlines the fact that products are being made today with insufficient knowledge of the release of nanoparticles and the potential impacts they may have on human beings and the environment;

3. Furthermore, underlines the fact that nanotechnology and nanomaterials, throughout their whole life cycle, raise major challenges for occupational health and safety, as many workers along the production chain are exposed to these materials without knowing whether the safety procedures implemented and the protection measures taken are adequate and efficient; notes that the number and diversity of workers exposed to the effects of nanomaterials is expected to increase in the future; calls, therefore, for sufficient time and budgetary resources to be made available for the technology to be assessed;

4. Recognises that current knowledge of the toxicity of nanoparticles is limited and that comprehensive information about what risks different nanoparticles may pose on workers is not available yet, but notes that preliminary results in most published studies indicate that the toxicity of insoluble particles of similar composition increases with decreasing particle diameter and increasing particle surface area; furthermore, notes that those

studies reveal a risk of serious health effects arising from ultrafine particles, air pollution and fibres;

5. Emphasises the utmost importance of the safe and responsible use of nanomaterials in the short, medium and long term, as well as of the development of responsible nanotechnology which integrates health and safety considerations with production and application approaches; considers it therefore necessary to formulate adequate thresholds which are scientifically justifiable;

6. Recognises that prevention is of central importance in order to mitigate the risks and to eliminate potentially negative influences; emphasises that, as the scientific base needs to be improved, the precautionary principle has to be the guiding principle, along with the principle of the elimination of risk at source, in order to maintain a high level of protection of health and safety at work as well as of the environment;

7. Draws attention to the fact that different categories of people might be at risk at different stages of the product lifecycle: in the production and handling stages, in packaging, transport and maintenance, during disposal and demolition, and where secondary and end-users, and consumers are concerned; recalls that risk assessment has to be based on normal use and accidents, as well as the fact that the features are inhalation, dermal and other routes of exposure; stresses that the relevant legislation has to take into account the categories of people at risk as well as the risks related to these categories;

8. Underlines the importance of the Commission and Member States ensuring that the Framework Directive 89/391/EEC and its individual Directives, and in particular Directive 98/24/EC on hazardous chemical agents at work, are fully complied with; considers that the key elements of these Directives, with regard to nanomaterials, are the risk assessment, the protection and prevention measures, the information and consultation rights and the right to be trained;

9. Calls on the Commission and Member States to provide additional incentives to foster compliance with the regulatory framework, including for example strengthening labour inspection bodies and other enforcement and professional agencies, where appropriate; also calls on Member States to ensure adequate training for health and safety specialists necessary to prevent known as well as potentially harmful exposures to nanomaterials;

10. Draws attention to the need for prevention and risk reduction measures to be undertaken even when the dangers of particular substances used are still unknown; invites the Bilbao Agency Risk Observatory and the Member States to step up their efforts in awareness-raising and the exchange of good practice;

11. Invites the Commission, in the context of the implementation of Directive 89/391/EEC, to consider the need for an adequate instrument to deal with the exposure of nanoparticles in the workplace as soon as further research on the ‘knowledge gaps’, in particular with regard to hazards and exposure risks, are resolved, allowing a comprehensive understanding of the properties and risks of those materials;

12. Considers that the placing of such substances on the market has to take into account the free movement of products, which can lead to secondary and end-use being in another

country; considers therefore that requirements regarding customer information and the labelling of products have to be clarified, and urges the Member States to ensure compliance with existing provisions on labelling and information in relation to nanomaterials, in the necessary languages, so as to ensure that workers are provided with transparent information and that a precautionary approach can be applied;

13. Furthermore points out that, in individual cases, provisions on worker protection and safety concerning nanomaterials should be available in several languages;

14. Emphasises that a clear assignment of liability to producers and employers arising from nanotechnology and from the use of nanomaterials is necessary;

15. Underlines the need for rapid improvement of the scientific knowledge and its uptake, in particular the research underpinning risk assessment and measurement, effective risk prevention and protection measures, in accordance with existing Community occupational health and safety legislation; considers it of the utmost importance that possible health and safety at work implications are addressed at the same time as research into new applications is being undertaken; moreover considers it vital that a substantial part of the RTD budgets for nanotechnologies is earmarked to occupational health and safety, consumer protection and environmental considerations;

16. Calls on the Commission and Member States to pay special attention to the social dimension of the development of nanotechnology, including to the accompanying social-science research; underlines the fact that nanotechnology should be judged in terms of its usefulness and its effect on humans and the environment; furthermore considers that the active participation of the social partners concerned has to be ensured from the earliest possible stage.

RESULT OF FINAL VOTE IN COMMITTEE

Date adopted	2.12.2008
Result of final vote	+: 41 –: 1 0: 0
Members present for the final vote	Jan Andersson, Edit Bauer, Iles Braghetto, Philip Bushill-Matthews, Alejandro Cercas, Ole Christensen, Derek Roland Clark, Luigi Cocilovo, Jean Louis Cottigny, Jan Cremers, Proinsias De Rossa, Harald Ettl, Carlo Fatuzzo, Ilda Figueiredo, Stephen Hughes, Ona Juknevičienė, Elizabeth Lynne, Thomas Mann, Jan Tadeusz Masiel, Maria Matsouka, Juan Andrés Naranjo Escobar, Csaba Őry, Siiri Oviir, Marie Panayotopoulos-Cassiotou, Pier Antonio Panzeri, Rovana Plumb, Bilyana Ilieva Raeva, José Albino Silva Peneda, Jean Spautz, Gabriele Stauner, Ewa Tomaszewska, Anne Van Lancker
Substitute(s) present for the final vote	Gabriela Creţu, Petru Filip, Marian Harkin, Magda Kósáné Kovács, Sepp Kusstatscher, Jamila Madeira, Viktória Mohácsi, Ria Oomen-Ruijten, Csaba Sógor, Anja Weisgerber

RESULT OF FINAL VOTE IN COMMITTEE

Date adopted	31.3.2009
Result of final vote	+: 21 –: 14 0: 0
Members present for the final vote	Adamos Adamou, Georgs Andrejevs, Margrete Auken, Pilar Ayuso, Irena Belohorská, Johannes Blokland, John Bowis, Hiltrud Breyer, Martin Callanan, Chris Davies, Avril Doyle, Anne Ferreira, Karl-Heinz Florenz, Françoise Grossetête, Cristina Gutiérrez-Cortines, Gyula Hegyi, Marie Anne Isler Béguin, Holger Krahmer, Linda McAvan, Roberto Musacchio, Miroslav Ouzký, Vittorio Prodi, Dagmar Roth-Behrendt, Guido Sacconi, Daciana Octavia Sârbu, Amalia Sartori, Carl Schlyter, María Sornosa Martínez, Thomas Ulmer, Anja Weisgerber, Åsa Westlund
Substitute(s) present for the final vote	Kathalijne Maria Buitenweg, Nicodim Bulzesc, Hanne Dahl, Philippe de Villiers, Maciej Marian Giertych, Hélène Goudin, Hartmut Nassauer, Claude Turmes
Substitute(s) under Rule 178(2) present for the final vote	Paulo Casaca