



Nanotechnology and the current legislation – Position Paper

Friends of the Earth Europe is concerned about the fact that nanotechnology is being developed and commercialized in a regulatory vacuum, with the products of nanotechnology research, such as nanoparticles and other nanomaterials, being manufactured and released into the environment without being subjected to adequate - if any - health and safety testing or environmental impact assessment. Friends of the Earth Europe believes that the current EU regulatory frameworks do not provide adequate oversight of nanomaterials. As a result, a modified or *sui generis*, nano-specific regulatory regime must be an integral aspect of the development of nanotechnologies.

A range of studies has been conducted in order to assess the current oversight mechanisms, taking into account the novel properties exhibited by nanomaterials. All of the studies mentioned below have identified a number of regulatory and knowledge gaps and similarly to Friends of the Earth Europe's observations, have concluded that amendments to the current regulatory frameworks are crucial to ensuring environmental and health safety of this advanced and rapidly expanding sector.

A scoping study conducted for the UK Department for Environment, Food and Rural Affairs has identified a number of regulatory gaps (1) originating either from exemptions under legislative frameworks (on tonnage basis), or from a lack of information, or uncertainties over:

- clear definition(s) encompassing the novel (or distinct) properties of nanotechnologies and nanomaterials; i.e. whether a nanomaterial should be considered a new or an existing material. In this context, one should note that The UK Royal Society recommended that chemicals in the form of nanoparticles or nanotubes be treated as new substance under REACH (2). Similarly, the Danish Board of Technology proposes to classify nanoparticles separately under CAS classification when they display specific properties due to the nanoscale (3).
- current scientific knowledge and understanding of hazards, and risks arising from exposure to nanomaterials
- agreed dose units that can be used in hazard and exposure assessments
- reliable and validated methods for measurement and characterization that can be used in monitoring potential exposure to nanomaterials
- potential impacts of nanomaterials on human health and environment (4).

Similarly, the Scientific Committee on Emerging and Newly Identified Health Risks acknowledged major gaps in the knowledge necessary for risk assessment and hazard evaluation of manufactured nanoparticles, such as nanoparticle characterisation, the detection and measurement of nanoparticles, the dose-response, fate and persistence of nanoparticles in humans and in the environment and all aspects of toxicology and environmental toxicology related to nanoparticles. It concluded that current risk assessment methodologies require some modifications in order to deal with the hazards associated with nanotechnology, and in particular that existing toxicological and

ecotoxicological methods may not be sufficient to address all of the issues arising with nanoparticles (5).

Following an analysis of four major pieces of EU environmental law, a study by Franco et al (2007) stated that “the applicability of environmental laws is limited due to difficulties in generating sufficient data on nanomaterials residing in the products according to their life cycles. Based on an analysis of gaps within the regulation along the life cycle of three different products containing carbon-based nanoparticles, the study concluded that it is often unclear if nanoparticles are covered by current legislation”. The main problem stems from the unavailability of metrology tools as well as the fact that thresholds are not tailored to the nanoscale and are based on bulk material, and that (eco) toxicological data and limits cannot be established with existing methodologies. As a result, the difficulty to generate universally recognized data along the life cycle of commercially available products puts a limit to the applicability of many laws. The study concluded that the *incremental approach* can only “be applicable with the implementation of due amendments” (6).

Similar conclusions have been reached in a recent European Parliament's study on Nanomaterials in Consumer Products (2006). While the paper is positive that “implicitly, the use of nanomaterials is regulated by most of these documents by making industry responsible for the safety of the chemicals or products they produce, thus enabling the authorities to take action if products pose a risk to health, safety or the environment”, it states that “it is, however, questionable if new risks arising from the presence of nanomaterials will always be recognized by the regulatory system, since the knowledge on the safety of nanomaterials (exposure assessment, toxicity thresholds, test schemes, etc.) is limited” (7).

The abovementioned (and other) studies have identified the following gaps in specific pieces of legislation:

- **RoHS Directive (2002/95/EC)** has gaps relating to the scope of legislation (similar to the Cosmetics Directive). RoHS requires that a producer ensures that new equipment put on the market does not contain more than the permissible maximum concentration values of hazardous substances. A regulatory gap arises from setting of thresholds of permitted concentrations of substances in consumer products. Regulatory provisions establishing maximum concentration levels are often enacted for substances where there exists an extensive body of dose-response and exposure data. According to Frater et al. (2006) “it is conceivable that thresholds set on the basis of known toxicity of particular substances are inappropriately set for the manufacture of those substances using nanomaterials” (8).
- **Safety at Workplace Directives (31/1989, 24/1998)** lack direct reference to the potential exposure of engineered nanoparticles. This is similar for other communitarian and national legislation on the protection of workers' health at workplaces. Even if the Framework Directive 31/1989 as well as Directive 24/1998 on the risks associated with chemical substances set guidelines to establish Occupational Exposure Limits (OELs) for workers, this poses some major challenges. Firstly, the establishment of OELs is typically based on complete risk assessment procedure which presently is not possible for engineered nanoparticles because of the extent and profoundness of uncertainties involved and a general lack of scientific knowledge. Secondly, nanoparticles are not easily detected by existing instruments. Thirdly, the most optimal parameter to determine the toxicity of nanoparticles is still undefined (9).

- **REACH Regulation (1907/2006)** poses similar problems, when it comes to inadequacy of the risk assessment methodologies (toxicity and ecotoxicity in particular). Moreover, certain substances may be introduced on the market both in nano and bulk versions, with the data generated only for the bulk form, thus omitting the hazard or risk information related to nanoparticles. Equally worrying is that substances used primarily in nano form may not meet the mass thresholds that REACH requires to provide toxicological data and assess environmental exposure. Currently, it is assumed that for many nanoparticles the threshold of 1 tonne per year per producer or importer would hardly be reached.

To solve these problems, Franco et al suggest that different thresholds and units than those given in mass terms would be more suitable. This is confirmed by the findings of the Scientific Committee on Newly Identified and Health Risks (June 2007) stating that “in relating exposure dose concentration of nanoparticles to their effects, the traditional use of mass or mass per unit volume alone is unlikely to be appropriate. Surface area and/or particle number per volume in addition to mass should be considered” (10). Moreover, the current knowledge gaps need to be filled with reliable toxicological and ecotoxicological data.

- **Waste Management Directives (12/2006, 689/1991, 439/1975, 53/2000).** Nano-wastes are tackled by waste management regulations in a non-specific way, because there are no specific references to engineered nanoparticles in existing laws. Similarly, it is not clear whether a waste containing nanomaterials should be considered and treated as normal waste, hazardous waste, waste for incineration and/or landfill or even as radioactive waste. There exist no provisions for waste recovery and disposal options which raises concerns relating to the definition, characteristics and liability for waste containing nanomaterials.

In general, nanoparticles are likely to follow the material or the substance in which they are contained and their fate depends on the way these wastes are treated. Wastes are typically disposed of in landfills or incinerated. Very little is known about the long-term behaviour of nanoparticles in a landfill. Release depends on the nanoparticles' mobility as well as on the degradability of the host material for fixed particles. When products are incinerated, the thermal properties of nanoparticles determine their fate. At the same time, even though historically wastes have ended in landfills or in incineration, the current trend points to increasing rates of recycling and composting, as we move to a more circular economy. It is therefore imperative to know how any nanomaterial will affect recycling processes, and whether they will break down in composting, and whether they have any influence on the compost quality and usability. Each article containing nanoparticle should therefore undergo a complete life cycle assessment before being placed on the market.

If a certain nano-waste falls within the scope of Directive 689/1991 on the management of hazardous waste, more severe obligations would apply. However, the lack of (eco)toxicological data makes it difficult to state if nanoparticles meet the criteria for hazardousness (11). Following a recommendation by Franco et al., Friends of the Earth Europe calls for an introduction of “free nanoparticles” in Annex II of the Directive on hazardous waste, which lists the constituents of a waste that render it hazardous.

- **IPPC Directive (61/1996):** The relevance of the IPPC Directive to manufacturing plants of nano-engineered substances and materials depends on whether they are encompassed by the list of industrial activities with a high pollution potential. Chemical installations for the production of a wide-ranging list of organic and inorganic chemicals are listed, however, there are no specific references to synthesized nanoparticles. Moreover, when it comes to a new manufacturing process, “such is the innovative nature of nanotechnology production that production process may not meet the pollution prevention and control activity descriptions” (Frater et al 2006). To address

these issues, Franco et al suggest establishing BREFs (Best Available Techniques reference documents) for nanoparticles. Friends of the Earth believes that the BREFs should be horizontal, not sectoral, in order to cover all possible processes for the generation of nanoparticles through industrial processes. Moreover, in order to bring new production processes under IPPC, the list of processes in Annex I has to be extended.

- **Pesticides and Biocides.** The regulatory framework covering pesticides is divided into plant protection products (Directive 91/414, Council Directive 79/117, Regulation 396/2005) and biocidal products (Directive 98/8/EC, Directive 76/769/EEC). Products belonging to either group need to be assessed and authorized before use. As many pesticides are a source of surface and ground water pollution, they are also a subject of water legislation. However none of these pieces of legislation currently consider or mention nanoscale products. Given that all new pesticides and biocides need to be approved for sale, a key issue confronting regulators is whether they agree with the contention that changing a chemical's particle size also changes its potential hazards to humans and the environment. Friends of the Earth strongly recommends that this is the case, so that all new products and any new formulations of existing products would require assessment before authorization.
- **Consumer products.** The General Product Safety Directive (GPSD 01/95) covers all products intended or likely to be used by (private) consumers unless these products are covered by more specific directives (e.g. toys, electrical equipment, machinery, personal protective equipment, construction products, medical devices and several others). All these directives follow the so-called "New Approach", which means that they contain only "essential requirements" (which often mean rather vague principles which cannot be directly enforced) and leave it to the industry-controlled standards bodies to elaborate detailed specifications based on mandates by the Commission. The GPSD solely calls for "safe" products and leaves the interpretation on what this precisely means to the industry and authorities. No suitable instruments (such as a comitology procedure, use of opinions of scientific committees) are available to establish legal limit values for chemicals in products let alone to take any measures with respect to nano ingredients. Friends of the Earth Europe believes that fundamental changes are needed with respect to this framework to fully address chemical hazards including nanoparticles.

There are similarly no restrictions with regard to nanomaterials mentioned in the marketing and use directive (76/769/EEC), nor is there a reference to nanomaterials in the Preparations Directive (1999/45/EC).

Friends of the Earth Europe recommendations:

As shown in the above, far from exhaustive, analysis substantial regulatory changes in existing laws are necessary in order to adequately and effectively address the fundamentally different properties of nanomaterials and new challenges that they present.

Many environmental laws (e.g. REACH, Directives on hazardous waste, etc) are based on (eco)toxicological classification of substances. Terms like "toxic" or "persistent" are often used as triggering factors to establish specific regulations, set emission limits, prohibitions and other requirements. These rules acquire a consistent meaning only when (eco)toxicological data are available for a substance (Franco et al). Additionally, the uptake, distribution, clearance and effects of nanoparticles may differ from those of the substances for which the Technical Guidance Documents were initially developed (SCENIHR 2007). Friends of the Earth Europe calls for more public funding into research designed to

produce reliable environmental health and safety data assessing the entire life cycle of the nanotechnology products.

The gaps relating to the definition of nanotechnologies and nanomaterials (e.g. where nanotechnologies and nanomaterials present new risks to existing environmental compartments) equally need to be bridged and the nomenclature gaps need to be filled in the existing legislation. Manufactured nanoparticles should be introduced separately to the relevant pieces of legislation in order to reflect their unique properties.

The new, or adapted regulatory framework must include mandatory labeling of nanotech products. At the same time, all who market nano-products, including nanomaterial developers, handlers and commercial users, the makers of products containing nanomaterials and retailers who sell nano-containing products to the public must be held accountable for liabilities incurred from their products.

Until a regulatory framework is created or the existing legislation is adapted in line with some of the recommendations above, a moratorium must be put in place on the release of nanomaterials and the use of nanotech applications.

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