

23 September 2015

NIA Opinion on the **Regulation on Novel Foods 2013/045(COD)**

After reviewing the draft European legislation updating the ‘Regulation on Novel Foods 2013/045(COD)’, it has become clear to the Nanotechnology Industries Association and within the nanotech supply chain that the proposed changes are unworkable. It is vague, unclear and contradicts firmly established nanomaterial regulations that have been effectively used by European institutions for years. Implementing it will create new, unnecessary challenges for SMEs, the drivers of economic growth, aiming to use nanotechnology to improve the daily lives of Europeans.

To include materials that are “composed of discrete functional parts...which have one or more dimensions of the order of 100 nm or less” fundamentally changes the accepted definition of engineered nanomaterials and risks countless products being caught in disproportional regulation. The term “discrete functional parts” adds further complexity as it has little scientific basis, opening it up to a wide range of interpretation when put into practice. This will drive innovators to avoid any products that could possibly be caught in this broad, unclear definition and, ultimately, consumers will miss out on the benefits.

Innovators that can overcome this uncertainty and continue to utilize cutting-edge nanomaterials, will then face a new requirement that their safety tests be ‘the most up-to-date’ – a vague term with no formal definition. This leaves companies subject to unpredictable changes in testing requirements with little notice, a burden no other industry faces.

Finally, if implemented, the text would require the European commission to change the definition of ‘engineered nanomaterial’ in the Food Information to Consumers Regulation. However, regulations cannot be updated overnight, which means companies will be faced with two parallel and competing definitions for an indeterminate period of time.

The Council claims that this regulation will ‘reduce administrative burdens,’ however, we believe it will achieve the opposite. Industry and innovators need regulation that is clear and grounded in science. It ensures they know when they are subject to nanomaterial regulations and are prepared to meet all the requirements. This approach provides them with predictability in regulations and assures the public that the nanomaterials used are safe. A conclusion all parties can welcome.

NIA urges Members of the European Parliament not to create uncertainty in a sector that is a leader in European innovation, and to engage in direct discussions with the European Commission, which is already working on a review of the European Commission Recommendation for a Definition of a Nanomaterial with the Joint Research Centre.

The Nanotechnology Industries Association

Formed in 2005 by a group of companies from a variety of industry sectors including healthcare, chemicals, automotive and consumer products, the Nanotechnology Industries Association (NIA) creates a clear single voice to represent the diverse industries in the multi-stakeholder debate on nanotechnologies. NIA provides a purely industry-led perspective, derived from the views of the collective membership and forms an interface with government, acting as a source for consultation on regulation and standards, communicating the benefits of nanotechnologies and interacting with the media to ensure an on-going advancement and commercialization of nanotechnologies.

For further information visit www.nanotechia.org or contact us on enquiries@nanotechia.org.

The NIA, Nanotechnology Industries Association, is the sector-independent, responsible voice for the industrial nanotechnologies supply chains; it proactively supports the ongoing innovation and commercialisation of nanotechnologies and promotes their safe and reliable advancement.

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