September 2013

AmCham EU response to the JRC survey on experiences made during the implementation of the EC recommendation of a definition of nanomaterial

The American Chamber of Commerce to the European Union (AmCham EU) welcomes the opportunity to participate in the JRC survey relating to the recommended EU definition of nanomaterial (2011/696/EU). This recommendation is due to be reviewed by December 2014 in light of stakeholder experience with its implementation and recent scientific and technological developments. As highlighted already in our response to the Commission's public consultation on proposed options related to the REACH annexes on nanomaterials (submitted to the Commission in September 2013[1]), we agree that the definition is a key element of the EU's core strategy for regulating nanomaterials. While changing such a key element just three years after its introduction as a reference for legislative and policy purposes may be less than ideal, we nevertheless hope that our suggested revisions to the definition will improve the alignment of Europe's approach to defining and regulating nanomaterials with the rest of the world.

As already highlighted in previous AmCham EU positions on a regulatory approach for nanomaterials, the EU criteria and definition should be aligned with any other definition at international level, specifically those developed and published through the International Organization for Standardization (ISO TC229). As such, we recommend that the term 'nanomaterial' in a revised EU recommended definition refer to nano-objects (as defined by ISO) which, as defined, comprises reference terms of nanoparticle, nanofibre (nanowire, nanotube and nanorod) and nanoplate, wherein one, two or three external dimensions are in the nanoscale (size range from 1 nanometre to 100 nanometres in any dimension).

Furthermore, we provide here as reference conclusions reached at the 8 March 2013 ISO TC229 meeting in Querétaro, Mexico, where the following resolution was unanimously ratified:

> ISO/TC 229 resolves to encourage its members to communicate with stakeholders, including governmental authorities, who have an interest in nanotechnology, about the value of using the output of the work of TC229 in their activities, including the benefit of harmonized and consistent approaches to address the development and use of nanotechnology.

[1] Final CP on REACH Annexes on Nanomaterials

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Indeed, we believe that the present Commission nanomaterial definition leaves room for improvement. It expresses today (in some respects similarly to ISO) the scope to be that of all "nanoparticles" (where "particles" is defined as '*…a minute piece of matter with defined physical boundaries*' and where number size distribution considerations are for where one or more external dimensions of such particles are in the size range 1 nm-100nm), whether they are occurring naturally, are formed incidentally or manufactured intentionally. While we agree that, from a safety point of view, the impact of any nanomaterial can be relevant to the safety of human health or the environment, we believe that for a definition that serves a regulatory purpose, the current definition, goes far beyond a reasonably identifiable and manageable scope, which we understand is meant to focus and control nanomaterials produced for commercial purposes.

As also emphasised in our response to the Commission consultation on the REACH annexes on nanomaterials, we active support the suitable regulation of nanomaterials, which are typically engineered or manufactured to exhibit novel characteristics, such as improved physical, chemical or biological properties, when compared to the same material without nanoscale features. With this understanding, we believe that a revised definition should only cover specifically engineered and/or manufactured forms of materials/substances at the nanoscale (as defined), as those that may occur naturally or be incidentally created and not enter a commercial supply chain are not relevant here.

Secondly, while some progress has been made in establishing reliable test methods for certain forms of nanomaterials, no broad-based/commercially viable laboratory sector currently exists to support creation of results under methods that are truly reliable in support of safety characterizations, and equally that offer a reasonable level of legal certainty. Certain industry and educational institutions have some internal capabilities, but those are not typically made available for broad-based commercial access across the globe and are often not used for such purposes. To avoid the definition of nano being open to debate and interpretation, standardised measurements, characterisation and metrology are necessary. We welcome the ISO efforts to develop standards for measurements, characterisation and test methods for nanotechnologies, which take into consideration needs for metrology and reference materials.

Thirdly, there is ambiguity in the use of the terms 'aggregate' and 'agglomerate'. ISO has devised more complete and scientifically calculable definitions for these two terms that we recommended including in any revised EU definition. These terms are better suited for use in any continuing dialogue around what should (and should not) be covered by a revised EU definition for nanomaterial. In this instance, it is plausible that certain aggregates (as defined by ISO) that are bound in certain ways, in which it is known or can be proven beyond a reasonable doubt to be 'inseparably connected' under any condition, should not be included in a revised EU definition.

Therefore, we strongly support and encourage JRC to gather further experiences and views from the regulated community beyond the current survey to further refine and increase the usability of an EU definition for nanomaterials. We

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believe that these recommendations to improve the definition would result in less ambiguity, improve the framework to interpret facts around nanomaterials and better align with published international standards and perspectives of other jurisdictions. This, we expect, would then increase the competitiveness of the EU nanotechnology and materials sector.

Lastly, we also stress, that even such an improved definition should not be made legally binding before there is a significant improvement and clear guidance for the regulated community on matters such as:

- Sample preparation and sampling in general;
- For individual or complex materials, reliable methods and capabilities in determining particle size measurements and distributions, and other characteristics which may impact safety; and
- Interpretation of results serving both safety and legal certainty.

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

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

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

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