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# AmCham EU agrees with Commission that REACH is the framework to regulate Nanomaterials

## Introduction

The American Chamber of Commerce to the European Union (AmCham EU) welcomes the European Commission's Second Regulatory Review on Nanomaterials (COM(2012) 572).<sup>1</sup> Nanomaterials and nanotechnologies have rightly been identified on both sides of the Atlantic as having huge economic potential. We are pleased that the Commission agrees, and aims to get the regulatory approach surrounding nanomaterials right. We welcome the review's conclusion that nanomaterials should be addressed under REACH using the regulation's tried and tested substance-by-substance approach.

We understand the next step in the debate will take place during the REACH review, and as industry actors who take compliance with REACH seriously, we are eager to be active participants in this debate.

However, we would like the Commission to take a strong line with Member States who try to bypass the science-based approach embodied by REACH, by moving forward independently. This approach is not only potentially contrary to the Single Market principles underlying the REACH Regulation, it is also counterproductive to the EU<sup>2</sup> and Member State governments' growth agenda by creating a climate of legal and regulatory uncertainty surrounding very promising new technologies, as well as existing technologies and products that have been using nanomaterials safely for decades.

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<sup>1</sup> [http://ec.europa.eu/nanotechnology/pdf/second\\_regulatory\\_review\\_on\\_nanomaterials\\_-\\_com\(2012\)\\_572.pdf](http://ec.europa.eu/nanotechnology/pdf/second_regulatory_review_on_nanomaterials_-_com(2012)_572.pdf)

<sup>2</sup> Nanotechnologies have been identified as key enabling technologies in the Commission communication 'Preparing for our future: Developing a common strategy for key enabling technologies in the EU',

[http://ec.europa.eu/enterprise/sectors/ict/files/communication\\_key\\_enabling\\_technologies\\_sec125\\_7\\_en.pdf](http://ec.europa.eu/enterprise/sectors/ict/files/communication_key_enabling_technologies_sec125_7_en.pdf)

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## **A coherent and consistent EU approach**

Much of the innovation on nanotechnologies is taking place in the US and AmCham EU member companies are well placed to share lessons from recent development there. We encourage as much regulatory convergence as possible between the US and EU in order to avoid regulations developed in isolation on either side of the Atlantic that could limit transatlantic trade and R&D collaboration. We ask the Commission to continue its ongoing dialogue with US officials on nanomaterials in the context of Transatlantic Economic Council (TEC) discussions, and to ensure that regulatory efforts in the EU take into account international efforts, such as those led in ISO and the OECD. With this in mind, AmCham EU is disappointed to see the emergence of national initiatives in this field, creating a fragmented regulatory framework.

Some Member State authorities criticise the REACH process for being too slow and seek to move on their own for political, rather than risk management, reasons. This leads to a climate where hazard considerations outweigh scientific risk assessment. This trend is very worrisome for industry, particularly in the field of nanomaterials, where there is significant R&D investment..

Rushed national decisions are not compatible with the medium to long-term R&D and deployment efforts made by industry. These national initiatives send the message that nanomaterials may not be welcome on the EU market. REACH, with its risk assessment approach, should be the framework where these scientific debates take place.

## **Transparency and confidential information**

AmCham EU takes note of the Commission's approach to have a web based information system that brings together published information on nanomaterials, such as the information provided in REACH registration dossiers or sectoral legislation. AmCham EU members share the Commission's view that 'current knowledge about nanomaterials does not suggest risks which would require information about all products in which nanomaterials are used'<sup>3</sup>. Information needs have to be assessed and demonstrated before any targeted information system is implemented. AmCham EU members therefore strongly support the Commission decision to launch an impact assessment to identify if an information gap exists. This approach will guarantee that the potential need for information is properly defined, and that the most cost-effective policy measures are implemented while taking into account the proportionality principle.

Problems of confidential information also need to be considered in this assessment. In the case of the French registry (NOR: DEVP1227946A)<sup>4</sup> for example, a number of our members have raised concern over the protection of the data that has to be reported as of 2013.

<sup>3</sup> European Commission's Second Regulatory Review on Nanomaterials (COM(2012), p 10

<sup>4</sup> [http://www.ineris.fr/aida/consultation\\_document/3379/version\\_pdf](http://www.ineris.fr/aida/consultation_document/3379/version_pdf)

## The need for legal certainty

Industry is apprehensive about the Commission's pledge to review its definition of nanomaterial in 2014, before it has even released the third regulatory review. While the definition needs work, and should eventually be aligned with a workable international definition, doing a review in 2014 may be premature. By 2014, industry will only just have gone through the second REACH registration period (starting in 2013.) For the first registration phase, industry had no recommended definition to rely on. The second registration phase will therefore be a learning exercise. Changing the definition before any lessons can be drawn from the registration process seems counterproductive.

AmCham EU agrees with the Commission's assessment that the definition of nanomaterial should be applied on a sector-by-sector basis. However, the Commission's recommendation for a definition of 'nanomaterial' should be the framework in which sector specific definitions fit and we would like to avoid standalone definitions in each sector. Therefore, we would like upcoming Commission and European Chemical Agency (ECHA) guidance to clarify that definition in sector-specific legislation should not go beyond the scope of the Commission's recommended definition.

We understand the Commission's pledge to update sectoral legislation and Best Available Techniques (BAT) reference documents (BREFs) to take into account developments and innovation in the field of nanotechnology. However, we ask that the Commission take into account consistency across various sectoral regulations and guidelines in so doing. These updates should be based on experience with the current framework, and lead to a measurable output.

## Conclusion

AmCham EU welcomes the regulatory approach proposed by the Commission in the second regulatory review on nanomaterials. We agree that REACH and its substance-by-substance risk assessment approach is the right way to address nanomaterials. We therefore welcome the Commission's REACH Review, and look forward to being a partner in the upcoming discussions on how best to include nanomaterials under the REACH framework in a way that is consistent with risk management and our companies' commitment to health and environmental protection.

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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 U.S. investment in Europe totaled €1.7 trillion in 2010 and directly supports more than 4.2 million jobs in Europe.*

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