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Size matters: New JRC report contributes to the groundwork for future EU regulations on nanomaterials

Despite the growing utilisation of engineered nanomaterials in consumer products and innovative technological applications, there is at present no widely accepted definition of the term "nanomaterial" that is suitable as a basis for legislation on their safe use. Responding to a request of the European Parliament, the European Commission's Joint Research Centre (JRC) published today a reference report entitled "Considerations on a definition of nanomaterial for regulatory purposes". The report discusses possible elements of a definition aiming at reducing ambiguity and confusion for regulators, industry and the general public. It recommends that the specific term "particulate nanomaterial" should be employed in legislation to avoid inconsistencies with other definitions and that size should be used as the only defining property.

"This report makes an explicit distinction between broader definitions of nanomaterial and a more specific definition limited to nanomaterials with regulatory relevance, as currently required by authorities. It draws on the extensive experience of JRC in different scientific fields and represents an important contribution to the debate on how to deal with novel nanomaterials in European legislation" stated Elke Anklam, Director of the JRC's Institute for Health and Consumer Protection.

Nowadays, many different nanomaterials are either used commercially or produced in significant quantities for research and development purposes. This has triggered concern about their safe use and possible impact on human health and the environment. At the same time there is no internationally harmonised definition of "nanomaterial" that would fulfill the requirements for use in legislation, either at European or international level. On the contrary, the existing multitude of definitions can lead to ambiguity and confusion for all involved.

Current EU legislation applies to nanomaterials without specifically addressing them, with the exception of recently adopted or proposed legislation (such as the new Cosmetic Products Regulation or the Novel Foods Regulation). In 2009 the European Parliament called for the introduction of a comprehensive science-based definition of "nanomaterial" as part of nano-specific amendments to relevant Community legislation. The EP also called on the European Commission to promote the adoption of a harmonised definition at the international level.

A definition for nanomaterials should fulfill the requirements of being broadly applicable in EU legislation and policies, legally clear and unambiguous, enforceable through agreed measurement techniques and procedures, and in line with other approaches worldwide. For this reason, the authors of the report recommend using **size** as the only defining property. To focus the definition on materials of potential regulatory relevance, it should concern only "**particulate nanomaterials**" since some of these materials currently raise health and environmental concerns.

A lower limit of 1 nm for the size range of interest (the "nanoscale") is considered as a reasonable figure. The upper limit of the nanoscale should be equal to or greater than 100 nm in order to include a wide range of currently used nanomaterials of regulatory concern. Other specific physico-chemical properties and attributes (e.g. state of agglomeration, biopersistance, or whether intentionally manufactured) may be relevant in the scope of particular legislation. Therefore it may be necessary to adapt the general definition to the needs of a specific implementation.

The report emphasises that the adoption of a definition will involve policy choices, and entail political decisions. Whereas there is a clear need for a consolidated definition of the term "(particulate) nanomaterial", the task of establishing a size based definition is not straightforward, and should ideally involve consultation, with stakeholders in the world of academia, regulatory bodies, industries and possibly NGOs.

For further information and report: http://ihcp.jrc.ec.europa.eu/

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