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Committee on the Environment, Public Health and Food Safety
The Chairman

IPOL-COM-ENVI D (2013) 36547

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Mr Antonio TAJANI
Vice-President of the European Commission
Commissioner Janez POTOČNIK
Commissioner Tonio BORG
Commissioner Neven MIMICA
Commissioner Máire GEOGHEGAN-QUINN
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Dear Vice-President,
dear Commissioners,

In consultation with the Coordinators of the Committee on the Environment, Public Health and Food Safety, I would like to bring to your attention the following comments regarding the Commission Communication of 3 October 2012 entitled "Second Regulatory Review on Nanomaterials" (COM(2012) 572).

This second review is to be considered as the follow-up of the 2008 Commission Communication on regulatory aspects of nanomaterials and to the calls the European Parliament had subsequently made in its resolution on Regulatory Aspects of Nanomaterials of 24 April 2009 (2008/2208(INI)).

Parliament was then convinced that the benefits of nanomaterials should be realised in a safe and responsible manner within a clear regulatory and policy framework which should address both existing as well as expected applications and their potential health, environmental and safety impacts. Parliament was at the same time concerned about a significant lack of knowledge and information about nanomaterials. In particular, it disagreed with the notion of the Commission that improving the implementation of existing legislation alone could adequately address safety-concerns relating to nanomaterials as long as there is (i) a lack of knowledge and information on their use and safety and (ii) a lack of specific provisions on nanomaterials in Union legislation.

Against this backdrop, Parliament called for a review of all relevant legislation within two years, in order to ensure safety for all applications of nanomaterials of concern over their life-cycle, and for implementing the principle of "no data, no market" for nanomaterials.

In the meantime, specific provisions on nanomaterials have been introduced in topical Union legislation, notably owing to Parliament's initiative in the course of more general revisions (including food information, cosmetic products, biocidal products, waste electrical and electronic equipment and restriction of the use of certain hazardous substances in electrical and electronic equipment), or have been considered in this regard. The respective amendments demonstrate Parliament's continued commitment to its conclusions of 2009 and underscore the need for specifically addressing nanomaterials in relevant Union legal acts themselves.

The Committee trusts that nanomaterials specific provisions will be further integrated into relevant Union legislation, including the current revision of the Directive on medical devices. The Commission Recommendation on the definition of nanomaterial should serve as a useful basis for a coherent approach to the definition. In addition, it continues to be important to ensure that legislative provisions and instruments of implementation fully reflect the particular features of nanomaterials (which may differ significantly from one nanoform to another, depending on parameters such as size, surface functionalization etc.) to which workers, consumers and/or the environment may be exposed. The Committee also notes that existing measurement methods for determining (number-weighted) size distributions have limitations and that no single measure can cover all nanomaterials, and therefore appreciates ongoing efforts to develop standardised and certified measurement techniques for all nanomaterials.

REACH is the central piece of chemicals regulation in the EU, yet it has contributed to only very limited information on nanomaterials and their regulatory control so far. As the review and the corresponding study by the JRC point out, rather few nanomaterials have been registered at all and the respective registrations lack adequate data needed to assess risks. Only little information is specifically addressing safe use of the specific nanomaterials. Moreover, most of the substances registered under REACH which have nanoforms have not been classified by registrants for any hazardous endpoint and there is a general lack of exposure data.

The Commission plans to approach these shortcomings in REACH registrations by adapting Annexes of the Regulation and developing improved guidance. While modifications of the Annexes to specify clear and relevant requirements for all nanomaterials falling under REACH are most welcome, it is also clear that more fundamental limitations of REACH should be addressed in order to address nanomaterials explicitly: due to the threshold of 1 tonne/year, certain nanomaterials will remain out of the scope of registration; without a definition of nanomaterials within REACH, legal requirements for such materials remain open to interpretation; present registration deadlines and volume thresholds for data requirements are inadequate for nanomaterials; exposure information will continue to be lacking, as an exposure assessment is obligatory only if a substance is registered for above 10 tonnes/year *and* classified as dangerous.

These limitations are problematic as they may prevent REACH from generating information on the actual and specific risks for many nanomaterials. The Commission in fact states that the considerable lack of data on exposure has been hindering the establishment of specific provisions and risk management responses for nanomaterials in EU environmental legislation (such as to environmental quality standards, emission limits, waste treatment). At the same time, it considers that potential risks are best addressed 'upstream' by REACH and product legislation. Clearly, adaptations to REACH Annexes alone seem insufficient to ensure that the relevant data are acquired systematically. The Commission should consider to propose specific legislation aimed at complementing REACH in relation to nanomaterials.

Parliament had also called for the compilation of an inventory, by June 2011, of the different types and uses of nanomaterials on the European market in order to provide reliable information on their use, including in consumer products, and to make this inventory publicly available. The Committee is not satisfied that an EU-wide inventory on consumer products using nanomaterials has still not been created. The lack of information has led to national inventories being established or discussed in the meantime in a number of Member States, inter alia to address the traceability of nanomaterials.

Nonetheless, the Committee appreciates the information on the use of nanomaterials, including health and safety aspects, compiled in the staff working paper accompanying the Communication. While the commitment of the Commission to create a web platform to link to all relevant existing information sources is a step in the right direction, the fact that existing reporting schemes and databases are incomplete and lacking clarity and quality control is however an unsettling weakness. To reduce information deficits in the planned web platform, the Commission should ensure that all references are based on harmonized notification requirements and quality standards (e.g. along the lines of regulatory provisions introduced by Parliaments in cosmetics and food legislation).

In any case, the planned web platform, even if set up properly and promptly, cannot overcome deficits in existing information and can thus not replace the inventory that has been called for. An inventory at EU level would be by far preferable over separate inventories in Member States for regulators and the general public as well as industry. The Committee therefore welcomes that the Commission committed, albeit late, to make an impact assessment on measures to increase transparency and ensure regulatory oversight, including nanomaterials currently falling outside existing regulatory schemes, and urges the Commission to complete it without further delay as the basis for possible further action.

In order to improve transparency for consumers and traceability of nanomaterials, Parliament had called for the clear labelling of all ingredients present in the form of nanomaterials in substances, mixtures or articles. While on the initiative of Parliament, requirements for the labelling of nano-ingredients have been introduced to a certain extent for food, cosmetic and biocidal products, the Commission only envisages similar provisions for other regulatory schemes where ingredient labelling already exists. However, in the absence of concrete proposals, it should be noted that for articles, regulatory schemes for *ingredient* labelling currently do not exist. Information provided on nanomaterials used therefore remains random or incomplete, if it is provided at all. The Committee considers it important that the issue of a more comprehensive labelling of nano-ingredients in articles is actively pursued further by the Commission, taking into account information to be acquired, for instance, through the web platform on the use of nanomaterials.

In summary, while the Commission has reviewed Union legislation on nanomaterials for a second time following the resolution of the European Parliament from April 2009, the concerns of Parliament remain topical. The Committee therefore reiterates its call on the Commission to proactively address nano-specific regulatory issues throughout all Union legislation relevant for applications of nanomaterials with potential health, environmental or safety impacts over their life-cycle. Importantly, this is echoed by the requirements just adopted by the co-legislators in the 7th Environment Action Programme "*to develop by 2018 an EU strategy for a non-toxic environment ... building on horizontal measures to be undertaken by 2015 to ensure: 1) the safety of manufactured nanomaterials and materials with similar properties ...*" The Commission should in particular, in addition to improving the implementation of REACH, initiate complementary legislation to overcome intrinsic limitations of the REACH regime with regard to nanomaterials. Furthermore, the Commission should ensure that proper information on the use of nanomaterials becomes available to regulators as well as the public in the form of an up-to-date inventory as soon as possible. Finally, the Commission should undertake initiatives to achieve a comprehensive labelling of nanomaterials in products, including articles.

Yours sincerely,

M. Groote

Matthias GROOTE

Draft letter on 2nd regulatory review of nanomaterials

BACKGROUND

- **ENVI Coordinators meeting on 6 November 2012**

A.12. Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee Second Regulatory Review on Nanomaterials
COM(2012)0572
Responsibl ENVI –
e:
Opinions: EMPL, ITRE, IMCO, JURI
[MF]

Decision: **Letter from Chair to Commission to be prepared jointly by representatives to be appointed by the political groups. (The groups were asked to indicate each one person responsible.)**

- **Draft letter by secretariat circulated to/ finalized with political group staff**

1. technical meeting 27.6.2013	2. technical meeting 4.7.2013
ALDE - Bargum Greens - Singhofen ECR - Wilson	S&D - Dimitrakoudi ALDE - Bargum Greens - Singhofen ECR - Geier

- **<u>Final draft letter</u> circulated to groups for approval by coordinator - 11.7.2013**

support expressed for	**opposition expressed for**
EPP - Richard Seeber **S&D - Linda McAvan** **ALDE - Chris Davies** **Greens/EFA - Satu Hassi** **GUE/NGL - Kartika Liotard**	**ECR - Julie Girling**
	EFD without feedback