The European Union's chemical legislation needs revision

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To the Editor — In the *Second Regulatory Review on Nanomaterials*[1], the European Commission acknowledges that nanomaterials are revolutionary materials and that important challenges exist in regard to hazard and exposure assessments. Yet, they conclude that current risk-assessment methods are applicable to nanomaterials, and that the European chemical legislative (known as REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals) "…sets the best possible framework for the risk management of nanomaterials"[1]. Here, I argue that significant changes to REACH and the accompanying annexes are required to answer the call made by the public, downstream users and progressive businesses for clearer and more definite regulatory rules specific to nanomaterials[2].

Under REACH, unambiguous substance identification is essential[3]. Briefly, a chemical substance is defined by its chemical composition including any additive used to preserve stability and any impurity derived from the processes used for its manufacture[4]. Substance identity is therefore independent of, for instance, primary particle size distribution and various surface treatments, which are necessary to stabilize the substance. This means nanomaterials with markedly different properties — for example, the bulk and nanoform of a material, or various forms of surface-treated nanomaterials[5,6] — are considered to be the same under REACH. In the European Commission's *Staff Working Paper*[7], which accompanies the *Second Regulatory Review on Nanomaterials*[1], over 60 nanomaterials are cited to be on the market. Yet, a survey by the European Commission and the European Chemicals Agency (ECHA) found only seven nanomaterials were registered under REACH in the first round of registrations in 2010 as — among others — substances that were produced and imported at >1,000 tons per year[7,8].

For correct and unambiguous substance identification, a distinction between the bulk and the nanoforms of a given material needs to be specified in the legal text of REACH[9]. Furthermore, the European Commission should acknowledge that nanomaterials cannot be identified solely by chemical composition, and that additional main identifiers (such as primary particle size distribution, shape (including aspect ratio), specific surface area and surface treatment) should be included in the *Technical Guidance for Identification and Naming of Substances* provided by ECHA[3]. Only this will make clear that the properties and behaviour of nanomaterials differ fundamentally from each other and from the bulk[5].

Specific substance identification of nanomaterials could mean that some would not meet REACH's tonnage bands, which lay down the environmental, health and safety information requirements that need to be met by industry. Although lowering the tonnage band to, for example, 1 kg (ref. 10) has been suggested, I contend that if nanomaterials are commercialized in Europe, their registration should be independent of production volumes, and submission of (eco)toxicological data to regulators should be mandatory. Moreover, given the urgency of generating data on nanomaterials, registration fees must be reduced to encourage registration. As recommended by the consortium contracted by the European Commission to advise on fulfilling information requirements for nanomaterials under REACH, manufacturers should be required to perform accurate physicochemical characterization using multiple techniques because this is essential for assessing the potential (eco)toxicity of nanomaterials[11]. Furthermore, ECHA should offer confidential technical assistance to small- and medium-sized enterprises to meet these requirements and to ensure the innovation of safe nanomaterials[12].

In contrast to the *Second Regulatory Review on Nanomaterials*[1], the *Staff Working Paper*[7] highlights many of the challenges mentioned here and acknowledges that much more research and legislative grinding-out is needed. For instance, it recognizes that the information in REACH registrations pertaining to nanoform(s) is ambiguous, further underlining the importance of having REACH and the *Guidance for Identification and Naming of Substances* consider nanospecific properties and implement specific requirements for (eco)toxicological information. Furthermore, the *Staff Working Paper* acknowledges that nanomaterials may have a wide range of potential toxic effects, that there are few measured exposure data and that few environmental fate and behaviour studies are available. It concludes that "…risk characterisation and combining hazard and exposure data necessarily remains at a very preliminary and qualitative level"[7]. Unfortunately, the limitations of current regulation and risk-assessment approaches outlined in it were not transferred to the *Second Regulatory Review on Nanomaterials*[1].

Referring to the 2009 report[13] of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), the European Commission repeatedly calls for a case-by-case risk assessment of nanomaterials. However, the issues crippling hazard identification are not easily overcome and merit more than a few caveats as stated by the European Commission[1]. For instance, hazard-relevant physicochemical properties still need to be identified for nanomaterials. Furthermore, there are currently no standardized (eco)toxicity test guidelines in use[11]. Moreover, monitoring and detection equipment for exposure assessment need to be developed and there are no standards on how to measure nanoparticle dose in humans, the workplace and the environment[14]. Even if required only for commercialized nanomaterials, case-by-case risk assessment of nanomaterials is time- and resource-intensive[15] as outlined in the 2012 report by SCENIHR and two other scientific committees[16]. Under the heading '5.2.Towards a new conceptual framework in risk assessment', the report states "It is also evident that the risks posed by a number of products from new technologies (for example, biological products, manufactured nanomaterials) are unlikely to be adequately assessed using current methodologies alone"[16].

Another disturbing aspect of the *Second Regulatory Review on Nanomaterials*[1] is that it focuses only on first-generation nanomaterials (that is, passive nanostructures such as nanoparticles). The *Staff Working Paper*[7] acknowledges that second- and third-generation nanomaterials (for example, targeted drug-delivery systems and novel robotic devices) are entering early stages of market development, yet they offer no vision or strategic planning in ensuring the generation and development of

environmental, health and safety information, and regulations in a timely manner.

Finally, the European Commission repeatedly downplay the concerns by stating that[1] "…nanomaterials are similar to normal chemicals/substances in that some may be toxic and some may not." The analogy highlights that manufacturers, scientists and the European Commission are not aware of which nanomaterials are toxic just as we did not know about industrial chemicals before they came into widespread use during the twentieth century, resulting in significant human health and environmental damage as documented by the European Environmental Agency[17,18]. One fears that the European Commission either does not understand the challenges and problems before them when it comes to regulation and risk assessment of nanomaterials, or they grossly underestimate them. ❐

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Substance identification of nanomaterials not key to ensuring their safe use

To the Editor — In the preceeding Correspondence piece 'The European Union's chemical legislation needs revision' (*Nature Nanotech.* **8,** 305–306; 2013) Hansen focuses on substance identification as being a key issue in bringing clarity on the different properties of the bulk- and nanoforms of the same substance; in the extreme interpretation, all nanoforms would be considered as different substances. It argues that nanomaterials should be registered independently of their tonnage.

In particular, it claims that "the European Commission should acknowledge that nanomaterials cannot be identified solely by chemical composition, and that additional main identifiers (such as primary particle size distribution, shape (including aspect ratio), specific surface area and surface treatment) should be included in the *Technical Guidance for Identification and Naming of Substances* provided by ECHA", and, that "Only this will make clear that the properties and behaviour of nanomaterials differ fundamentally from each other and from the bulk." This suggests that those additional main identifiers are the main solution to clearly identifying differences between the properties and behaviour of nanomaterials from their corresponding bulk forms and among each other (for example, the same nanopowder of different diameters, or with different surface coatings).

The European Commission has committed to further work on substance identification. However, this is only one element to getting clarity on the differences between the properties and behaviour of nanomaterials. Trying to identify unambiguous rules for substance identification for all cases is probably elusive and might result in ever more complex rules on what is considered as the same substance as opposed to different substances, without necessarily resulting in more safety of nanomaterials. Rather, we consider that focusing on clarifying what is needed to demonstrate the safe use — whether that is done in one or several dossiers — is more promising to make progress on nanomaterial safety. (See the *Second Regulatory Review on Nanomaterials*, section 5.2; http://go.nature.com/2bPFN7)

Clarifying the rules on how to demonstrate the safe use of nanomaterials is the purpose of the envisaged amendment to the annexes of the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulation, as outlined in section 5.1 of the *Second Regulatory Review on Nanomaterials*. Because co-decision regulation requires several years of legislative work, changes to the annexes (which can be done in a time frame of one to two years) are the most promising route to rapidly getting more clarity on which nanomaterials are covered in the REACH registration dossiers, to address specificities on the risk assessment of nanomaterials and to generate more information on their hazards and risks. Clearly, this should be supported by efforts from Member States to engage in substance evaluation, and to launch a dialogue between authorities and registrants to identify unclear information and remaining information gaps, as well as ways to fill in those gaps.

Furthermore, Hansen claims that registration of nanomaterials "should be independent of production volumes, and submission of (eco)toxicological data to regulators should be mandatory". However, it fails to argue why nanomaterials should be treated differently from other chemicals in this respect. In particular, it does not give evidence that nanomaterials as a category of substances are more hazardous than other chemical substances, nor that the risks of hazardous nanomaterials are more severe than those of conventional hazardous chemicals. Therefore, it is unclear why lower or no tonnage thresholds for REACH registration should apply to nanomaterials compared with other chemical substances.

The one-tonne-registration threshold for chemicals has been agreed between the co-legislators of the European Parliament and Council as an appropriate balance between ensuring that a maximum of