Regulatory aspects of nanomaterials

2008/2208(INI) - 17/06/2008 - Non-legislative basic document

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 standards[30], 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.