Position Paper

Reset Governance: Nanomaterials as a case study on negligence

NGO demands for adequate EU governance of nanomaterials

Civil society organisations renew calls for more public policy regulating human health and environmental safety of nanomaterials. The European Commission's continuing resistance to the development of a clear regulatory framework hampers the safe use and development of nanomaterials. These materials still cannot have their hazard profiles and exposure scenarios characterised, and so risk assessment is not yet possible.

The Commission's *laissez-faire* approach applies to all nano-related EU policy areas, from unjustified delays in the revision of REACH Annexes and the definition of nanomaterial, to failure to implement or enforce provisions in the Cosmetics Regulation and the Food Information to Consumers Regulation. Further, the European Commission violates its own internal processes on the identification and impact assessment of transparency measures on nanomaterials by choosing one option in advance of the final assessment by its own Regulatory Scrutiny Board.

The precautionary approach enshrined in EU treaties is too often treated as in automatic conflict with EU competitiveness or jobs. This false conflict is created by a European Commission and private industry prioritising industrially biased interests, thereby placing the health of EU citizens and the environment at unnecessary risk. Civil society organisations demand governance of nanomaterials that respects EU objectives of a high level of protection of environmental and human health and consumer safety.

In particular, the signatories demand:

- **A nanomaterials framework regulation to govern in a harmonised way human health and environmental protection for all potential uses of nanomaterials.**
  The framework legislation should set a legally binding definition as well as common principles for regulation, and should act as the overarching legislation to which all relevant existing and future legislation addressing nanomaterials should align. The framework legislation should set out mandatory information requirements on nanomaterial-specific identification and characterisation, hazard, exposure and risk management measures, and specific market data. It should also be designed to cover nanomaterials already on the market, and introduce a pre-market information requirement in advance of nanomaterials being placed on the market by a given future date. This regulation would apply to all nanomaterials with an annual production volume of a minimum of 100g and could adopt a tiered approach similar to that used in REACH.

- **The framework legislation should enshrine REACH's "no data, no market" principle.**
  Pressure on industry to provide necessary and robust information remains urgent, especially given the relatively little and poor quality of information provided by industry on nanomaterials to date whether in the context of REACH or the Cosmetics Regulation. Specific data demands on nanomaterials, with test methods adapted to nanomaterial specificities, need to be supplemented by the "no data, no market" principle. Enforcing this principle requires that products be taken off the market or not granted access when there are still significant data gaps. No release of manufactured nanomaterials into the environment should be allowed, until adequate safety data is available.

- **A lifecycle approach be taken to the governance of nanomaterials.**
  This should be done through the adoption of a full producer responsibility approach spanning across the lifecycle of a nanomaterial or product containing them – from production to use and end-of-life management. Such an approach would also support efforts in creating a sustainable and toxic-free circular economy.

- **The market data collected through the framework regulation be made publicly available.**
  In this way, the public would be able to exercise its right to know and make informed choices about which products to buy. The information would also be useful for researchers and academia to prioritise safety research, and to regulators for the development of adequate regulatory risk management measures.

- **Mandatory labelling be required for any product already legally requiring an ingredient list.**
  Labelling should be neutral, as in the case of the Cosmetics Regulation, thereby integrating the "right to know" principle from REACH while avoiding communicating specifically positive or negative messages about the presence of nano in the product. In this way, a harmonised approach would be taken to consumer awareness for cosmetics, food, detergents, medicines, pesticides, and any future products. Product labelling requirements should supplement legally required pre-market safety assessments, not act as their substitute.

- **The framework legislation to include harmonised definitions of terms relevant to nanomaterials.**
  This would serve to harmonise all legislation addressing nanomaterials as a minimum, and would not preclude further refinement of definitions according to the regulated product. The definition of nanomaterial should be based on the 2011 Commission recommendation, but with a reduced number size distribution threshold of 10% which may be replaced by a threshold between 1 and 10% or higher, according to adequate scientific data to justify a lower or higher threshold and depending on the application, product, or product group under consideration. The 10% threshold is based on the European Food Safety Authority's recommendation for food, but is higher than a SCENIHR opinion of 0,01%.

- **All research projects involving nanomaterials be required to include EHS research that is to be made publicly available.**
  Nanomaterials-related research funding has always been orders of magnitude greater for the development of applications than for environmental, health and safety impacts (EHS) or ethical, legal and social aspects (ELSA). This badly weighted research support encourages and reinforces gaps in safety information for applications under development and for products already on the market. At the same time, researchers testing potential new applications do not necessarily have the expertise needed to undertake EHS/ELSA analysis of the applications. This un-precautionary approach is unacceptable for such novel substances and materials.

- **Bio-monitoring of the environment, the public and of workers be introduced.**
  Little exposure knowledge exists despite requirements in both occupational health and safety and general product safety legislation. A structured programme of bio-monitoring would help to identify short-term, acute exposure reactions, as well as longer-term chronic reactions, and would add to other

EU bio-monitoring activities, thereby potentially helping to increase knowledge of cocktail effects.

- **Any REACH registration dossiers featuring nano-forms automatically be placed on the CoRAP list for evaluation.**
  Until the framework legislation is adopted, thorough assessment of nanomaterials should be undertaken by automatically placing all nanomaterials and nano-forms on the REACH Community Rolling Action Plan.

- **Decision-making processes be designed based on effective participatory processes.**
  Development of the public policy framework on nanomaterials has been characterised by very poor participatory processes, lacking transparency and accountability. Nanomaterials warrant more transparent, inclusive and reflexive processes, with the Commission behaving in an accountable manner. Such an approach should result in more transparent decision-making, and would help to rebuild confidence in the Commission and industry.

Signatories