CENTER FOR INTERNATIONAL ENVIRONMENTAL LAW

Additional Comments to the Commission's Public Consultation on SCENIHR's opinion on "Scientific basis for a definition of the terms nanomaterials"

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The European Commission tasked the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) to provide advice on the essential elements of a science-based definition of nanomaterials. SCENIHR published a pre-consultation opinion on July 13th and opened a two month public consultation on the main elements of its opinion.

As the coordinators of NGO responses to this consultation, the European Environmental Bureau (EEB) and the Center for International Environmental Law (CIEL) submit the following additional comments to the technical discussion:

A technical definition of nanomaterials has value because it enables regulatory activities in a field where big promises as well as major concerns for human health and the environment have been highlighted for many years.

Despite numerous warnings from many well-respected scientific bodies that nanomaterials could have serious, negative impacts on human health and the environment, regulation designed to address those concerns is still mostly absent from the EU regulatory framework. This has been partly due to endless and sometimes artificial debates about the question of definition.

The debate on terminology has become passionate, in part because a definition can make legislation possible. Anticipating that, some policy makers may be tempted to narrow the scope of the definition so that it excludes certain types of nanomaterials from potential future regulation.

However, the present understanding of nanomaterials properties and potential health and environmental impacts is still very limited and therefore warrants much more research and careful evaluation. **Narrowing the knowledge gap cannot be achieved by reducing the scope of investigation. A definition that is too narrow would artificially exclude uncertainty from the policy debate, at a time when responsible governance at EU level is called for by the EU parliament, scientific institutions, insurance companies and stakeholders alike.** Conversely, a wide definition of nanomaterials would allow more research and a better understanding of all nanomaterials, whether they may present concerns for human health or not.[1]

Early evidence has shown that some particles up to several hundred nanometers share many of the novel properties of nanomaterials under 100nm that are critical for risk assessment.[2]

[1] As stressed by SCENIHR's statement that "[the] uncertainty (…) warrants the careful evaluation of possible risks associated with nanotechnology products".

[2] These novel properties include very high reactivity, bioactivity and bioavailability, increased influence of particle surface effects, strong particle surface adhesion and strong ability to bind proteins. Cedervall et al, 2007; Garnett and Kallinteri 2006; Linse et al. 2007.

Moreover, SCENIHR has acknowledged that science cannot set an upper size limit value for nano-properties. Accordingly, we recommend the adoption of a broad size-based definition of nanomaterials that uses the largest applicable size range (e.g., 0.3-300 nm[3]). We further call for the undertaking of a sensitivity analysis to verify that the adopted size range captures as much material as possible about which there is already concern (including fullerenes), while avoiding materials that do not give rise to nano scale-related concerns.

Another option that would provide sufficient precaution and flexibility could be a "two-trigger" system in which the first trigger would be particles in the 0.3-300 range, and the second trigger would capture materials with larger or smaller dimensions that have similar physico-chemical properties to particles of the same substance in the 0.3-300nm size range.

In either case, the adopted definition must include a revision clause, so that it is updated as the body of scientific knowledge grows. This would allow appropriate research for the reduction of the knowledge gap and enable policy makers to design and adapt tools to regulate nanomaterials in the present and future.

SCENIHR's opinion confirms that "nanomaterials" do not form a homogeneous group of substances. Whatever substances are included in the definition may consequently need to be treated differently by regulators, based on their specific properties and the risks they may or may not present (which can only be properly assessed by using a sufficiently broad scope for the definition).

Narrowing the scope of the definition at this stage could lead to potentially harmful substances escaping scrutiny, as well as the potential exclusion in the future of substances that are presently unknown. That would deprive legislators of the necessary flexibility that is critical for the regulation of very complex issues, including future generations of nanomaterials.

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[3] See for example Friends of the Earth Australia's Discussion paper on nanotechnology standardisation and nomenclature issues, August 2008, available at http://www.ecostandard.org/downloads_a/2008-10-06_foea_nanotechnology.pdf