CONSULTATION RESPONSE

AmCham EU response to the public consultation on the impact assessment on possible measures to increase transparency on nanomaterials

AmCham EU calls for an impact assessment on the transparency measures for nanomaterials adopting the existing harmonised reporting and communication mechanisms as a baseline option

Executive summary

AmCham EU welcomes the opportunity to provide comments on the impact assessment for possible measures to increase transparency on Nanomaterials on the market. Although AmCham EU supports appropriate regulation of chemicals, including nanomaterials, it is concerned that the establishment of a registry will create more confusion for the public. We therefore request that the impact assessment include, as a real baseline option, a scenario that utilises existing reporting and communication mechanisms rather than registries. If the EU nevertheless proceeds to develop a registry, the EU should first adopt a uniform definition of nanomaterials.

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AmCham EU speaks for American companies committed to Europe on trade, investment and competitiveness issues. It aims to ensure a growth-orientated business and investment climate in Europe. AmCham EU facilitates the resolution of transatlantic issues that impact business and plays a role in creating better understanding of EU and US positions on business matters. Aggregate US investment in Europe totalled €2 trillion in 2013 and directly supports more than 4.3 million jobs in Europe.

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AmCham EU welcomes the opportunity to provide comments related to the impact assessment on possible measures to increase transparency on Nanomaterials on the market. As explained below, AmCham EU questions the utility and value of any registration system and particularly is of the opinion that a registration system should not be developed until the EU has adopted a uniform, workable definition of engineered nanomaterials.

It appears that the sole purpose of a registry is to indicate that a nanomaterial is present in a product. The registry will neither provide information on hazards and risks that might be associated with a nanomaterial, nor risk management options. That information is already subject to production and communication under other laws. As the draft impact assessment notes:

> *In particular, this impact assessment will not directly address the question whether and how risk assessment and risk management of nanomaterials can be improved, as this is part of the ongoing revision of the REACH Annexes. Measures to increase knowledge on nanomaterials on the market will not generate new information on potential hazards of nanomaterials.*

The draft impact assessment does offer some suggestions for how information on the presence of a nanomaterial in a product might prove useful:

> *Nevertheless, information on the presence of nanomaterials on the market may generate information on possible sources of exposure to nanomaterials. This may allow for a better assessment of where exposure and risks potentially occur in the workplace, during distribution and consumption, and at the end of life stage. Furthermore, such information may be used for setting enforcement priorities or for enhancing risk assessment. Moreover, information that would make nanomaterials traceable on the market could be used in case of acute incidents requiring the withdrawal of products containing those nanomaterials.*

There is no reason to believe that information on possible sources of exposure cannot be derived from existing reporting and communication mechanisms. Given that the information needed to assess and address any risks presented by nanomaterials will not be included in the registry, and already is provided to the authorities and consumers by other means, there is no need to, or value in, establishing a registry.

<u>The Baseline Policy Option:</u>

The policy options under consideration are the following:

0. Baseline scenario - not do anything
1. Recommendation on how to implement a "best practice model" for Member States wishing to establish a national system *(soft law approach)*
2. Structured approach to collect information *("Nanomaterials Observatory")*

3. Regulation creating an EU nanomaterial registry with one annual registration per substance for each manufacturer/importer/downstream user/distributor
4. Regulation creating an EU nanomaterial registry with one annual registration per use (including substances, mixtures and articles with intended release)

France has already established a mandatory reporting scheme for manufactured nanomaterials produced, imported or distributed in its territory[1] and Belgium and Denmark have notified draft legislation for national registries to the European Commission. Therefore the Baseline scenario was proposed for these countries that have already established measures. The Baseline scenario has also incorporated existing reporting schemes, such as the requirements under the Cosmetics Regulation (EC) No 1223/2009 for placing cosmetic products containing nanomaterials on the EU market, to submit information on the nanomaterial(s) through the Cosmetic Product Notification Portal[2]. As explained above, it is unlikely that any registry will communicate accurate information about engineered nanomaterials to the public without being misleading. Hence, the Impact Assessment should also include, as a real Baseline option, a scenario that relies solely on existing reporting and communication mechanisms rather than registries (e.g. Safety Data Sheets; labels).

Definition of Nanomaterials

AmCham EU has already expressed its view that an EU definition should only cover specifically engineered nanomaterials, rather than any naturally occurring or incidentally manufactured particles already present in our environment and in our products for a long time with a long history of safe use. Hence, we were pleased to see that the present consultation has only requested views considering "manufactured nanomaterials"; even though the impact assessment has invited stakeholders to use the definition of nanomaterials as recommended by the Commission in its document 2011/696/EU[3].

This discrepancy shows that first and foremost the definition of nanomaterials needs to be revised and agreed upon at EU level, before any regulations are established. As highlighted already in AmCham EU's response to the Commission's Public Consultation on proposed options related to the REACH Annexes on Nanomaterials, we very much agree that the definition is a key element of the EU's core strategy for regulating nanomaterials. We therefore support the potential revision of the definition, to provide legal certainty. This would help increase Europe's ability to harness the full potential of nanotechnology in all sectors of its application, while enabling adequate human health and environmental safety protection.

On that basis, we support the present approach of the Commission to only cover nanomaterials which are engineered intentionally.

1 The Interministerial decree No. 2012-232 entered into force in January 2013 (www.r-nano.fr)
2 http://ec.europa.eu/consumers/sectors/cosmetics/cpnp/
3 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:275:0038:0040:EN:PDF