National Institute for Public Health
and the Environment
Ministry of Health, Welfare and Sport

Opinions in the Netherlands on European registration

Opinions in the Netherlands on European registration of consumer products containing nanomaterials

Executive summary

Seven questions regarding registration of consumer products containing nanomaterials

1. Why is a Dutch stakeholder analysis performed on a European inventory?

The market for consumer products containing nanomaterials is growing very rapidly worldwide (Woodrow Wilson database, 2010[1]; Wijnhoven *et al.*, 2011). Under the existing regulatory framework, including the General Product Safety Directive[2], these consumer products must be safe when they are placed on the market. There are, however, particular uncertainties concerning the evaluation of the safety of nanomaterials for human health and the environment. One of the main uncertainties stems from the fact that there is limited insight in which consumer products contain nanomaterials. This has fuelled growing interest in the establishment of a European register of products containing nanomaterials.

The Dutch Parliament is among those who have been calling for registration of such consumer products. Indeed, it has adopted a motion on the mandatory notification of products containing nanomaterials. In response to this motion the National Institute for Public Health and the Environment (RIVM) was asked to perform an inventory on the opinions and needs of stakeholders in the Netherlands with regard to registration of consumer products, including food products, containing nanomaterials. The scope of this inventory was to be prepared in anticipation of an eventual European registration system being established.

2. What was done?

Discussions around registration generally focus on the tool to be used, i.e. a database. However, stakeholders have more divergent opinions on the questions concerning or the exact aims to be addressed by such a database. A dialogue between stakeholders was facilitated in order to poll views on how to address the lack of information on consumer products containing nanomaterials and under what conditions a register could actually help. Such inventories provide insights into common and contradictory views, which in our opinion are essential if we are to make progress. Too often, stakeholders seem to jump to conclusions about each other's intentions and views on the usefulness of a database.

Dutch stakeholders were selected and invited to participate in the dialogue. Representatives of various ministries, enforcement authorities, industries and non-governmental organisations were first interviewed by RIVM researchers prior to the establishment of a discussion panel. They were then invited to participate in the discussion panel, which was led by RIVM. The results of the interviews were used as input for this panel. The main points on the agenda were:

1) Is a register/database of products containing nanomaterials desirable?
2) How can we in the Netherlands best prepare for a European register/database?
3) What information should be registered?

For a more detailed description of the interviews with and discussions between stakeholders, a separate report has been published (Wijnhoven and Noorlander, 2013; in Dutch).

3. What is going on in Europe?

The European Commission has not yet introduced a European register of products containing nanomaterials. The lack of operational instruments at a European level has driven some member states to initiate their own national activities on regulation of nanotechnologies and nanomaterials.

France was the first country to adopt a decree concerning mandatory registration of products containing nanomaterials. The decree (2012-232, which came into force in January 2013) requires companies that manufacture, import and distribute nanomaterials in quantities of ≥ 100 g to submit an annual declaration containing information on quantities and use to the authorities. This decree applies to importers, producers and distributors of nanomaterials, as well as to professional users and research laboratories located in France. The registration is focused on substances at the nanoscale that are intentionally manufactured and introduced into a product from which they are likely to be extracted or released under normal or reasonable conditions of use. By requiring this registration, France aims to obtain a better understanding of nanomaterials and their use, improve traceability, improve its knowledge of the market and the volume of nanomaterials involved, and collect information on (eco)toxicology of nanomaterials (Paultre, 2013).

Belgium has expressed its intention to introduce a national register similar to the French system. An assessment of the scope of the draft legislation and an impact assessment will be conducted by a consultancy this year, and the law could potentially come into force by December 2013. Which products and what information will have to be registered is still under discussion, as is the question whether registration will only apply to the products from

[1] *http://www.nanotechproject.org/inventories/consumer/*
[2] *General Product Safety Directive, 2001/95/EC, OJ L 11.*

which the nanomaterials are released or to all products that contain nanomaterials. The purpose of registration in Belgium will be to ensure the sustainability of this innovative technology, to create confidence and transparency for the general public and workers, to ensure traceability, hence allowing for government intervention in case of hazards to public health, workers or the environment, to acquire a better knowledge of the market, the features of those materials and their potential exposure risks, and to set up a knowledge database which may be necessary as and when a national or European regulatory system evolves (Piñeros Garcet, 2013).

Denmark plans to introduce legislation that will establish a national database of products containing nanomaterials and will require producers and importers of such products to report information to the government. The draft legislation was presented to the Danish Parliament in November 2012; if the proposals are approved the law should come into force on 1 September 2013. Denmark intends to register nanoproducts, i.e. mixtures and articles that contain or release nanomaterials. The purpose of registration in Denmark will be to provide an overview of the nanoproducts that are on the Danish market, the extent of their use and the purposes they are used for, to provide information for knowledge-building in respect of exposure of nanomaterials and its consequences for consumers and environment, and to inspire the European Union to develop a solution for registration of nanoproducts (Ingerslev, 2013). However, because only producers and importers will have to register consumer products containing nanomaterials, it will not be feasible to ensure the traceability of products in the supply chain.

Italy is working on a voluntary register. Italy intends to register mixtures, articles and consumer products from which nanomaterials are released. Information on mixtures, articles and consumer products that contain nanomaterials is optional. The information registered will be available for use by the relevant ministries (responsible for human health, environment, industry, etc.) and national institutes (responsible for human health, environmental protection and research, worker protection) in relation to their field of expertise. It will also be published in periodic reports for the purpose of informing the public about types and uses (Polci and Alessandrelli, 2013). Because this is a voluntary register, however, it is uncertain how complete it will be, and it will not be enforceable.

In **the Netherlands**, a motion put forward in the Dutch Parliament by Besselink and Gesthuizen has been adopted on mandatory notification of products containing nanomaterials. In this motion, the development of a European registration of products containing nanomaterials is supported. Although national registration of these products is neither envisaged nor preferred (Besselink and Gesthuizen, 2009), the necessity of gaining an insight into opinions and needs of Dutch stakeholders on this issue has been acknowledged in Dutch policy.

4. Do the existing legislative frameworks already cover consumer products containing nanomaterials?

REACH, potentially the most suitable piece of legislation for filling the information gaps on nanomaterials, only registers nanomaterials before they are processed in a product, and does not provide detailed information on nanomaterials in products or end products. Therefore, REACH cannot cover the safety issues around products containing nanomaterials. In addition, the GPSD - the relevant product legislation - does not provide the required information as this product legislation is based on the precautionary principle that every product on the market must be safe. The GPSD does not mention nanomaterials specifically and appears to be too general. Some specific types of legislation address nanomaterials (for biocides, cosmetics[3] and food[4], discussed by Bleeker *et al.*, 2012, 2013), but these only cover a small fraction of the large variety of consumer products containing nanomaterials.

REACH[5], the main EU regulation on chemicals, is assumed to be the regulatory cornerstone for ensuring the safe use of chemicals for man and the environment and thus also for nanomaterials. In particular, REACH registration is potentially the best piece of legislation for filling the information gaps on nanomaterials. However, only limited information has been gathered on nanomaterials in the first registration phase, demonstrating that REACH is not living up to the expectations for nanomaterials (Azoulay, 2012). This is at least partly due to the following shortcomings in the current legislation.

REACH currently does not define nanomaterials and leaves it up to the registrant to decide whether a substance is a nanomaterial or not, according to his own criteria. This clearly underlines the need for a definition of nanomaterial (according to the EC recommendation) to be implemented in the REACH regulation.
Since REACH distinguishes different registration dates for chemicals that were already on the market (so called "phase–in" substances) and those that are newly introduced on the market,

[3] *Regulation (EC) No 1223/2009 on cosmetic products; Regulation (EU) No 1169/2011 on the provision of food information to consumers; Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food.*
[4] *Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products.*
[5] *Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemical Substances (REACH), establishing a European Chemicals Agency [...].*

nanomaterials sharing the same chemical composition as a non-nanomaterial with phase-in status will automatically benefit from the status of the non-nanomaterial, regardless of the fact that the nanomaterial is being newly introduced. If such non-nanomaterials are manufactured or imported in quantities of 1-100 tonnes per year per registrant, they do not need to be registered until 2018. This may lead to the undesirable situation whereby nanomaterials manufactured as part of these lower quantities will not be registered, so there will be no information available on them.

Production volumes also play a significant role in determining whether and how substances are accounted for under REACH. The overall rule of thumb is that the higher the volume, the more information is required. REACH registration requirements only apply to production volumes of one tonne or more per year per manufacturer or importer. This volume threshold is inadequate for nanomaterials as these are usually produced in much smaller quantities. For nanomaterials, therefore, a solution is needed that will prevent nanomaterials from remaining under the radar.

Risk assessment information made available in the context of REACH will be based on testing guidelines that may need to be improved in order to take on board the specific hazards and exposure pathways of nanomaterials. In principle, the OECD has concluded that the commonly used OECD Test Guidelines are in general appropriate for nanomaterials, although in some cases they may need to be adapted to the specificities of nanomaterials. Furthermore, if a bulk substance is characterised as non-hazardous, as is the case for the vast majority of substances from which nanomaterials are derived, this classification will be extended to the nano form of the substance, with no additional requirement to generate data on specific effects of the nano form.

Although three REACH Implementation Projects on Nanomaterials (RIP oNs[6]) have been carried out to address the concerns around nanomaterials, some of the issues identified above have not yet been fully resolved. The main concern, i.e. the lack of information on nanomaterials, cannot currently be resolved by REACH. However, discussions on improving REACH for nanomaterials are still on going.

Besides these concerns around whether REACH is fit for purpose for addressing the concerns on nanomaterials, the safety of products containing nanomaterials is also of importance. The structure, size and behaviour of nanomaterials can change during the production process. This means that nanomaterials in a product may have to be seen as different from nanomaterials before being processed in a product.

GPSD, the regulatory frameworks for products, is based on the precautionary principle, i.e. products can only be placed on the market if the potential human health, safety and environmental risks are sufficiently controlled. The rapid development of nanomaterials in combination with a potentially different behaviour has raised concerns that these materials may introduce other hazards than those caused by non-nanomaterials during exposure, or even new hazards. Even if this different behaviour of nanomaterials can be tackled effectively in new or existing regulations on nanomaterial production, the situation is further complicated by the fact that nanomaterials may change when used in a product and during its future life-cycle. Nanomaterials are not specifically mentioned in product legislation and may thus potentially require the legislation to be changed.
As indicated above, only a few types of legislation currently address nanomaterials specifically (cf. Bleeker *et al.*, 2012, 2013). As the cosmetics and food regulations[7] were adopted before the Commission Recommendation on the definition of nanomaterial[8], these regulations include deviating definitions. As a result, the publication of the Recommendation initiated renewed discussion on the definitions in these legislations. Furthermore, the Cosmetics Regulation provides for the obligation to notify cosmetic products containing nanomaterials to the Commission electronically from July 2013. It also includes the obligation to indicate ingredients in the nano form followed by the word 'nano' in brackets. Similarly, the EU regulation on food information to consumers[9] provides for mandatory labelling from 13 December 2014 of any product containing engineered nanomaterials with the suffix 'nano' in brackets in the list of ingredients.
The regulation on biocides[10] adopted the definition from the Recommendation and provides for the separate assessment of nanomaterials in biocidal products, while also prohibiting the simplified approval procedure for nanomaterials.

5. Why do we need to register consumer products containing nanomaterials?

According to Dutch stakeholders, there are two main goals which an overview of products containing nanomaterials should aim to meet:

1) Transparency for consumers
2) Traceability in the supply chain

Both goals could deliver insights into exposure to nanomaterials

[6] *See e.g. http://ec.europa.eu/environment/chemicals/nanotech/index.htm#ripon.*
[7] *Regulation (EC) No 1223/2009 on cosmetic products; Regulation (EU) No 1169/2011 on the provision of food information to consumers; Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food.*
[8] *Commission Recommendation of 18 October 2011 on the definition of nanomaterial (2011/696/EU).*
[9] *Regulation (EU) No 1169/2011 on the provision of food information to consumers.*
[10] *Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products.*

from consumer products and the assessment of the potential risks of these products.

Transparency for consumers

Transparency for consumers means providing consumers with information on which products contain nanomaterials. Stakeholders have differing opinions on what information should be available to consumers. A register of consumer products containing nanomaterials is seen as a helpful tool that will enable consumers to make a conscious decision as to whether they would want to buy such products or not. Information on consumer products containing nanomaterials should become publicly available and easy accessible in order to support free choice in respect of these products. A register or database could be a useful tool to achieve this. However, the required content of such a database needs thorough discussion among stakeholders, as this requires multi-stakeholder activity and interaction. Clarity about each stakeholder's role in developing and maintaining a register will be helpful.

Traceability in the supply chain

An overview of consumer products containing nanomaterials could be used to improve traceability in the supply chain and may lead to better control of incidents and risks. What information needs to be registered for this purpose has not yet been addressed and needs further discussion. It should be noted that in order to achieve traceability in the supply chain, information on products containing nanomaterials, rather than consumer products only, would be required. All stakeholders subscribed to the importance of traceability. A register/database, preferably at European level, could be one of the options for supporting such traceability. In addition, an overview of products containing nanomaterials could be of value to different stakeholders in the product chain, provided that the information is publicly available.

Clear central management and establishment of such a product register at a European level were seen as pre-requisites for both purposes. A national product register could result in overlaps with EU legislation and in different obligations and regulations in individual EU member states. This in turn could lead to increased costs for authorities and enterprises that need to notify their products. If a European register is set up, specific attention should be paid to avoiding duplicate obligations. European substance-related regulations (REACH and CLP[11]) and product-related regulations (Cosmetics[12], Novel Food[13], additives (FIAP)[14] and Food[15]) should be used as the basis for a European product register, since both contain appropriate points of departure (e.g. registration and notification requirements).

6. Do Dutch stakeholders foresee alternative options for mandatory European registration?

Yes, the discussion panel revealed ideas for alternative options. Product labelling was mentioned as an alternative option for achieving transparency, and dedicated registration of relevant information by industrial partners themselves was seen as an alternative option for ensuring traceability in the supply chain.

Transparency for consumers

Mandatory registration or a database of consumer products containing nanomaterials was not seen as the sole option for achieving transparency for consumers. The discussion between stakeholders revealed that product labelling could be seen as an alternative to a register. There is an ongoing discussion about the labelling of products containing nanomaterials. The EU cosmetics regulation and food legislation require products containing nanomaterials to be labelled (name of the ingredient, followed by 'nano' in brackets). Comparable labelling requirements for other types of consumer products were seen as a solution by some stakeholders.

Traceability in the supply chain

An alternative option to mandatory registration or a database of consumer products containing nanomaterials could be registration by industrial parties. It became clear from the discussion with stakeholders that central registration or a central database is not the ultimate means for ensuring traceability in the supply chain. It is the opinion of the industrial parties involved that all the necessary information is already available in the supply chain. The industrial parties state that it is merely a matter of organising their information. In this approach, it was concluded that the European Commission should set a framework and rely on timely delivery of information by industry in case of incidents. Consensus between supplier (industry parties) and recipient (government) about the information requested should be achieved at a detailed level in order to secure traceability wherever necessary.

[11] *Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and [...].*
[12] *Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on Cosmetic Products.*
[13] *Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients.*
[14] *Food Improvement Agent Package (FIAP) (OJ, L354, 51). REGULATION (EC) No 1333/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on food additives.*
[15] *Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers [...].*

7. Which further actions were recommended?

1. Investigate the best option for the purpose of "transparency for consumers": either by means of a European register/database of consumer products containing nanomaterials or by means of product labelling.

Depending on the results of the investigation, the following questions or subjects should be addressed:

European register/database

- Which products should be registered?
- What definition for nanomaterials should be used?
- What kind of product information should be registered?
- Who will be responsible for and manage the register/database?
- Who will gain access to which information?
- What are the costs and benefits?
- Is a European register/database feasible?
- Who has what responsibility (government, EU, industry, NGOs, consumers, workers)?
- What can the Netherlands contribute to the realisation of a mandatory European register?

Product labelling

- What kind of information should be labelled?
- Which information is of added value for consumers?
- What definition for nanomaterials should be used?
- EU regulation should be adapted to ensure that all consumer products containing nanomaterials are labelled.

2. Investigate the best option for the purpose of "traceability in the supply chain": either by means of a European register/database of consumer products containing nanomaterials or by industry being responsible for managing the collection of relevant information in the supply chain.

Depending on the results of the investigation, the following questions or subjects should be addressed:

European register/database

See recommendation 1.

Responsibility of industry for information in the supply chain

- What kind of product information should be registered by industry?
- Is the required information available in the supply chain?
- Can industry manage the registration process?
- In what form should the information be delivered and within what period of time?
- Who may request information?
- EU should set a regulatory framework for industry.

3. The opinions and results of the investigation should be communicated to the EU; in that case, the Dutch point of view can be taken into account in the decision process on mandatory European registration of consumer products containing nanomaterials.

4. Lessons to be learned from the initiatives in EU member states, addressing the most important issues:

- What purposes can be achieved by the national registers?
- What is the added value of a national product register?
- What would the registered information be used for?
- Is it possible to perform a costs-benefit analysis?
- Do these national initiatives have to be harmonised at the EU level?

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