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AmCham EU position on the European Commission draft recommendation on the definition of the term ‘nanomaterial’

The American Chamber of Commerce to the European Union (AmCham EU) believes in innovation as a driver for social, technical and economic progress in line with the Europe 2020 strategy. Against this backdrop, AmCham EU is asking for adequate regulation of nanotechnologies, which first requires a clear common internationally agreed-upon definition and accordingly would like to provide the following comments concerning the Commission draft recommendation on the definition of the term ‘nanomaterial’.

AmCham EU supports the harmonisation of the definition of nanomaterials with international standards

AmCham EU agrees with the Commission’s position that nanomaterials are subject to the same legal requirements as bulk materials, hence their uses are governed by existing legislation. However, for the sake of clarity and in the interest of implementation of a safe and responsible approach to their regulation, AmCham EU supports the development of a regulatory definition of nanomaterials which will be used in EU policies and legislation and contribute to increased legal certainty.

However, in light of the global nature of the development and use of nanotechnologies, we strongly support definitions that are being developed by the International Organization for Standardization (ISO). We believe that the considerations for a definition developed under the ISO process will ultimately reflect the deliberations of many of the world’s foremost experts in nanosciences and nanotechnologies (with input from academia, government and industry) and therefore represent the most comprehensive understanding of technical expertise, accomplished through a long-standing and transparent process established by international collaborations.

In our view, ensuring the consistency of definitions with an international standard is necessary to support regulation in today’s global marketplace. Hence, the development of the definition of nanomaterials at the EU level should be integrated into international initiatives, especially through the ISO. We appreciate the Commission’s intention to regularly review and, if necessary, amend the proposed definition considering new experience, scientific knowledge and technological development, but not taking into account the

AmCham EU position on the European draft Commission Recommendation on the definition of the term “nanomaterial” Page 2 of 3

recently published definition and approach by ISO¹ and the on-going work taking place within ISO and the OECD’s Working Party on Nanotechnology, is in AmCham EU’s view a missed opportunity that could lead to a premature regulatory approach which is inconsistent with (preliminary) international standards.

AmCham EU supports a definition of ‘particulate nanomaterials’

AmCham EU is of the opinion that the JRC Reference Report of 2 July 2010, ‘Considerations on a definition of nanomaterial for regulatory purposes’² is more in line with the ISO approach. In agreement with the JRC report, AmCham EU’s opinion is that the subject of nanomaterial regulation should be intentionally manufactured nano-objects and their agglomerates, since nano-specific health and environmental effects are more likely to occur with free, unbound particles than materials with an internal nanostructure, and the proposed definition should highlight these important differences. The JRC Report defines these materials as ‘particulate nanomaterials’. Accordingly, the term ‘particulate nanomaterial’ needs to be introduced in the Commission proposal for a definition in order to clearly distinguish intentionally manufactured nano-structured materials from other types of nanomaterials.

AmCham EU supports a workable and technically enforceable definition

The draft overarching definition is proposed to be used together with case by case specific criteria established in the framework of specific legislation. AmCham EU is of the opinion that such an approach would not efficiently meet the objectives of managing potential health, safety and environmental risks related to nanomaterials or ensure their safe, responsible use.

We support a definition which is readily applicable and technically enforceable. On that basis, while we support the size range of 1-100 nm as representative, we do not believe that the criteria about number size distribution percentage and surface area by volume are objectively workable until there is a final and comprehensive international scientific agreement on measurement techniques for nanomaterials.

Present manufacturing controls are not sufficient to ensure that the distribution of nanomaterials in a product is consistent from batch to batch. Therefore, measurement techniques and sampling protocols must be developed in cooperation with ISO in order to ensure that an EU definition would serve its purpose in an efficient and balanced manner. On that basis, instead of number size particle distribution, AmCham EU considers a standards approach based on

¹ See ISO TS 80004-1 Nanotechnologies – Vocabulary – Part 1: Core Terms and ISO/TS 27687:2008 Nanotechnologies – Terminology and definitions for nano-objects- nanoparticle, nanofibre and nanoplate

² JRC Reference Report ‘Considerations on a Definition of Nanomaterial for Regulatory Purpose’, 2010

AmCham EU position on the European draft Commission Recommendation on the definition of the term “nanomaterial” Page 3 of 3

weight distribution more feasible, provided that the scientific community represented by ISO does agree on a measurement methodology.

AmCham EU supports restricting the scope of the definition to intentionally engineered nanomaterials

AmCham EU considers that the condition for the definition based on dimensions of ‘internal and surface structures in the size range of 1-100 nm’ is unworkable as it will include virtually all solid materials. Most materials will have nanoscale texture on the surface which could be the result of natural forces or manufacturing, but without any intention to create ‘nano’ structures.

Including materials with internal structures in the 1-100 nm range would include many materials and alloys that have segregated phases, such as steel or other metals. It would also define integrated circuits that have nanometer scale devices and nanoporous materials which are solid and would pose no risk to the environment or to humans. AmCham EU is of the opinion that specifically restricting the definition to intentionally engineered nanomaterials is necessary to resolve this problem.

AmCham EU would like to emphasise that unless the approach concerning a regulatory definition of ‘nanomaterial’ is developed carefully and on a harmonised scientific basis, it may give rise to a disproportionate economic burden for verification of the nano-character of materials and may also complicate the practical dimension linked to such a regulatory definition. In our view only harmonised standards and harmonised governmental approaches reduce bureaucracy and complexity, fostering rational, consistent and reasonable regulation, and allowing industry to focus on innovation, production and economic growth.

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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 €1.2 trillion in 2008 and currently supports 4.8 million direct jobs in Europe.

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