

12 September 2013

AmCham EU's response to the Commission's Public consultation relating to the REACH Annexes on Nanomaterials

The American Chamber of Commerce to the European Union (AmCham EU) welcomes the opportunity to participate in the public consultation relating to the REACH Annexes on nanomaterials and is pleased to submit its combined responses integrating the position of its contributing members. As highlighted already in our response to the Commission's Second Regulatory Review on Nanomaterials, we agree with the regulatory review's conclusion that nanomaterials, as a specific physical form of chemical substances can be addressed by REACH, using the chemical regulation's inclusive, risk based and substance specific approach. We concur with the Commission's position that 'REACH sets the best possible framework for the risk management of nanomaterials when they occur as substances or mixtures'.

As industry actors who take REACH compliance seriously, we are eager to actively participate in this consultation and provide our input in the attached questionnaire.

We understand that the questionnaire collects input concerning the technical aspects related to nanomaterials, in order to identify potential further data requirements to improve the efficiency of the regulatory process for nanomaterials under REACH. This approach calls for striking a balance between additional hurdles such as cost, time and increased administrative burdens that could hinder competitiveness and real benefits measured in improved safety and consumer confidence. On that basis:

- We emphasise that information requested for registration purposes under REACH should not be used as an opportunity to gather further data at a high cost just for the sake of academic interest;

American Chamber of Commerce to the European Union
Avenue des Arts/Kunstlaan 53, 1000 Brussels, Belgium
Telephone 32-2-513 68 92 Fax 32-2-513 79 28
Email: info@amchameu.eu

Secretariat Point of Contact: Julie Linde Kjeldsen ; jlk@amchameu.eu +32 2 289 1015



AmCham EU Position on Endocrine disruption

page 2 of 3

- We believe that data requirements should always be supported by validated and accessible measurement techniques that are proven to deliver unambiguous results;
- We believe that hazard considerations should not lead the way in a risk based framework and the exposure to primary nano particles should be the basis for any additional data requirements; and
- We believe the request for further information should be properly substantiated and the most effective policy measures should be implemented, taking into account the principles of proportionality and the need to establish a regulatory framework that will not stifle innovation and industrial competitiveness of Europe.

We are actively supporting the suitable regulation of nanomaterials that are developed to exhibit novel characteristics, such as improved physical or chemical properties compared to the same material without nanoscale features. These nanomaterials are specifically engineered for these functions and we recommend that different data requirements should only be targeting these new forms of substances, rather than those that have already been manufactured in this form for decades and fall under the scope of definition of nanomaterials, as provided in the Commission's Recommendation on the definition of nanomaterial, published on 18 October 2011.

While the consultation recommends five options in addition to the baseline option (Option 1; the current requirements), we believe that the most efficient option would contain a combination of elements from the different options suggested. The selection of these elements could be based on the outcome of this consultation, identifying under each option the measures with the highest average efficiency scores. For certain elements, the baseline measures (i.e. the present status quo) may be sufficient, while for others the most suitable measures can be selected on the basis of their optimum cost/benefit ratios. Hence, in our responses, we have considered Option 5 as the most efficient among the suggested options, particularly because it:

1. Has an exposure based approach;
2. Contains uses of reasonable filters and exclusion criteria before requesting further data;
3. Builds on available information;
4. Considers aggregates as bulk particles; and

AmCham EU Position on Endocrine disruption

page 3 of 3

5. Provides a pragmatic approach to the handling of coated nanomaterials.

However, we submit that even this option contains elements that we do not believe would significantly improve the overall efficiency of the regulation of nanomaterials, such as for instance including no specific obligations for nanoforms in the 10-100 tonnage band. In contrast, certain measures under some of the other options seem to provide relevant efficiencies, and we recommend making use of these these measures in the final combined option. Examples can be provided upon the detailed review of our responses to the questionnaire.

We would also highlight the need for regulatory convergence surrounding nanomaterials in the EU and the US to facilitate transatlantic trade and collaboration in the field of this highly important enabling technology. We recommend the EU share its proposed regulatory changes with its US counterparts in the context of the Transatlantic Trade and Investment Partnership (TTIP) to arrive at mutually reinforcing regulatory efforts in this domain.

Finally, we also highlight that some of the data requested by these options could be considered highly confidential, hence the protection of the submitted information must be safeguarded.

We thank you again for the opportunity to contribute to this very important debate.

Anna Gergely
Chair of the Nanomaterials Working Group
American Chamber of Commerce to the EU

* * *

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 €1.9 trillion in 2012 and directly supports more than 4.2 million jobs in Europe.

* * *