EUROPEAN PARLIAMENT

2004 *2009*

Committee on the Environment, Public Health and Food Safety

2008/2208(INI)

19.1.2009

DRAFT REPORT

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

Committee on the Environment, Public Health and Food Safety

Rapporteur: Carl Schlyter

PR_INI

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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 on "Regulatory aspects of nanomaterials" (COM(2008)0366) and the accompanying Commission staff working document (SEC(2008)2036),

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

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

– 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 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)[4],

– 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[5] and its daughter directives,

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[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
[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
[4] OJ L 396, 30.12.2006, p. 1
[5] OJ L 183, 29.6.1989, p. 1

– having regard to Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety[1] 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[2],

– 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[3], 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[4] and Directive 2006/12/EC of the European Parliament and of the Council of 5 April 2006 on waste[5],

– 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 (A6-0000/2009),

A. whereas the use of nanomaterials and nanotechnologies (hereinafter referred to as "nanomaterials") promises 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 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,

C. whereas nanomaterials are likely to be the next "big thing", especially given that manipulating all matter has been man's ultimate dream for centuries,

D. whereas the current discussion about nanomaterials is characterised by many contradictions or even paradoxes, with disagreement and thus political struggles, starting at as basic a level as the definitions, for instance:
   – while nanomaterials are generally considered to be materials of a size in the *order* of 100 nm or less, this is often misrepresented as a *range* between 1 and 100 nm, even though the term “order” relates to a dimension rather than to a precise size,
   – while many people believe that different properties due to size effects should be an independent criterion for the definition of nanomaterials, others suggest using this in a cumulative manner, thus limiting the scope of the definition,
   – while some people suggest that the definition should be further narrowed to insoluble and persistent nanomaterials, thus already applying potential risk considerations at the level of definitions, others argue against such an *a priori* limitation,

[1] OJ L 11, 15.1.2002, p. 4.
[2] OJ L 262, 27.9.1976, p. 169.
[3] OJ L 24, 29.01.2008, p. 8
[4] OJ L 327, 22.12.2000, p. 1.
[5] OJ L 114, 27.4.2006, p. 9.

E. whereas in the context of REACH, it has so far not even been possible to agree on guidance on the identification of nanomaterials, leaving important decisions in the context of registration to economic operators,

F. 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,

G. whereas presentations about the potential benefits of nanotechnologies predict an almost infinite diversity of future applications of nanomaterials; however, the same diversity shrinks to near zero when it comes to a regulatory discussion about nanomaterials,

H. whereas there is a major controversy about the possibility of assessing the safety of nanomaterials: while the scientific committees of the Commission point to major deficiencies not only in key data, but even in methods of obtaining such data, many representatives of industry claim that all relevant data are available and that there are no methodological deficiencies,

I. whereas 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,

J. whereas the value of the Commission Communication on "Regulatory aspects of nanomaterials" is seriously undermined by the complete absence of any information about the specific properties of nanomaterials, their actual uses, and potential risks and benefits,

K. whereas the Commission presented only a legalistic overview of relevant Community legislation without considering current or likely future use of nanomaterials and without detailing the specific nature of nanomaterials and the resulting challenges,

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

M. whereas a broad application of patents to nanomaterials could stifle further innovation,

N. whereas the likely convergence of nanotechnology with biotechnology and information technology raises serious ethical questions,

1. Is convinced that the benefits of nanomaterials can only be realised within a clear regulatory framework that fully addresses the very nature of potential safety problems relating to nanomaterials;

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. Considers it highly misleading for the Commission to state, in the absence of any nano-specific provisions in Community law, 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 blind to its risks;

4. Considers that as long as current legislation is devoid of any nano-specific provisions, and as long as data and even methods to 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 proposed implementation focus does not provide the "safe and integrated approach" to nanotechnologies advocated by the Commission, given that numerous nanomaterials are already on the market, particularly in sensitive applications such as personal care products or cleaning products, without adequate safety assessment, and without adequate consumer information about these uses;

6. Calls on the Commission to propose reviews of all relevant legislation by the end of 2009 to fully implement the principle "no data, no market" for all applications of nanomaterials in consumer products or in products leading to discharges to the environment;

7. 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;

8. Reiterates its call for labelling of consumer products containing nanomaterials;

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

10. Calls for potential patent rights to be limited to specific applications or production methods of nanomaterials, and not to be extended to nanomaterials themselves, to avoid stifling innovation and to avoid creating a North-South "nano-divide";

11. Considers that ethical guidelines need to be developed in due time to ensure full respect for ethical values in possible future use of nanotechnology converging with biomedical applications;

12. Considers that regulatory action on nanomaterials should also address nanomaterials that are created as unintended by-products of combustion processes, given the very high number of air pollution-related deaths every year;

13. 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.