



Raising standards for consumers



POSITION PAPER

European Commission proposal for additional measures to increase transparency and ensure regulatory oversight on nanomaterials

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ANEC's answers

1. Problem definition

The members of CARACAL and other stakeholders are invited to comment on this analysis and to provide elements on the following questions, which will be used in the Commission's evaluation of the extent of the problem:

-What existing knowledge indicates a need for more (or less) information for nanomaterials compared to other chemicals? Are there any examples of past cases or incidents where more information could have made a difference in addressing risks?

-What unknown elements could cause particularly serious risks and what is the reasoning for your assessment of the seriousness? What is the likelihood that those effects are likely to occur and what factors influence your assessment of the likelihood?

Consumer organisations like ANEC have long been concerned about the use of hazardous chemicals in consumer products. The current European regulatory framework for consumer products does not ensure a sufficient level of consumers' protection against exposure to dangerous chemicals¹.

For many consumer products including products to which consumers are exposed on a daily basis such as clothes, furniture and child-care articles, there are virtually no chemical requirements in the European legislation - apart from a few restrictions under REACH. Nanomaterial specific provisions including appropriate product declaration and tracking requirements for consumer articles ought to be urgently adopted.

Enforcement cannot be expected to work in absence of clear-cut chemical provisions for products.

-What detail of information is needed for public authorities/policy makers/consumer and environmental organisations to inform their decisions/proposals and how would a new transparency instrument create value added to existing instruments?

Key features:

- Obligatory data provision by manufacturers/importers
- Substances, mixtures and products/articles
- Low threshold (eg: 100gr/user/yr)
- Chemical and toxicological characteristics
- Product database (brand/type)

¹ Updated ANEC position paper "Chemicals in consumer products: The need for a European legislative framework", October 2011 (ANEC-ENV-2011-G-040)

- “nano” or “nanoscale” before or after substance name
- CA number
- size range
- specific surface area
- aspect ratio
- amount (per product)
- other (e.g. free or bound, surface coating, etc.)
- available toxicological data

Added value:

We are concerned about the increasing number of products containing or claiming to contain nanomaterials which are already sold on the EU market without having been subject to a proper safety assessment². It must be ensured that no misleading claims and advertising can be made on the use of nanomaterials.

-In what concrete way could the information generated by a new transparency instrument such as a nanomaterial registry facilitate addressing potential health and environmental risks should they become known? Why do we need traceability? What would be the value-added compared to existing information and tools?

No one (person, organisation, company or authority) has a complete overview of the usage of nanomaterials and nanoparticles in consumer products. It is essential that governments and regulators are able to assess exposure of consumers and the environment coming from nanomaterials to enable them to take an appropriate approach to the management of risk. This need becomes all the more important when there is significant uncertainty over the potential impact of the materials in question. This is certainly the case for nanomaterials for which there are well reported gaps in the knowledge of environmental toxicology, toxicokinetics, and human toxicity³.

In order to develop and implement effective prevention strategies and monitor their impact, the EU needs comprehensive and comparable information on nanomaterials and their uses. The considerable differences that would exist among countries in the absence of harmonised approach in gathering this information could hamper the creation of a level playing-field in Europe for

² ANEC/BEUC inventory of consumer products which claim to contain nanomaterials.

³ Emergnano: A review of completed and near completed environment, health and safety research on nanomaterials and nanotechnology. March 2009.

consumers and businesses alike.

-What information would be needed by consumers to make informed choices? How could a new transparency instrument provide this information? How likely is it that consumers will use this instrument? What would be the advantage compared to other possible tools such as ingredient labelling?

Any claims industry makes about health, safety and/or environmental aspects of products containing nanomaterials should be scientifically substantiated.

In the case of products which contain a list of ingredients on the label (such as food), we call for the name of the ingredient in nano form to be followed by the word 'nano' in brackets in the ingredients' list. For products that do not contain a list of ingredients, the need for labelling should be evaluated on a case-by-case basis taking into account the level of consumer exposure.

In addition, for all categories of products, the presence of nanomaterials should be indicated in the product technical files and/or the safety data sheets. It would allow governments and competent bodies to assess those products which are most likely to be of greatest concern based on current understanding and would allow for proper exposure assessments to be carried out.

2. Objectives

The members of CARACAL and other stakeholders are invited to comment on this approach and to provide any additional objectives that should be analysed to ensure coherence with other EU policies and strategies, Fundamental Rights or other policy priorities.

The European Commission 2nd Regulatory Review on nanomaterials points out that the applicable legislation must ensure a high level of health, safety and environmental protection and mentions that in this context, transparency of information on nanomaterials and products containing nanomaterials is essential⁴.

The precautionary principle is detailed in Article 191 of the TFEU. It aims at ensuring a higher level of environmental protection through preventative decision-taking in the case of risk. It also covers consumer policy, food and human, animal and plant health. The precautionary principle may be invoked when a phenomenon, product or process may have a dangerous effect, identified by a scientific and objective evaluation, if this evaluation does not allow the risk to be determined with sufficient certainty. For this reason, the precautionary principle has been incorporated in the General Product Safety Directive⁵.

⁴ Article 38, Charter of Fundamental Rights of the European Union (2007/C 303/01), Article 114.3, Treaty on the functioning of the European Union (TFEU, 2007)

⁵ Directive 2001/95/EC, article 8.2.

3. Development of main policy options

The members of CARACAL and other stakeholders are invited to comment on this approach and to suggest any additional options or sub-options that should be taken into account.

In some Member States (e.g. in the UK), voluntary reporting schemes calling on industry to volunteer information on the use of nanomaterials have been established but have not been very successful⁶. We therefore call on the introduction of a mandatory notification of all nanomaterials which are used in products - whatever the nature of the product - before products can be placed on the market and for those products already on the market.

National compulsory declaration measures have been taken in France and are examined in Italy, Belgium and the Netherlands. There is a risk of market fragmentation, harmonization is needed at EU and international levels.

⁶ The UK scheme received only 12 submissions in 2 years.

About ANEC

ANEC is the European consumer voice in standardisation, defending consumer interests in the processes of technical standardisation and conformity assessment, as well as related legislation and public policies.

ANEC was established in 1995 as an international non-profit association under Belgian law and is open to the representation of national consumer organisations in 33 countries.

ANEC is funded by the European Union and EFTA, with national consumer organisations contributing in kind. Its Secretariat is based in Brussels.



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