Procedure file

Basic information

INI - Own-initiative procedure	2008/2208(INI)	Procedure completed
Regulatory aspects of nanomaterials Subject 3.40.01 Chemical industry, fertilizers, plastics 3.50.08 New technologies; biotechnology 3.70 Environmental policy 3.70.13 Dangerous substances, toxic and radioactive wastes (storage, transport) 4.15.15 Health and safety at work, occupational medicine 4.20 Public health 4.60.02 Consumer information, advertising, labelling 8.50 EU law		

Key players

European Parliament	Committee responsible	Rapporteur	Appointed
	ENVI Environment, Public Health and Food Safety	Verts/ALE SCHLYTER Carl	29/09/2008
	Committee for opinion	Rapporteur for opinion	Appointed
	EMPL Employment and Social Affairs	PSE CREMERS Jan	09/09/2008
	ITRE Industry, Research and Energy	The committee decided not to give an opinion.	
	IMCO Internal Market and Consumer Protection	The committee decided not to give an opinion.	
	JURI Legal Affairs	The committee decided not to give an opinion.	
Council of the European Union	Council configuration	Meeting	Date
	Competitiveness (Internal Market, Industry, Research and Space)	2891	25/09/2008
European Commission	Commission DG	Commissioner	
	Internal Market, Industry, Entrepreneurship and SMEs	VERHEUGEN Günter	

Key events

17/06/2008	Non-legislative basic document published	COM(2008)0366	Summary
23/09/2008	Committee referral announced in Parliament		
25/09/2008	Resolution/conclusions adopted by Council		
31/03/2009	Vote in committee		Summary
08/04/2009	Committee report tabled for plenary	A6-0255/2009	
24/04/2009	Results of vote in Parliament		
24/04/2009	Decision by Parliament	T6-0328/2009	Summary

24/04/2009	End of procedure in Parliament		

Technical information

Procedure reference	2008/2208(INI)
Procedure type	INI - Own-initiative procedure
Procedure subtype	Initiative
Legal basis	Rules of Procedure EP 54-p4; Rules of Procedure EP 54
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/6/65498

Documentation gateway

Non-legislative basic document		COM(2008)0366	17/06/2008	EC	Summary
Document attached to the procedure		SEC(2008)2036	17/06/2008	EC	
Committee opinion	EMPL	PE414.293	03/12/2008	EP	
Committee draft report		PE418.270	19/01/2009	EP	
Amendments tabled in committee		PE421.227	03/03/2009	EP	
Amendments tabled in committee		PE423.726	26/03/2009	EP	
Committee report tabled for plenary, single reading		A6-0255/2009	08/04/2009	EP	
Text adopted by Parliament, single reading		T6-0328/2009	24/04/2009	EP	Summary
Commission response to text adopted in plenary		SP(2009)3615	27/10/2009	EC	
Follow-up document		COM(2012)0572	03/10/2012	EC	Summary
Follow-up document		SWD(2012)0288	03/10/2012	EC	

Regulatory aspects of nanomaterials

PURPOSE: to carry out a review of the regulatory aspects of nanomaterials.

CONTENT: in its Communication ?Towards a European Strategy for Nanotechnology?, the Commission states that R&D and technological progress need to be accompanied by scientific investigation and assessment of possible health or environmental risks associated with nanotechnology. The ?Integrated, safe and responsible approach? has become the core of the EU policy for nanotechnology. The Communication ?Nanosciences and nanotechnologies: an action plan for Europe 2005 ? 2009?, specified that all applications and use of nanosciences and nanotechnologies must comply with the high level of public health, safety, consumers and workers protection, and environmental protection chosen by the Community. The Commission therefore announced a regulatory review of EU legislation in relevant sectors.

The present Communication reflects this commitment. It covers nanomaterials currently in production and/or placed on the market. In the absence of generally accepted definitions, the term nanomaterials is used in this Communication to cover commonly used terminology such as manufactured (or engineered) nano-sized and nanostructured nanomaterials. The Communication does not address nanomaterials or nanoparticles that occur naturally or are unintentionally produced, e.g. in combustion.

Community action in relation to managing the risks in order to meet regulatory requirements should mainly focus on the following activities:

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

Commission working groups, meetings of Competent Authorities and Agencies in charge of coordinating the implementation of regulation will have to examine on an ongoing basis whether and what type of further action is needed. Work is also needed on documents for voluntary use, such as regulatory guidance, European or international standards30, advice from Scientific Committees,etc. Similarly, ethical issues have to be dealt with, as indicated by the European Group on Ethics in Science and New Technologies (EGE). Similarly, input is required from the

relevant Agencies such as the European Medicines Agency, the European Food Safety Authority, the European Chemicals Agency or the European Agency for Safety and Health at Work (OSHA).

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

2) Improving the knowledge base: there is a need for a rapid improvement of the scientific knowledge basis to support the regulatory work. Research activities are ongoing under the Research Framework Programmes and in the Joint Research Centre, as well as in EU Member States and internationally within the OECD Working Party on Manufactured Nanomaterials and the International Organisation for Standardisation, ISO. In particular, research is needed in areas underpinning risk assessments and risk management like: i) data on toxic and eco-toxic effects as well as test methods to generate such data; ii) data on uses and exposures throughout the lifecycle of nanomaterials or products containing nanomaterials, as well as exposure assessment approaches; iii) characterisation of nanomaterials, development of uniform standards and nomenclature, as well as analytical measurement techniques; iv) for occupational health aspects, the effectiveness of a range of risk management measures including process enclosure, ventilation, personal protective equipment like respiratory protective equipment and gloves.

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

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

Also relevant are the provisions in REACH with obligations of data dissemination about environment, safety and health risks, on the one hand to industrial users and, on the other hand to the public at large via the Internet. Attention is also drawn to provisions in Community law creating a right of access to information in relation to programmes mainly implementing legislation on environmental protection.

4) Market surveillance and intervention mechanisms: authorities and Agencies in charge of implementing legislation should continue to carefully monitor the market, and use Community market intervention mechanisms in case risks are identified for products already on the market (e.g. safeguard clauses, health monitoring measures, food, feed and pesticide market controls, formal objections to standards, precautionary measures, vigilance procedures, measures based on new evidence or re-assessment of existing data, mutual exchange of information, alert/early warning systems, etc).

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

Regulatory aspects of nanomaterials

The Committee on the Environment, Public Health and Food Safety adopted the own-initiative report drawn up by Carl SCHLYTER (Greens/EFA, SE) on regulatory aspects of nanomaterials in response to the Commission Communication on the subject. It points out that 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, the EU 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. On the other hand, nanomaterials 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. Furthermore, the current discussion about nanomaterials is characterised by a significant lack of knowledge and information, leading to disagreement and political struggles, starting at the level of definitions.

Members are 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 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. They deplore 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.

The committee states that it 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. 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.

The report further considers that the concept of the "safe, responsible and integrated approach" to nanotechnologies advocated by the EU is jeopardised by the lack of information on the use of nanomaterials that are already on the market, particularly in sensitive applications with direct exposure of consumers.

Members call on the Commission to review all relevant legislation within 2 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. The committee also calls, inter alia, for the application of a "duty of care" for manufacturers that wish to place nanomaterials onto the market, and for certain specified amendments in the following sectors: REACH, waste legislation, environmental quality standards in air and water legislation, worker protection legislation, and consumer legislation.

Regulatory aspects of nanomaterials

The European Parliament adopted by 362 votes to 4, with 5 abstentions, a resolution on regulatory aspects of nanomaterials, in response to the Commission?s Communication on this issue.

The text adopted by Parliament had been tabled by the Greens/EFA, EPP-ED, PES, ALDE and GUE/NGL groups, pursuant to Rule 45(2) of the Rules of Procedure, as an alternative motion for a resolution to the motion for a resolution contained in the own-initiative report tabled by the Committee on the Environment, Public Health and Food Safety.

The resolution recalls that the current discussion about nanomaterials is characterised by a significant lack of knowledge and information, leading to disagreement starting at 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; (c) concerning problematic properties.

MEPs stress that a fully developed set of harmonised definitions is not currently available and that there is no clear information about the actual use of nanomaterials in consumer products.

In this context, the Parliament does not agree with the Commission's conclusions that: (a) current legislation covers in principle the relevant risks relating to nanomaterials; (b) the protection of health, safety and the environment needs mostly to be enhanced by improving implementation of current legislation, 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.

Therefore, the Commission is called upon to: (i) review all relevant legislation within two years to ensure safety for all applications of nanomaterials in products with potential health, environmental or safety impacts over their life cycle; (ii) 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.

MEPs call 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 and call 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.

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

The Parliament calls specifically on the Commission to evaluate the need to review worker protection legislation concerning inter alia: (a) the use of nanomaterials only in closed systems or in other ways that exclude exposure of workers as long as it is not possible to reliably detect and control exposure; (b) a clear assignment of liability to producers and employers arising from the use of nanomaterials; (c) whether all exposure routes (inhalation, dermal and other) are addressed.

The Commission is called upon to compile before June 2011 an inventory of the different types and uses of nanomaterials on the European market, to make this inventory publicly available and to report on the safety of these nanomaterials.

The Parliament also 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).

Moreover, MEPs stress the need:

- for a major stepping up of the funding of research into the environmental, health and safety aspects of nanomaterials over their life cycle;
- to promote coordination and exchange between Member States on research and development, risk assessment, guidance development and regulation of nanomaterials;
- to propose, as soon as possible, the establishment of a permanent and independent European network 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);
- to launch an EU-wide public debate on nanotechnologies and nanomaterials and on the regulatory aspects of nanomaterials;
- to develop stringent ethical guidelines, particularly for nanomedicine, such as the right to privacy, free and informed consent and the limits set on non-therapeutic human enhancement;
- to pay special attention to the social dimension of the development of nanotechnology by ensuring the active participation of the social partners concerned from the earliest possible stage.

Regulatory aspects of nanomaterials

The Commission presents a Communication on regulatory aspects of nanomaterials, which constitutes the follow-up to the 2008 Commission Communication. It assesses the adequacy and implementation of EU legislation for nanomaterials, indicates follow-up actions and responds to issues raised by the European Parliament, the Council and the European Economic and Social Committee.

This communication is accompanied by a Commission Staff Working Paper on Nanomaterial Types and Uses, including safety aspects which responds to the European Parliaments concern that the Commissions approach to nanomaterials is jeopardised by the lack of information on the use and on the safety of nanomaterials that are already on the market.

Benefits of nanotechnology: the total annual quantity of nanomaterials on the market at the global level is estimated at around 11 million tonnes, with a market value of roughly EUR 20 billion. Carbon black and amorphous silica, which have been on the market for decades, represent by far the largest volume of nanomaterials currently on the market. The group of materials currently attracting most attention are nano-titanium dioxide, nano-zinc oxide, fullerenes, carbon nanotubes and nanosilver. Those materials are marketed in clearly smaller quantities than the traditional nanomaterials, but the use of some of these materials is increasing fast.

Other new nanomaterials and new uses are being developed rapidly. Many are used in innovative applications such as catalysts, electronics, solar panels, batteries and biomedical applications including diagnostics and tumour therapies.

1) The benefits of nanomaterials: these range from saving lives, breakthroughs enabling new applications or reducing the environmental impacts to improving the function of everyday commodity products.

Products underpinned by nanotechnology are forecast to grow from a volume of EUR 200 billion in 2009 to EUR 2 trillion by 2015. These applications will be essential for the competitiveness of a wide area of EU products in the global market. Currently, the direct employment in nanotechnology is estimated at 300 000 to 400 000 jobs in the EU, with an increasing tendency.

Nanotechnology has been identified as a key enabling technology (KET) and the Commission has outlined a single strategy for KETs, built upon three pillars: technological research, product demonstration and competitive manufacturing activities.

In addition to cooperation such as in the OECD or at UN-level, the Commission has started a regular dialogue with the United States in the context of the Transatlantic Economic Council (TEC), with a view to avoiding unnecessary divergences.

2) Definition: Commission Recommendation 2011/696/EU contains the definition of nanomaterials which is intended to be used by Member States, EU agencies and companies. The Commission will use it in EU legislation. Where other definitions are used, provisions will be adapted in order to ensure a consistent approach, although sector specific solutions may remain necessary. The Commission will review this definition in 2014.

3) Safety-related aspects: natural and incidental man-made nanoparticles are ubiquitous in the human environment and their presence and behaviour is generally known and understood. However, limited data exist on manufactured nanoparticles in the workplace and the environment. There are major technical challenges in monitoring their presence, including those pertaining to their small size and low concentration levels and in distinguishing particles of manufactured nanomaterials from natural or incidental nanoparticles. Detecting nanomaterials in complex matrices such as cosmetics, food, waste, soil, water or sludge is even more challenging. While some monitoring methods exist, these often remain to be validated, which hampers comparability of data.

In the light of current knowledge and opinions of the EU Scientific and Advisory Committees and independent risk assessors, nanomaterials are similar to normal chemicals/substances in that some may be toxic and some may not. Possible risks are related to specific nanomaterials and specific uses. Therefore, nanomaterials require a risk assessment, which should be performed on a case-by-case basis, using pertinent information. Current risk assessment methods are applicable, even if work on particular aspects of risk assessment is still required.

Important challenges relate primarily to establishing validated methods and instrumentation for detection, characterisation, and analysis, completing information on hazards of nanomaterials and developing methods to assess exposure to nanomaterials.

4) REACH and CLP: pursuant to the REACH Regulation, chemical substances imported or manufactured in the EU must in most cases be registered with ECHA, demonstrating their safe use. The registration dossier or substance may be subject to evaluation. Depending on its characteristics, any substance may be subject to authorisation or restrictions. REACH applies equally to substances for which all or some forms are nanomaterials.

Regulation (EC) No 1272/2008 (the CLP Regulation) provides an obligation to notify to ECHA substances in the forms as placed on the market, including nanomaterials, which meet the criteria for classification as hazardous, independent of their tonnage.

The European Parliament called on the Commission to evaluate the need to review REACH concerning simplified registration for nanomaterials manufactured or imported below one tonne, consideration of all nanomaterials as new substances, and a chemical safety report with exposure assessment for all registered nanomaterials.

The Commission looks in detail at the assessments conducted, including the chemical safety assessments, as well as at the guidance available and studies planned. It is also taking steps to ensure that remaining implementation gaps in legislation relating, for example to water or industrial emissions - are addressed.

It states that overall it remains convinced that REACH sets the best possible framework for the risk management of nanomaterials when they occur as substances or mixtures but more specific requirements for nanomaterials within the framework have proven necessary.

It will, in the forthcoming REACH review, assess relevant regulatory options, in particular possible amendments of REACH annexes, based on available information on technical progress, including the REACH Implementation Projects on Nanomaterials and experience with the current registrations, in order to ensure clarity on how nanomaterials are addressed and safety demonstrated in registrations.

5) Access to information: lastly, with a view to improving transparency, the Commission will create a web platform with references to all relevant information sources, including registries on a national or sector level, where they exist. A first version mainly based on links to available information will be put on line as soon as possible. The Commission will assist in the elaboration of harmonised data formats, to improve exchange of information. In parallel, it will be launching an impact assessment to identify and develop the most adequate means to increase transparency and ensure regulatory oversight, including an in-depth analysis of the data gathering needs for such purpose. This analysis will include those nanomaterials currently falling outside existing notification, registration or authorisation schemes.

The Commission will follow closely the evolution of the dossier and will present a report to the European Parliament, the Council and the European Economic and Social Committee within a period of three years.