

ETUI Policy Brief

European Social Policy

Issue 2/2011

Nano governance: how should the EU implement nanomaterial traceability?

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Policy implications

This *Policy Brief* addresses the need for a governance response from the European bodies to establish a registry of nanomaterial-containing articles. Better comprehensive data is urgently needed to improve knowledge of what is on the market, who is exposed and what should be regulated. Member States welcome such inventories and have developed their own initiatives while at the same time exhorting the European Commission to step in on the process. Achieving

harmonisation of the national initiatives is crucial, for proper regulation is needed to ensure proper protection of human and environmental health, as well as an adequate level of risk management.

Introduction

A wide range of nanomaterial-containing products have been commercialised and are in daily use by consumers worldwide. Sectors identified as having products that incorporate nanomaterials are motor manufacturing; defence and aerospace; electronics and computers; energy and environment; food and agriculture; housing and construction; medical and pharmaceutical; personal care, cosmetics, sports and other consumer products. The use of engineered nanomaterials in a wide range of goods is spreading rapidly because although only atom-sized, these materials have specific physicochemical properties like high surface area, reactivity, electric conductivity, and surface energy which are more useful and quite different from the macroscopic versions of the same material.

But societal concerns about the life-cycle and possible risks of nanomaterials, and the lack of knowledge about them, call for more information to be disclosed and a proper regulatory framework. As yet, it is unclear exactly how many articles on the market contain nanomaterials. For instance, production workers have no idea whether they are handling nanomaterials, in what quantities, and whether or not they pose a danger. The debate on the regulatory framework for nanotechnologies has been rolling for nigh-on a decade; it is on the political agenda because stakeholder discussions with the regulatory bodies on the supply of information on nanomaterials are basically deadlocked.

The EU's REACH regulation on the registration, evaluation, authorisation and restriction of chemicals requires most manufacturers and importers to register their chemical substances as proof that they can be used safely. However, the regulation contains no specific provisions on nanomaterials, and the European Parliament has called on the Commission to evaluate the need to review REACH to ensure that the "no data, no market" principle applies to nanomaterials (European Parliament, 2009).

One key issue in the debate on whether the current regulatory framework is appropriate for nanomaterials is the need for a registry of nanomaterial-containing products. This is firstly because, while most Member States have favoured traceability systems for nanomaterials, some form of coordination is essential because each country has developed its own approach and this makes European harmonisation more difficult. This paper provides an overview of the proposals by those Member

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States like France, Italy, the Netherlands and Belgium who have actively developed such systems. Secondly, it is doubtful whether voluntary measures will provide enough information, and they are not followed by all industries. The proposal is to establish a mandatory registry to achieve a transparent regulatory framework for nanomaterials, which would require joint efforts by national authorities and the Commission.

Pressure from civil society

Politically, the discussion on a regulatory framework is set in a vicious circle where stakeholder groups – consumer groups, environmental lobbies and trade unions – want to know what is on the market, want more information on nanomaterials and more research into and funding for health, safety and environmental protection and for the precautionary principle to be applied. Civil society groups are calling for inventories or product registries to be produced. For instance, environmental groups and trade unions have consistently demanded information and traceability since the very outset of the nano debate, and their inclusion and consultation is key to a sound governance approach (Meili, C. et al. 2010).

In early 2010, for example, Friends of the Earth Germany launched an inventory for the German market (BUND 2010). In October the same year, the European Consumer Voice in Standardisation (ANEC) and the European Consumers' Organisation (BEUC) published an inventory of consumer products that admit to containing nanomaterials. They identified 475 new articles on the European market, leading them to press for disclosure through the creation of a public inventory where manufacturers would have to register their nanomaterial products on the European market (ANEC/BEUC, 2010).

The Center for International Environmental Law (CIEL) representing environmental organisations has also called for a mandatory registry. At the 'high-level event' on nanomaterial traceability held under the Belgian Presidency of the European Union, CIEL commented that knowing what is on the market is a prerequisite for adequate regulation, and experience has shown that a mandatory register is the only way to collect comprehensive information on nanomaterials on the market. Furthermore, considering the current knowledge gap, this information is the only way to derive exposure information, which is necessary to assess and limit the risks associated with these materials (CIEL, Belgian Presidency 2010).

The European Trade Union Confederation (ETUC) stepped into the debate in 2008 with its first Resolution on Nanotechnologies and Nanomaterials. In its second resolution (December 2010), the ETUC calls for transparency and traceability of nano-articles and more specifically urges Member States to develop harmonised mandatory registers of nanomaterial-containing articles, including a life-cycle assessment of them.

These social stakeholders are united in calling for transparency of information in order to protect against potential hazards; their common agenda is for a better information supply, and for

Member States and the European Commission to move on with bringing that about.

The pressure of national and European initiatives

The Belgian Presidency's initiative

The Belgian Presidency of the European Union (1 July – 31 December 2010) put this issue on the European political agenda with a strong proposal for national authorities to hold discussions on coordinating national strategies and bringing forward concrete measures on risk management, information and monitoring of nanomaterials.

Its September 2010 high level event titled "Towards a regulatory framework for nanomaterials traceability" brought together representatives of consumer associations, environmental protection groups, labour organizations, industry federations and the scientific community with the aim of developing an operational incident response framework and achieving improved risk management of nanomaterials.

The Belgian proposal was presented to the REACH Competent Authorities Sub-Group on Nanomaterials (CASG Nano) in a bid to get movement on coordination of national databases of nanomaterials on the market. It is currently trying to engineer collaboration between France, Italy, Germany and the Netherlands to take its proposal forward.

Where Member's States' initiatives are concerned, few countries have given consideration to nanomaterial traceability. Where the different country approaches converge is in calling for more information on nanomaterials on the market, and this arguably is moving the European Commission to coordinate these actions at the European level.

France

The recent *Grenelle II* act passed in 2010 is the French law on national commitments to the environment which also takes in public health and the strategy for the national governance of sustainable development. It also includes some measures on nanomaterials. It requires the public and consumers to be informed about the quantities and uses of manufactured, imported or marketed nanoform substances; the materials that might release such nano-substances; and the presence of nanomaterials in articles, such as by labelling nanoform substances by name.

The situation in France is quite straightforward; the new Article 523-1 of the Environmental Code makes it mandatory to report substances in nano form. This makes France the first country to set up this type of mandatory reporting scheme enabling both substances and their use to be identified. Taking this forward, the Ministry for Ecology, Sustainable Development, Transport and Housing issued regulations for public consultation in January 2011 to define procedures for implementing the statutory

provisions on application of the annual electronic return of nano form substances put on the market. Failure to comply will result in a fine. This will improve knowledge of substances on the market, their uses and volumes, and their traceability all along the chain of use. It will also serve to collect information on their toxicological properties and eco-toxicology.

Italy

The unmonitored growth of nanomaterials applications on the market and their possible impact on human health and the environment prompted the Italian government to look at developing a legal instrument for collecting information to inform consumers, workers and those indirectly exposed about risk management and safety measures. Following the Belgian Presidency's high-level conference, Italy is looking for other countries to sign up to a joint project with the European Commission. Italy's Ministry of Health is therefore drafting regulations on a national nanomaterials database with stakeholder participation which it believes would be a valuable complement by making data available to increase knowledge of nanoform substances.

The Health Ministry's Preventive Health Department sees the national database as comprising a general section holding information on firms or research centres, and a specific section containing details of each nanomaterial manufactured, imported or used, with identifying particulars of the nanomaterial, sector, estimated quantity of the substance contained in the product, identified uses, exposure conditions, risk management and disposal measures. Notifying entities will input the data online, utilising a database - the International Uniform Chemical Information Database - that has already been used for REACH registration. Access to the database is clearly the key issue; as the project stands, Italy's REACH Competent Authority would administer it, most probably supported by the Institute of Health. In principle, the database would provide information to all REACH implementation stakeholders, national and EU bodies involved in chemical legislation and workplace safety, and consumers.

The Netherlands

Traceability has been studied in the Netherlands in terms of precaution and transparency as key principles for nanomaterials policy. Use is made of the risk assessment paradigm, a stepwise policy formulation method based on knowledge development, and a big focus is placed on stakeholder participation rather than simple consultation in an attempt to raise all stakeholders up to the same level of information. To implement this policy, fifteen percent of the 125 million euro innovation subsidy has been allocated to risk-related research for a 5-year period and the National Programme on Nanotechnology is currently prompting the industry to create safe working conditions.

It is worth noting that the Netherlands is trying to drum up interest among other Member States in following its approach on nanosafety programmes, and is also lobbying for more European legislation on liability for precaution and traceability of nanomaterials.

Other countries

Other countries, although lower profile, are moving towards action, crafting their strategies from a national agenda. This makes a harmonised European strategy more difficult to achieve. The UK Government response to the Science and Technology Committee report published in January 2010 was to recommend that the Food Standards Agency work with other government departments to develop a scheme to collect information on nanomaterials in general. Germany's Environment Minister has also referred to the need for a registry at EU level. (ENDS Europe DAILY, 03/02/11).

Outside the EU, Norway is following REACH as its main chemicals regulation. The Pollution Control Authority has announced the establishment of a national product register to which articles containing hazardous chemicals must be notified. When notifying their products, companies are asked voluntarily to disclose as a separate item in their declaration whether they contain nanomaterials. According to the Product Register, the main reason for going with voluntary registration was to get a rapid broad brush picture of the market.

A need for a regulatory framework

Despite the complexities of setting up a harmonised registry, the differing steps taken by Member States are reason enough to have the European Commission coordinate those initiatives and bring forward a proposal. A consideration of the different national approaches on nano-registries reveals lines of convergence on the idea that all substances should be able to be evaluated and that public inventories and labelling bring transparency. This calls for a governance approach by the European Commission, and the Belgian Presidency initiative was key in bringing the Commission to an awareness of the need to translate it into policy in short order.

Arguably, a mandatory registry will underwrite the development of a source of data usable by authorities and other stakeholders, in which industry participation will also be meaningful. It would provide a gateway for access to information and services. The information generated will facilitate monitoring of any human or environmental contamination, and identification of liability for any harmful effects. In terms of policy, such information will be helpful to update existing regulations.

Registry information will expand consumers and users' understanding and knowledge of where to seek assistance. Having this information available will increase confidence and improve the proper use of nanomaterial articles. It would give a clearer picture of who is exposed to what, and hence guide risk management. It would give a better understanding of what is on the market and would cover nanomaterials produced or imported in quantities under one tonne, linking in to the REACH regulation.

From a policy perspective, voluntary measures have the benefit of serving as a test bed for later regulatory measures, but such

measures are open to the criticism that they impede proper regulation. The short-term gain is offset by the facts that voluntary schemes have too little take-up among firms, lack control, and tend not to disclose negative information.

Member States' actions reflect considerable interest in the idea of a nano-registry. They are converging on the need for more, and more accessible, information, and acknowledge the ineffectiveness of voluntary programmes. But going down the voluntary road for information's sake is no solution.

Also, for Member States to go it alone is only a suboptimal solution. Effective EU-wide coordination of such a register would facilitate data sharing, link-ups for harmonisation, and a coordinated risk strategy. Done at an early juncture, it would bring down social costs in the long term, and stimulate public interest.

The ideal situation would be for Member States to join forces in working on a harmonised scheme. The European Commission and its Joint Research Centre could take an urgent position on the matter to work as coordinators for the Member States in housing and running the mandatory registry. As a regulatory step, the European Chemicals Agency (ECHA) which is collecting registrations of chemicals substances under REACH, should be tasked with developing a separate inventory of all nanoform substances for which a Classification and Labelling notification has been received, or for which the registration dossier evidences a nano form content.

Conclusion

Nanotechnologies are part of the rush to innovate, but much uncertainty still surrounds the risks of nanomaterials. Research and development are moving on apace, but health and safety and precaution are lagging far behind. Lessons from the past – such as asbestos - and the present - the quite literal fall-out from the Fukushima nuclear plants - are examples of the potential repercussions. Reliance on the current safety and precautionary approaches and the very little information available are not enough - accurate data are urgently needed.

Nanomaterial traceability is not just about tracing products or recording information; it also plays into health and safety and market surveillance. It can deliver specific objectives like supporting manufacturers who take responsibility for their products. For Europe, responsible nanotechnology innovation involves putting enforcement into practice.

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The ETUI is financially supported by the European Union. The European Union is not responsible for any use made of the information contained in this publication.