

## **“3<sup>rd</sup> CIAA Nanotechnology” Dialogue MEETING Brussels, 23<sup>rd</sup> March 2010**

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The revision of the EU regulation on novel foods is expected to clarify the rules that apply to nano in food products. The Council adopted its first reading position on 15 March 2010. The Parliament started its second reading on 24-25 March 2010 and will have three months to adopt its second reading position. The regulation could be finalised as early as July 2010, though further negotiations may be necessary. Nano is not the only element under discussion. The adaptation of the Regulation to the Lisbon Treaty has important implications, because of the Treaty's changes to the comitology procedures and the importance of the latter in the implementation of the Novel Foods Regulation.

The Parliament and Council have agreed on the following definition for nanomaterials within the revised Novel Foods Regulation: “any intentionally produced material that has one or more dimensions of the order of 100 nm or less or is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic to the nanoscale. Properties that are characteristic of the nanoscale include: (i) those related to the large specific surface area of the materials considered; and/or (ii) specific physico-chemical properties that are different from those of the non-nanoform of the same material”.

From a safety and risk management perspective, the Commission considers it important to include substances that behave as nanomaterials and have nano properties. The Commission also considers that the definition of nanomaterials must fit with international standards. Even though the definition to be included in the revised Novel Foods Regulation is already agreed, the Commission intends to develop an overarching “working definition” of nano, applicable across the board but to be adapted in individual pieces of legislation to fit the specific needs of different applications. This “working definition” is being developed by a Commission working group composed of various Directorates-General, and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) has been asked to provide scientific input on the definition [http://ec.europa.eu/health/scientific\\_committees/emerging/docs/scenihr\\_q\\_024.pdf](http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_q_024.pdf). SCENIHR's draft opinion is expected in June 2010 and may be followed by a consultation. The Commission plans to finalise the working definition by the end of 2010.

Against this background, the Commission would like to maintain the possibility of revising the definition of nanomaterials in the Novel Foods Regulation through a delegated or implementing act (new comitology procedure).

Regarding labelling, the Parliament has called for the mandatory labelling of nano in the Novel Foods Regulation and in the proposal for a Regulation on Food Information to Consumers. While the Commission does not yet have a formal position on this question, it considers that if labelling is deemed necessary, this provision would make more sense in the horizontal legislation on Food Information to Consumers. The issue will be debated between the EU institutions during second reading.

There is a perceived risk that applications submitted for a risk assessment opinion from the European Food Safety Authority (EFSA) will not be complete enough for EFSA to deliver an opinion. The Commission has thus asked EFSA to provide guidelines for the risk assessment of nanomaterials.

The Commission is drafting a new Nano Action Plan 2010-2015, which will identify priorities for the development of nanotechnologies. The Commission's top priorities are safety and innovation. DG SANCO would like the establishment of a mandatory register for all nanomaterials, not only food-related, to be part of the Action Plan. DG Enterprise is considering organising a public debate about nano, like some Member States have done, but nothing has been confirmed at this stage.