

Nanomaterials: No need for additional inventories

Cefic's reply to the Commission on additional measures to ensure transparency and adequate regulation

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Cefic considers transparency of information on nanomaterials as paramount in communicating with the supply chain, the authorities and society. Manufacturers, importers and downstream users are already legally required to fill in European databases on substances (such as the ECHA databases for REACH and CLP) and products (cosmetics, biocides, food ingredients, etc.). These databases inform about the safety of nanomaterials.

To further improve communication with policymakers and society, Cefic is willing to contribute to the **European Commission's web platform and the Impact Assessment** mentioned in the Second Regulatory Review on Nanomaterials. If information generated and filed to the various notifications and regulatory schemes was published on a web platform, it would already increase transparency to a large extent and cover most needs. This includes information on nanomaterials used in food, cosmetics, medical devices, biocidal products as well as substances submitted under REACH (once Annexes are adapted for nanomaterials) and CLP.

We acknowledge that some countries have chosen, for their own national needs, to establish, or are considering establishing national inventories, either by creating new ones (France, Belgium), or by adapting existing databases or laws (Norway, Denmark). Cefic considers that a variety of national reporting schemes, including their associated reporting requirements, will create unnecessary burden and confusion, since each member state has its own definition of a 'nanomaterial' and differing exemptions for reporting. Such confusion leads only to administrative costs for authorities and companies, with no benefits for consumers.

Thus Cefic believes that additional reporting schemes, whether national or European, beyond existing data requirements, will not improve transparency, neither benefit to consumers.

Moreover Cefic supports the Commission's view that labelling beyond existing requirements is unnecessary. Such requirements specific to nanomaterials already exist for food, cosmetics and biocidal products. Labelling should be limited to the hazardous substances for which mechanisms already exist today (CLP).

Arguments supporting the above statement:

1. Cefic shares the view of the 2nd Regulatory Review of the Commission that REACH is an appropriate tool to cover nanomaterials, whilst additional updating of the guidance and amending REACH Annexes may be needed. REACH, once adapted to nanomaterials and suitable measurement methods agreed, will contribute to increase transparency about nanomaterials. Similarly other specific legislation can add more to the information already available on nanomaterials used in products.
2. The "overarching" nanomaterial definition in the EU Commission Recommendation is a constraint, as it needs to be adapted to individual sector specific regulations. Furthermore, currently **no standardised methods exist** to measure whether a material is a nanomaterial or

not and these discussions are ongoing. So consistent implementation of a “nano inventory” is not possible. Generally, the sector-specific nanomaterial definitions will have narrower scopes than the “overarching” definition. Consequently, the individual sectoral regulations will use different nanomaterial definitions:

- For instance, the Cosmetics and the Biocidal Products Regulations have definitions of their own to ensure applications of nanomaterials are well regulated in these sectors. An additional national or European inventory would not necessarily generate more data than existing already.
 - As long as no common definition exists and no standardised measurements are available, the information collected in nanomaterial product registers is arbitrary.
3. For some nanomaterials and products containing nanomaterials, a new cross-sectoral “nano inventory” would generate a heavy burden for companies, duplicating work. **Avoiding double regulation** is particularly important for the EU Commission.
 4. A European or national inventory of nanomaterials may pose difficulties when **addressing different categories of users** (consumers, competent authorities, other stakeholders) due to the various purposes requested (traceability, right-to-know...). And information provided to consumers may be confusing or misleading.
 5. An inventory stigmatises nanomaterials, **hampers innovation and damages competition** by creating additional burden (e.g. costs), especially for SMEs.
 6. An inventory could be interpreted as a **“discriminating” criterion**, whereby nanomaterials are considered as hazardous substances (such as PBT, SVHC), whereas nanomaterials are not toxic per se. Some downstream users already prefer to de-select nanomaterials, whatever their safety profile.
 7. An inventory would raise concerns about the **protection of confidential business information** (e.g. name of customers and suppliers).
 8. If **risks** are identified, they can be detailed under the REACH Regulation, existing sectoral legislation and also through existing tools such as the General Product Safety Directive and its RAPEX system or other specific instruments under EU products and workers’ health and safety legislation.
 9. Cefic doubts whether a nano inventory is a suitable **tool for communicating** with consumers. Recent surveys show that currently European citizens know little about nanomaterials and do not ask for inventories (e.g. NanoView in Germany conducted in 2013). The EU Commission should first explore what information citizens want and how this should be communicated.