Trans Atlantic Consumer Dialogue

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Resolution on the need for a mandatory reporting scheme and inventory for nanomaterials contained in consumer products

Background

In its 2009 Resolution on Consumer Products Containing Nanoparticles[1], the TACD called for establishing mandatory reporting schemes[2] in the EU and the US as there is an urgent need to identify which kind of nanomaterials are used in which consumer products. Moreover, the TACD called for establishing a publicly available inventory[3] of consumer products containing nanomaterials[4].

The TACD emphasized the call for more transparency concerning what foods and other products containing nanoparticles are available on the market in its submission to the Transatlantic Economic Council (TEC) in September 2010[5].

There is an urgent need to improve the traceability of nanomaterials in products and to enhance transparency for consumers as more and more products containing nanomaterials or claiming to contain nanomaterials are available to consumers in the EU and the US. In October 2010, ANEC and BEUC released their updated inventory of products claiming to contain nanomaterials. Compared to 2009, many more products (475 across the categories of appliances, cross cutting, electronics, food & drink, products for children, health & fitness and home & garden) were found to be claiming to use nanomaterials. Only 4% of products present in the inventory of 2009 were missing from the purported market in 2010. Worryingly, some manufacturers do not use a nanoclaim when advertising the product on their homepage. h\However, the same products often have a nanoclaim when sold/ advertised on other websites such as internet shops. As was the case in 2009 BEUC and ANEC did not test the products but looked for the claims about nanotechnologies and nanomaterials that consumers can find while shopping[6]. The updated inventory was presented to the Health and Consumers Commissioner John Dalli at a high-level workshop on Friday 22 October 2010.

In Denmark a similar inventory has been compiled by the Danish Environmental Protection Agency. In 2007, the inventory[7] contained 243 products, and a soon to be published[8] update will show that there are now more than 600 products on the Danish market.

In the US, the Woodrow Wilson Center[9] established an inventory of nanotechnology-based consumer products which, as of March 2011, had more than 1,300 entries. The Project on Emerging Nanotechnologies Director David Rejeski stated, “When we launched the inventory in March 2006, it contained 212 products. If the current trend continues, the number of products could reach 3,400 by

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1 TACD Resolution on Consumer Products Containing Nanoparticles, June 2009.

2 We use the term “mandatory reporting scheme” for a system under which manufacturers have to report to a public body which nanomaterials are used in which products and in which quantities before placing the products on the market.

3 We use the term “inventory” for a public accessible database which lists all consumer relevant products which contain nanomaterials. Ideally such a database should have different search options for the general public such as a search per manufacturer, per product and per nanomaterial.

4 In this paper we use the term “nanomaterial” for engineered/ manufactured nanomaterials. In our understanding this includes soluble and non-soluble nanomaterials. Moreover, the term comprises manufactured nanomaterials if they are present in products due to by-products from a manufacturing process which involves the bulk form.

5 TACD Recommendations to the Transatlantic Economic Council, September 2010, http://tacd.org/index.php?option=com_docman&task=cat_view&gid=57&Itemid=40

6 http://www.anec.eu/attachments/ANEC-PT-2010-Nano-017.xls

7 http://www2.mst.dk/common/Udgivramme/Frame.asp?http://www2.mst.dk/Udgiv/publikationer/2007/978-87-7052-468-1/html/default.htm

8 The Technical University of Denmark has announced that it will publish the inventory in June 2011

9 Woodrow Wilson International Center for Scholars, http://www.nanotechproject.org/inventories/consumer/

2020."[10] PEN believes this to be a very conservative number. Rejeski testified in 2009, "These products are available in shopping malls or over the Internet, and we have purchased many of them online. Thanks to business-to-consumer (B2C) e-commerce, nanotechnology products easily flow across international borders, raising control, trade, and oversight issues."[11] In the absence of mandatory government reporting schemes this list and another list kept by the International Center for Technology Assessment on silver products have been compiled relying primarily on product claims made on the Internet.[12]

Following significant pressure for a reporting scheme from Parliament, NGOs and consumer groups, in 2010, the European Commission asked the consultancy "Milieu" to analyse the current status of information reporting on nanomaterials in the context of the EU chemical legislation (REACH and CLP) and to assess the need for additional information reporting. Although the initial aim of the study[13] was to explore the feasibility of setting up a voluntary reporting scheme, the consultants felt that the chemicals legislation has serious gaps[14] with regards to nanomaterials and recommended setting up a mandatory reporting system. The study recommended keeping such a mandatory reporting system within the REACH framework.

1. Why is there a need for a mandatory reporting scheme?

No one (person, organisation, company or authority) has a complete overview of the usage of nanomaterials and nanoparticles in consumer products. It is essential that governments and regulators are able to assess exposure of consumers and the environment coming from nanomaterials to enable them to take an appropriate approach to the management of risk. This need becomes all the more important when there is significant uncertainty over the potential impact of the materials in question. This is certainly the case for nanomaterials for which there are well reported gaps in the knowledge of environmental toxicology, toxicokinetics, and human toxicity[15]

Voluntary reporting schemes have been experimented with in various EU countries and around the world, with very limited reporting of nanomaterial product data[16]. Consequently, national compulsory declaration measures are being taken in France[17] and are being examined in Italy, Belgium and the Netherlands[18].

In the US, since December 2008 the voluntary Nanoscale Materials Stewardship Programme (NMSP) has received submissions on only a small fraction of the number of products which are available to US consumers. In order to address the remaining environmental health and safety data gaps, the US EPA is considering launching a mandatory reporting scheme[19]. In addition, the US EPA uses the regulation on pesticides to require reporting on health effects related to nanomaterials used in pesticides.

While there may be benefits of reporting schemes at national level, there is a risk of market fragmentation. Thus, harmonization is needed at EU and international level. The TEC provides an excellent forum to share the experiences about the development of harmonised reporting schemes in the EU and US and to work to ensure that such schemes are harmonised.

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[10] Cited in "Nano-enabled Consumer Products Continue to Rise," Project on Emerging Nanotechnologies, March 11, 2011. http://www.nanotechproject.org/news/archive/9231/

[11] David Rejeski, "Comments submitted to the Consumer Products Safety Commission," Project on Emerging Nanotechnologies, August 18, 2009, http://www.nanotechproject.org/process/assets/files/8278/pen_submission_cpsc.pdf

[12] See 'nano silver product list' available at: http://www.nanoaction.org/nanoaction/page.cfm?id=239

[13] Milieu/RPA (2010): Information from Industry on Applied Nanomaterials and their Safety: Final Report. Proposal for an EU Reporting System for Nanomaterials, p. ii.

[14] Among the gaps identified are the following: 1) substances placed on the market of less than 1t p.a. will not be registered under REACH, 2) in case a specific use will not be reported in the registration dossier, there may be an information gap in the communication between different economic operators 3) significant time lags in REACH and CLP implementation.

[15] Emergnano: A review of completed and near completed environment, health and safety research on nanomaterials and nanotechnology. March 2009.

[16] The UK scheme received only 12 submissions in 2 years.

[17] Outcome of Grenelle (French initiative on environmental policy): Commitment n°159 about manufacturing of nanomaterials (organization of public debates, mandatory system of reporting, cost/benefits analysis, information and protection of workers),Mandatory reporting scheme, which aim is traceability, risk management and workers protection, to be in place in two years time (obligation for manufacturers, importers and distributors about identity of nanomaterials and downstream users, unique database). It will anticipate and complement REACH as it will also cover substances under 1 t/y. Enforcement decree to be drafted soon.

[18] Regulering van onzekere risico's van nanomaterialen mogelijkheden en knelpunten in de regelgeving op het gebied van milieu, consumentenbescherming en arbeidsomstandigheden, STEM, 2010; Legal feasibility study on the introduction of a nanoproduct register, Öko-Institut e.V., Produced with the support of the Federal Environment Agency, and with funding from the Federal Ministry for the Environment, Nature Conserva-tion and Nuclear Safety, Germany, 2010.

[19] Milieu/RPA (2010): Information from Industry on Applied Nanomaterials and their Safety: Final Report. Proposal for an EU Reporting System for Nanomaterials, p. ii.

2. Official calls for a reporting scheme

The role of the Belgian EU Presidency (July – December 2010)

The Belgian EU Presidency organised a workshop "Towards a regulatory framework for the traceability of nanomaterials", held on 14th of September 2010. In the conclusions from the workshop, the Belgian Presidency calls for:

- developing harmonized compulsory databases of nanomaterials and products containing nanomaterials;
- using such databases as the base for traceability, market surveillance, gaining knowledge for better risk prevention and for the improvement of the legislative framework;
- taking into account in the design of such databases the need for providing information to the citizens, workers and consumers regarding nanomaterials and products containing nanomaterials as well as the industry's need for data protection[20].

EU Council Conclusions on environmental & Health action plan on 20 Dec 2010

On December 20th 2010, the European Environmental Council adopted some conclusions on nanomaterials and nanotechnologies, as part of its recommendations to the European Commission about the preparation of a second Environment and Health Action Plan (EHAP). The Council "invites the Commission to" (....) evaluate the need for the development of specific measures for nanomaterials relating to risk assessment and management, information and monitoring, including the further development of a harmonized database for nanomaterials (…)".[21]

The European Parliament on nanotechnologies

In 2009, the European Parliament (EP) had shown in its resolution on nanotechnologies[22] disagreement with the Commission's view[23] that present legislation is sufficient to cover nanotechnologies. The EP had been calling on the Commission "(…) to review existing legislation and to compile an inventory of the different types and uses of nanomaterials on the European market, while respecting justified commercial secrets such as recipes, and to make this inventory publicly available (…)"[24]. Moreover, the EP reiterated "calls on the Commission for the provision of information to consumers on the use of nanomaterials in consumer products: all ingredients present in the form of nanomaterials in substances, mixtures or articles should be clearly indicated in the labeling of the product (…)"[25].

The European Parliament called on the Commission to compile such an inventory before June 2011.

4th annual nanotechnology Safety for Success Dialogue

On 29-30 March 2011, the EU Commission organised the 4th nanotechnology Safety for Success Dialogue, a workshop which brings together regulators and stakeholders. At this occasion, a call for a mandatory database was made and a joint project from Belgium, France, Italy, NL and Germany as observer was presented[26].

US EPA approach on pesticides

The US EPA has proposed regulations that require reporting of an active ingredient as a "new" pesticide if it is a nanoscale form of a pesticide (FIFRA - Federal Insecticide, Fungicide, and Rodenticide Act or PRIA – Pesticide Registration Improvement Act)." This would apply even when a non-nanoscale form of that same active or inert is already in a registered product[27]. Unfortunately, this new regulation is being held up at the White House Office of Management and Budget after complaints from nano-silver and other pesticide industry lobbyists.

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[20] http://docushare.anec.org/docushare/dsweb/Get/Document-65461/CONCLUSIONS%20OF%20THE%20HLE%20100914_FINAL.pdf

[21] http://www.consilium.europa.eu/uedocs/cms_Data/docs/pressdata/en/envir/118646.pdf

[22] European Parliament resolution of 24 April 2009 on regulatory aspects of nanomaterials (2008/2208(INI)), http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+TA+P6-TA-2009-0328+0+DOC+PDF+V0//EN

[23] Expressed in the Commission Communication of 17 June 2008 on „Regulatory aspects of nanomaterials" (COM(2008)0366).

[24] European Parliament resolution of 24 April 2009 on regulatory aspects of nanomaterials (2008/2208(INI)), point 16.

[25] Ibidem, point 17.

[26] Report to plenary from break-out group 1 (INTELLIGENCE).

[27] See comments of Bill Jordan, Office of Pesticide Programs, US EPA http://www.nanotechproject.org/process/assets/files/8309/epa_newpolicy_nanomaterials.pdf

3. What should a mandatory reporting scheme look like?

3.1 What information has to be reported to the authorities?

All nanomaterials which are used in products - whatever the nature of the product – should be notified before the products can be placed on the market. Independently of the intended user group and product the minimum statement should take the following form[28]:

- identification of the substance to include:
  - CAS number and name of the substance
  - Size range
  - Specific surface area
  - Aspect ratio
- the quantity in which the substance is used;
- the toxicological profile of the substance and relevant safety data;
- information about the test methodologies used and reasonably foreseeable exposure conditions;
- A full risk assessment for the use of the nanomaterial in the specific product.

Current annual production estimates of nanomaterials are very uncertain. The degree of uncertainty about production levels was a key finding of a study that estimated annual U.S. production of nano-titanium dioxide at somewhere between 7800 and 38,000 tons per year.[29] Nanomaterial manufacturers should be required to submit to competent authorities an annual report on the production level of each kind of Engineered Nanoscale Materials the manufacturer produces to assist in pre-market safety assessment and post-market surveillance programs. The per firm production levels would be maintained as confidential business information while overall levels would be published as part of the competent authority's annual reporting on nanotechnology regulation and oversight.

In addition, for all products including food, the presence of nanomaterials should be indicated in the product technical files and/or the safety data sheets. Any definition of nanomaterials for such a purpose must have an upper size limit of at least 300nm[30]. These requirements would allow governments and competent bodies to assess those products which are most likely to be of greatest concern and would allow for proper exposure assessments to be carried out.

For products containing nanomaterials already available to consumers, industry should provide the above information to the authorities without delay or remove the product from market until which time they can provide the required information.

A harmonised mandatory reporting scheme will anticipate and be complementary to the REACH requirements as it would apply to all nanomaterials irrespective of tonnage threshold, etc. The mandatory reporting scheme should be harmonised at the EU level, but should be divided to show country and sector specific data. As a lot of the products are marketed in many EU countries, resources can be saved if the inventory is set up at EU level. Based on the EU inventory, national inventories can be made available in the Member States.

As a prerequisite for an EU harmonised reporting scheme, the adoption of a regulatory definition of nanomaterial is essential. As European and American consumers, we support the principles adopted in the definition proposed by the European Commission in the draft Recommendation of October 2010, although we believe the upper size limit should be of at least 300nm.

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[28] ANEC comments on prCEN ISO/TS 13830 "Manufactured nanoparticles - Guidance on labelling", May 10 (ANEC-PT-2010-Nano-006).

[29] Christine Ogilvie Hendren etal., "Estimating Production Data for Five Engineered Nanomaterials As a Basis for Exposure Assessment," Environmental Science and Technology, March 10, 2011, 2564 and Table 2, 2566. http://pubs.acs.org/doi/pdfplus/10.1021/es103300g.

[30] For drugs, the upper size limit should be 1000nm.

The development of mandatory reporting schemes in the US and EU should be harmonised and the TEC would provide a suitable arena for this to take place.

In the US, the Environmental Protection Agency has proposed mandatory reporting for nano-pesticides[31]. No other US agency has proposed mandatory reporting of nano-materials, although the FDA has used guidance documents relative to nano-drugs and says that it will consider "size" as an aspect of food contact substance approvals.

3.2 Who should provide the information on nanomaterials?

Economic operators (manufacturers, importers and retailers[32]) should nominate a responsible person who is required to collate and report the information detailed above to the authorities in charge of administrating the mandatory register.

3.3 Who should have access to the information?

The United Nations Economic Commission for Europe (UNECE) Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters, 25 June 1998, the "Åarhus Convention" establishes, inter alia, the right of the public to receive environmental information that is held by public authorities. For this reason, the information of the reporting scheme should be publicly available, whilst respecting justified commercial secrets.

3.4 How would the reporting scheme be used?

The mandatory reporting scheme would be used by national authorities to monitor exposure and ensure traceability as it provides information along the supply chain of substances and products containing nanomaterials. Main users could be:

- Regulators;
- Market Surveillance Authorities;
- Agencies working on occupational health and safety;
- Toxicologists;
- Poison emergency centers.

4. How to inform consumers about nanomaterials in consumer products?

4.1 Inventory of products containing nanomaterials and nanoparticles

A product inventory should provide members of the public with clear and easily understood information on what products sold to them use nanomaterials, why they use nanomaterials, and what the uncertainties surrounding their use may be. This information should be required of manufacturers and should respect justifiable commercial secrets.

The public inventory would be used to inform the public of where nanomaterials are used and to highlight the benefits and uncertainties of the nanomaterials to allow consumers to make informed purchasing decisions. Main users could be:

- Consumer organisations;
- Environmental NGOs;
- Trade unions;
- Individual consumers.

[31] Bill Jordan, Office of Pesticide Programs, US EPA
http://www.nanotechproject.org/process/assets/files/8309/epa_newpolicy_nanomaterials.pdf p.16

[32] Retailers would only be required to feed-in data into a mandatory register and product inventory for own-brand products which contain nanomaterials. However, we point out the need for retailers to be informed about the products they sell and to be able to give meaningful information to consumers about nanomaterials.

In order to effectively inform consumers, the inventory of products containing nanomaterials should allow for unambiguous product identification. As a minimum, the following information should be provided: product brand, type, article number, batch number, and picture. It is also important to specify in which part of the product/component the nanomaterial is used. For example, in case of food, it should be specified whether the nanomaterial is present in the food itself or in the packaging (food-contact material).

4.2 Labelling

Products which contain a list of ingredients on the label should indicate the presence of the nano form by adding the word 'nano' in brackets after the ingredient in the ingredients' list. This will soon be required for cosmetics under EU law. We ask for this to be introduced in particular for nanomaterials used in food including food packaging.

For products that do not contain a list of ingredients, the need for labelling should be evaluated on a case-by-case basis taking into account the level of consumer exposure. The format of the labelling would also have to be decided on a case-by-case basis.

However, labelling requirements for products should not at all be considered sufficient or be regarded as an acceptable substitute for pre-market safety assessment systems. Regulatory measures ought to be initiated to prevent exposure of consumers and the environment to potentially dangerous nanomaterials and to ensure that consumer products are safe. Requiring only labelling requirements for products shifts the responsibility onto consumers to decide whether to be exposed or not and is thus not acceptable. Moreover, labelling requirements need to be backed up with broader consumer information about nanotechnologies and nanomaterials.

Labelling of materials as 'nano' must be accompanied by clear information on that nanomaterial to enable consumers to make an informed purchasing decision. This information could be supplied by the manufacturer to the public inventory.

National authorities, such as the Environment Protection Agencies, should be able to give more information to consumers. And we call for such bodies to be required to develop sources of clear consumer information on the use, benefits and uncertainties of nanomaterials.

4.3 Claims

All claims which are made about health, safety and/or environmental aspects of products containing nanomaterials should be scientifically substantiated and supported by publicly available information of the methods used to substantiate the claim. Claims made for the efficacy of a product should be backed up by rigorous evidence.

5. TACD Recommendations to the EU and US governments

Today there is a serious lack of information on which products using nanotechnologies are already on the market, in the pipeline or at the research stage. More transparency regarding the uses and applications of nanomaterials is needed[33].

Mandatory Reporting Scheme

We urge the US and EU, with the help of Member States, to set up an extensive mandatory reporting scheme of all nanomaterials used in all products available on the market. At EU level we advocate for one single EU-wide inventory and that all economic operators (producers, importers, and retailers of own branded products) marketing products containing nanomaterials in the EU should be required to register.

Inventory

[33] Small is beautiful but is it safe? ANEC/BEUC joint position paper on Nanotechnology - June 2009 (ANEC-PT-2009-Nano-002final).

In addition, we call for a publicly available inventory of products containing nanomaterials with which consumers come in direct, close or regular contact, and products which lead to discharges into the environment. Such an inventory would not only be in line with the public's right to know what they are being exposed to but would also ensure a proper evaluation of exposure of humans and the environment to nanomaterials. For example, in Europe, the inventory should be based on an EU inventory but should also show which products are available in which EU country and the annual production level of each nanomaterial that enters the market.

Labelling

The requirements to inform the consumer of the presence of nanomaterials in consumer products by labelling must be clearly defined in regulations.

Claims

Claims made on labels of products containing nanomaterials must be substantiated and meet regulatory requirements. Compulsory information to the public about the presence of nanomaterials in products is a way to regulate false claims and avoid unfair commercial practices[34].

[34] For more information see TACD resolution on Consumer Products Containing Nanoparticles, June 2009.