

European NGOs position paper on the Regulation of nanomaterials

Nanomaterials are different from their bulk counterparts. They are specifically engineered to exploit the novel properties deriving from their size. The European Commission's 2012 Second Regulatory Review on Nanomaterials considers that, as with other substances, some could be hazardous, whilst others may be safe. Therefore, as for every other chemical substance placed on the EU market, nanomaterials need to undergo a thorough risk assessment, including an assessment of the potential risks deriving from their novel properties. Current EU legislation does not guarantee that all nanomaterials on the market are safe by being assessed separately from the bulk form of the substance. Therefore, we ask the European Commission to come forward with concrete proposals for a comprehensive revision of the existing legal framework addressing the potential risks of nanomaterials.

1. Nanomaterials are different from other substances.

We are concerned that EU law does not take account of the fact that nano forms of a substance are different and have different intrinsic properties from their bulk counterpart. Therefore, we call for this principle to be explicitly established in the REACH, and Classification Labeling and Packaging (CLP) regulations, as well as in all other relevant legislation. To ensure adequate consideration, the submission of comprehensive substance identity and characterization data for all nanomaterials on the market, as defined by the Commission's proposal for a nanomaterial definition, should be required.

Similarly, we call on the European Commission and EU Member States to ensure that nanomaterials do not benefit from the delays granted under REACH to phase-in substances, on the basis of information collected on their bulk form.

Further, nanomaterials, due to their properties, are generally much more reactive than their bulk counterpart, thereby increasing the risk of harmful impact of nanomaterials compared to an equivalent mass of bulk material. Therefore, the present REACH thresholds for the registration of nanomaterials should be lowered.

Before 2018, all nanomaterials on the market produced in amounts of over 10kg/year must be registered with ECHA on the basis of a full registration dossier specific to the nanoform.

2. Risk from nanomaterials must be assessed

Six years after the entry into force of the REACH registration requirements, only nine substances have been registered as nanomaterials despite the much wider number of substances already on the EU market, as demonstrated by existing inventories. Furthermore, the poor quality of those few nano registration dossiers does not enable their risks to be properly assessed. To confirm the conclusions of the Commission's nano regulatory review assuming that not all nanomaterials are toxic, relevant EU

legislation should be amended to ensure that all nanomaterials are adequately assessed for their hazardous properties.

Given the concerns about novel properties of nanomaterials, under REACH, all registration dossiers of nanomaterials must include a chemical safety assessment and must comply with the same information submission requirements currently required for substances classified as Carcinogenic, Mutagenic or Reprotoxic (CMRs).

3. Nanomaterials should be thoroughly evaluated

Pending the thorough risk assessment of nanomaterials demonstrated by comprehensive and up-to-date registration dossiers for all nanoforms on the market, we call on ECHA to systematically **check compliance for all nanoforms**, as well as check the compliance of all dossiers which, due to uncertainties in the description of their identity and characterization, are suspected of including substances in the nanoform. Further, **the Community Rolling Action Plan (CoRAP) list should include all identified substances in the nanoform and evaluation should be carried out without delay.**

4. Information on nanomaterials must be collected and disseminated

All EU citizens have the right to know which products contain nanomaterials as well as the right to know about their risks to health and environment and overall level of exposure. Given the uncertainties surrounding nanomaterials, the Commission must guarantee that members of the public are in a position to exercise their right to know and to make informed choices pending thorough risk assessments of nanomaterials on the market.

Therefore, a publicly accessible inventory of nanomaterials and consumer products containing nanomaterials must be established at European level. Moreover, specific nano-labelling or declaration requirements must be established for all nano-containing products (detergents, aerosols, sprays, paints, medical devices, etc.) in addition to those applicable to food, cosmetics and biocides which are required under existing obligations.

5. REACH enforcement activities should tackle nanomaterials

REACH's fundamental principle of "no data, no market" should be thoroughly implemented. Therefore, **nanomaterials that are on the market without a meaningful minimum set of data to allow the assessment of their hazards and risks should be denied market access through enforcement activities.** In the meantime, we ask the EU Member States and manufacturers to use a precautionary approach in the assessment, production, use and disposal of nanomaterials.