NGO comments on Transparency measures for nanomaterials on the market: Working conclusions

GENERAL COMMENTS

The EEB disagrees with most of the Commission's working conclusions with regard to the transparency measures for nanomaterials (NMs) on the market. In our view, the Commission's conclusions are biased towards industry's economic interests whilst disregarding environmental health and safety concerns and the public right to know. We believe the working conclusions fail to provide the right balance between private and public interests.

We are deeply concerned that the Commission has interpreted the results of the studies related with the transparency measures commissioned by the Commission and the public consultation in a misleading way.

The public consultation revealed widespread agreement among all but industry's stakeholders on the need for an EU nanoregister. In most questions formulated during the public consultation there was strong agreement from citizens and NGOs, most MS authorities and non-industry stakeholders.

The public consultation revealed widespread agreement among almost every non industry stakeholder on:

- the main objectives of a nanoregister;
- the utility of a nanoregister;
- the health and/or environmental hazards and health or/and environmental incidents associated with nanomaterials;
- a registry being important for helping managing environmental health and safety concerns;
- the need for a register to improve transparency and consumer trust;
- the likelihood that information provision would stimulate innovation with no substantial impact on competitiveness;
- the need for notification per use to enable full traceability;
- the type of information concerning products containing nanomaterials to be provided;
- the need for information presented to be suitable for the user and tailored for targeted groups;
- the fact that a European nanomaterial registry would extend the information already collected under REACH in two main areas. Firstly, there would be an explicit reference to the presence of nanomaterials and, secondly, a registry would not need to be restricted by the current one tonne per annum threshold which applies to chemicals under REACH.

Most of these conclusions are ignored in the Commission's conclusions.

The Commission's conclusions are not based in facts but in old vague assertions put forward by industry stakeholders. The over-inflated estimates of the regulatory burden to industry of a nanoregister do not stand up to scrutiny.[1]

The Commission's conclusions dismiss the increased transparency measures as a way of addressing concerns regarding the environmental health and safety impacts of nanomaterials (NMs) and the public right to know.

In spite of the paucity of information, there are significant documented health concerns associated with nanomaterials. Research on humans and animals indicates that many nanomaterials are able to enter and persist in the body, rapidly migrate to the organs, get deep into the lungs, cross the blood/brain barrier into the brain, cross the placenta, penetrate the skin, and even some protective equipment. The role of nanomaterials in some forms of environmental degradation is also well known, e.g. atmospheric nanomaterials play a central role in ozone depletion.

Smaller means more concerning, this should have been highlighted by the Commission.

Information on hazards and exposure are indispensable prerequisites for decision making on the safe management of chemicals.

It is crucial to bear in mind that the public has a right to access information about the chemicals to which they are exposed. This will enable them to make informed choices and to avoid products containing harmful chemicals, so creating pressure on industry to develop safer substitutes. Therefore, information on nanomaterials must be collected and disseminated. Raised levels of awareness through a nanoregister would help minimise potentially dangerous human and environmental exposure to nanomaterials, and thereby reduce associated adverse health effects.

In light of the early warnings and key data gaps regarding the risks associated with nanomaterials compilation of necessary information and transparency measures should be driven by the precautionary principle. This is the only way to adequately manage the potential risks associated with nanomaterials.

SPECIFIC COMMENTS

Slide 3: Transparency

It is astonishing to learn that the Commission still doubts that there is a lack of transparency while ignoring SCENIHR's conclusion that*:* "there is a general lack of knowledge about the characteristics of nanomaterials in relation to environmental and population exposure".

The German Federal Environment Agency also concluded that "due to failing transparency concerning the type, amount and applications, estimation of exposure and thus evaluation of the potential risk for human health and the environment emanating from nanomaterials is possible only to a very limited extent. In this respect, an NPR [nano product register] could provide a remedy."[2]

According to Friends of the Earth Australia, hundreds of food items sold in grocery stores contain nanomaterials. Although some provisions have been added to certain sectoral regulations their implementation is far from satisfactory (see discussions on the definition in the regulation on food information to consumers, the absences of a register for nanomaterials in cosmetics more than 12 months after it was supposed to be made public, etc…). The lack of reliable information is usually used as an argument to explain those implementation hiatus. A public register would therefore support the enforcement of existing measures rather than impair it, and allow for implementation of existing measures rather than duplicate work. [3]

Nanomaterials are estimated to be widely used in consumer products too: as they are used in a variety of sectors and in numerous products, such as paint, catalysts, sports items, surface treatment products, textiles, vehicle tyres, cosmetics, electronic items and analytical chemical equipment. However, the public has no information on which of these products contain nanomaterials (see previous comments on defective implementation of existing provisions for cosmetics, food information to consumers etc…).

The same applies to biocide and pesticide products.

Nanomaterials have been used in consumer products for around 20 years without basic data being submitted by industry. An estimated 3,000 NMs are used in the EU.

The acknowledged general lack of information on the chemical substances EU citizens are exposed to is the reason why we have the REACH registration system today. However, REACH 'no data, no market' doesn't apply to NMs due to the 1t/y threshold. Only 9 nanomaterials are registered as such under REACH.

The Coommission has also dismissed the fact that 65% of nano substances registered in France in 2014 were produced and/or imported in quantities less than one tonne, the threshold below which the obligation to REACH registration does not apply. This figure can be extrapolated to the EU countries to show the dearth of knowledge on NMs.

Therefore, there is still a general lack of information on which nanomaterials are manufactured and used in the European market, their uses, volumes, intrinsic properties and hazards as well as who produces them, where the producers are placed and in which consumer products they are integrated in. The only way to overcome this lack of knowledge is by an EU nano register.

The Commission's conclusion that "the Information from FR notification system by and large confirms picture drawn in Commission Staff Working Paper" is false. The French register contains between 243 and 422 different substances notified as nanomaterials on the French market, while the Commission Staff Working Paper only states around 20 concrete nanomaterial substances estimated in the EU market. Moreover, 127 substances registered in France were not found in the ECHA's database (which only contains 9 nanomaterials). This clearly shows crucial information on what nanomaterials are present in the EU market that was unknown by the Commission. The information provided by the French notification system not only showed which nanomaterials are currently used in France and it's physic-chemicals characteristics, but also provides valuable broad information regarding which companies use

NMs, in what amounts and for which purpose. Furthermore, titanium dioxide production estimates by the Commission are shown to be very much underestimated (10,000 t/a was estimated in the EU vs 15,000 t/a only in France).

The Commission's statement that "additional information on the presence of nanomaterials on the market mostly concerns materials previously considered as "conventional" materials (80% entered the market before 1981) and fine powders (pigments & dyes account for 66%) that were not developed as a nanomaterial" implies that these substances are therefore safe. This assertion is not valid since firstly, those chemical were registered in the bulk form. The properties of nanomaterials can vary greatly from bulk forms of the same chemical – hence the need for a separate safety assessment. Secondly, the fact that these chemicals have been used for years doesn't demonstrate that they are used safely (another reason why REACH was created). It is also worth to insist that absence of evidence of harm is not evidence of absence of harm.

Slide 4: Market for selected nanomaterials

The fact that the estimated tonnes per annum of nano titanium dioxide reported in the French nanoregister surpasses global estimates in the 2nd Regulatory Review demonstrates just how inadequate current estimates of nanomaterial use are. Estimates of the quantities of nanomaterials being used are essential in order for regulators to conduct basic risk assessments. For example, The German Federal Environment Agency states that:

"The objective of such a product register is the creation of an overview of products containing nanomaterials that have applications in the consumer area and in an open environment. This enables public authorities to set priorities in enforcement and monitoring, to estimate exposure for humans and the environment and, in the case of adverse effects, to ensure traceability."[4]

Slides 5-6: Nanosilver

The assertion that nanosilver in articles is not intended to be released under normal conditions of use is misleading. Nano-silver waste that is not recycled will end up in the environment either as solid waste in landfills or on agricultural land, emission from wastewater treatment plants, or as residual waste from incineration plants. The anti-microbial strength of nano-silver, which makes it desirable in the treating of wounds, could pose a threat to the microbial communities in the environment. Nano-silver bioaccumulates in the soil and has been shown to have impacts on plants, micro-organisms and aquatic organisms. The rapidly growing number of products creates the possibility of a 'mass discharge' of nano-silver into the environment.

Nano-silver is now one of the most commonly used nanomaterials. It is used in clothing, materials, food packaging, surfaces, appliances, toothbrushes and baby bottles. It is also a powerful anti-microbial that is used by hospitals for the treatment of wounds and ulcers.

Its widespread and unnecessary use in a variety of consumer products means that resistance is likely to develop, which will reduce the efficacy of nano-silver in circumstances where it is most needed. Additionally, there are concerns that the use of nano-silver may have impacts on human health. Nano-

silver can penetrate biological barriers and attach itself to the outside of cells. Nanoscale silver can also enter the bloodstream and reach all organs of the body including the brain, heart, liver, kidneys, spleen, bone marrow and nervous tissue. Animal studies have shown placental transfer and foetal uptake of nano-silver.[5]

A nanoregister will allow regulators to track the use of nanosilver in consumer products and to accurately assess the risks posed by the widespread use of nanosilver to human health and the environment.

Slide 9: Scope

The EEB strongly disagrees with the Commission's conclusion that "full coverage (including articles/mixtures without intended release) seems hardly manageable, as it will cover a very significant share of all manufactured products". REACH covers a huge number of chemical substances (12,890 unique substances so far) so establishing a nanomaterial register would be perfectly possible.

The German Federal Environment Agency shares this view stating in its concept for an EU nanoregister that "substances and mixtures (manufactured or imported) that comprise or contain nanomaterials are subject to notification. Furthermore, articles that intentionally or unintentionally release nanomaterials (analogous to Article 7 (2) in connection with (3) REACH) should be subject to notification."[6]

We agree with the Commission that exemptions can make the system manageable, especially for nanomaterials already registered in any other system, such as REACH. However, unlike the Commission, we do see clear justifications why particular product groups should be exempted, e.g. NM already notified.

The EEB also disagrees with the statement that "a very significant burden is imposed on industry which does not have factual value for health and environmental purposes". Granted, the first year of implementation of French mandatory registration requested a significant effort from the companies in 2013; the implementation of a new task inevitably generates costs of organizing, collecting and entering information.

But it should also be taken into account that these costs significantly decrease once the registration practice is routinely installed in companies. As soon as 2014, the 2nd year of mandatory registration implementation in France, industry representatives acknowledged that the amount of work was much less burdensome.

The German Federal Environment Agency argues that an EU-wide nanoregister will provide public authorities with "a comprehensive overview on the use of nanomaterials in various sectors, information on the possible exposure of humans and the environment to nanomaterials and support in the selection of possible risk management measures. In addition, it supports the competent authorities in charge of the permission and enforcement of environmental, consumer and workers' health protection rules by informing about the notifier and the nanomaterials used."[7]

If the European Union fails to adopt a nanoregister this is likely to result in more member states adopting nanoregisters to meet important environmental health and safety objectives. This will result in a much greater administrative burden for industry than an EU wide nanoregister.

Slide 10: REACH

The Commission's statement that 62% of substances are already covered by REACH registration dossiers is highly misleading since the REACH registration dossiers do not contain specific information on the nanoforms of the substances.[8] Currently only 9 nanoforms are registered through REACH.

To say that 90% of substances are supposed to have REACH registration dossier by 2018 is highly unrealistic as acknowledged by ECHA. It is worth reminding the Commission that the European Chemical Industry Council (CEFIC) already announced that 80-90% of all existing NMs should have been registered by the first registration deadline of 2010. When 2010 registration figured showed that it was not the case, industry reverted to affirming that all NM would be registered by the second deadline. Now that ECHA has proved that this had not been the case, it is claimed that it will happen in the next registration. This appears as a pure delaying technique and recent legal action from TiO_2 registrant against a request by ECHA to provide more information about the nanoforms indicate without a doubt that possible registrants of nanomaterials are willing to resist any attempt to collect meaningful information on nano forms through REACH.

Slide 11: To what degree does the new information allow improved management of health and environmental risks?

The Commission seems not to understand that chemical risk management starts with both chemical characterisation (including the nanoform) and exposure information. Hence, it is obvious that the increased information on the NMs present in the environment will certainly improve the risk management of those.

The Commission's conclusion that "exposure information from a registry on its own does not allow the identification of risks" is untrue and suggests a lack of basic knowledge regarding risk assessment methodologies. In order to profile the risks of nanomaterials and therefore, perform adequate risk management, the information on both the intrinsic properties and exposure of nanomaterials is essential.

Scientists have warned that the main public health concerns with nanomaterials will result from chronic low dose exposures over a life time potentially leading to increased incidences of degenerative diseases, as is the case with ultrafine particle exposure in aerosols.[9] A nanoregister therefore also implies the importance of independent scientific committees assessing the safety of NMs.

Furthermore, the French authorities recognised that the register has greatly increased the communication in the various existing supply chain, prompting information to be circulated to downstream users, plant managers and workers, allowing precautionary approach to occupational risks to be implemented in many workplaces.

Although mainly focused on B to B, the increase circulation of information down the supply chain also had an indirect positive effect on B to C communication, allowing companies in direct contact with consumers to collect and disseminate more information about their own products. It similarly allows companies to comply with existing regulatory labelling requirement for their product (almost impossible without proper communication of information down the supply chain). The French authorities as well as many companies down the supply chain recognized the value of this increased flow of information and identified it as one of the clear and important achievement made possible only though the implementation of the French register schemes.

Therefore, with the registration system and transmission by suppliers of their declaration number(s) to their customers, many companies were informed by their(s) supplier(s) of the presence of nanomaterials in the products they were buying and could in turn inform their own customers. In the end, more stakeholders realized they were handling products containing "nanos substances". Through this awareness, some of them have hopefully are now able to limit occupational exposure to these substances and take appropriate precautionary measures.

The lack of health incidents identified in the public consultation is hardly surprising given that the majority of nanomaterials are unlabelled and workers are unaware that they are handling them. Research suggests that the majority of potential health affects associated with nanomaterial exposure will be long-term. Hence the need to track nanomaterials through the supply chain so that companies and workers can adopt appropriate risk management strategies.

A nanoregister will allow scientists to identify key industries and companies handling nanomaterials; and key sectors of the community that are exposed to nanomaterials; so that more detailed epidemiological studies can be carried out.

The same applies with regard to traceability, which is the main reason why a nanoregister is needed. Without traceability protection is not possible, neither is the recall of certain nanomaterials if health concerns are detected. The Commission ignores the value of traceability as a way of demonstrating safe use.

There are numerous benefits associated with increasing information along the supply chain. According the German Federal Environment Agency these include:

1. Improved responsiveness to adverse effects of products containing nanomaterials;
2. More transparency concerning nanomaterials on the market;
3. Freedom of choice concerning the purchase of products containing nanomaterials;
   Transparency for all market participants. Product responsibility can only be perceived with knowledge of the composition of a product. The provisions of an NPR [nano product register], appropriately designed, ensure communication in supply and processing chains.[10]

The French authorities also recognised that the French register increased traceability, what is especially relevant for workers since the companies became more aware of the use of NMs in the workplace.

We are deeply concerned that the Commission appears to be dismissing the public consultation's major agreement that notification per use would enable traceability.

Slide 12. Consumers

It is highly unacceptable that the Commission concludes that relevance for consumers is limited without consulting consumer and citizen's organisations. All consumer, citizen, health and environment organisations demand information on nanomaterials through a register since the human and environmental exposure is highly relevant to protect health and environment.

Once again, the Commission seems to disagree with all non-industry stakeholders that information on the presence of nanomaterials will improve transparency and consumer trust (although consumers clearly state that it would in their answers to the public consultation).

The Aarhus convention (endorsed by the EU) grants EU citizens access to any environmental information and a right to be involved in environmental decision-making. The current process of organizing a public consultation to dismiss more than half of the responses, and arbitrarily drawing conclusions that are in direct contradiction with contributions from individuals, as well as consumers and environmental organizations can be considered a violation of the Aarhus convention obligations.

The fact that the information on specific consumer products containing nanomaterials in France is not currently publicly available is not a valid argument for the EU to not make this information available to the EU public through an EU register. Firstly there is the unfounded assumption that the European registry would have the same limits observed in current French register. Secondly, information to consumers on nanomaterials in products can only be collected if a mandatory notification scheme for companies is put in place. Finally, the fact that the French register is not intended for directly granting consumers with information doesn't provide evidence that a registry is not an appropriate tool to provide consumers with relevant information. In fact, a registry and labelling are the only tools to provide consumers with relevant information.

Moreover, the French authorities develop reports for consumers with the information generated by the register, which are of high interest and importance to French citizens.

The critics addressed by French civil society shall be addressed by enlarging the publication of the registered data. But in any case, they should not be used to dismiss the creation of the UE register that this French civil society fully supports (see the responses to the consultation from French CSOs and citizens: Avicenn, France Nature Environnement, CFTC, CGT, Sarah Dubernet, groupe EELV Aquitaine, etc.).

We should also keep in mind that other national initiatives exist that collect data on nanomaterials in products, giving information that is more significant for consumers, such as the Danish Nanodatabase[11], the Woodrow Wilson database ("The Project on Emerging Nanotechnologies")[12], the ANEC-BEUC 2010 inventory of consumer products containing nanomaterials (ANEC-BEUC 2010)[13], the online database of the German Environmental NGO 'BUND' (Friends of the Earth Germany)[14] and the nanotechnology products database of Nanowerk[15].

This initiatives show that people are extremely interested in transparency and knowing in which product you can find nanomaterials. For instance, the online database of the German Environmental NGO 'BUND' (Friends of the Earth Germany) is one of the most used sites from all BUND topics. 2014 brought almost 90.000 views.

At the European level lessons should be learnt from all existing tools at national level.

Slide 13: Costs

The over-inflated estimates of the regulatory burden to industry of a nanoregister do not stand up to scrutiny. As the German Federal Government observed in its study attempting to assess the impact of an EU-wide register "The companies were not interested or not able to substantiate the high burden that they allocate to such a register with reliable figures".[16]

The Commission cannot apply characterisation costs as costs derived from the registration on NMs. According to the risk management obligations under occupational and chemicals legislations, all companies using chemical substances have to demonstrate they are used safely. For this reason, companies using chemicals in the workplace have to first characterise them in order to develop the appropriate risk management measures. Therefore, characterisation costs cannot be duplicated.

Slide 14: Internal market, competitiveness, innovation, CBI.

If the Commission believes that no major effects on flow of goods with nanomaterials are detected, this would suggest that an EU registry would be possible without major obstacles. If there are no negative impacts predicted, it is unclear what the compelling reason is to not adopt a nanoregister, given the clear environmental health and safety and transparency benefits. National authorities would certainly also benefit from the availability of more consistent data.

Regarding competitiveness and innovation, it is disturbing that the Commission appears to have dismissed the conclusions put forward by stakeholders other than those from industry. It is deeply worrying that the Commission does not appear to have taken into account the conclusions of the studies and public consultation that companies wouldn't have less innovation materials if a nanoregister is established and that information provision would stimulate innovation, while no substantial impact on competitiveness is foreseen.

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[1] Umweltbundesamt (2014) Impact Assessment of a European Register of Products Containing Nanomaterials, http://www.umweltbundesamt.de/sites/default/files/medien/378/publikationen/texte_23_2014_assessment_of_impacts_of_a_european_register_of_products_containing_nanomaterials-schwirn.pdf, p.3.

[2] Umweltbundesamt (2012)

[3] FoEA (2014) *Way too little: Our government's failure to regulate nanomaterials in food and agriculture,* http://emergingtech.foe.org.au/wp-content/uploads/2014/05/FOE_nanotech_food_report_low_res1.pdf, p. 8.

[4] Umweltbundesamt (2012) Concept for a European Register of Products Containing Nanomaterials, http://www.umweltbundesamt.de/sites/default/files/medien/378/publikationen/information_concept_nanoregister_npr_e_0.pdf
[5] FoEA (2011) Nano silver: policy failure puts public health at risk, http://emergingtech.foe.org.au/wp-content/uploads/2011/10/Nano-silver_2011.pdf
[6] Umweltbundesamt (2012)
[7] Umweltbundesamt (2014) Impact Assessment of a European Register of Products Containing Nanomaterials, http://www.umweltbundesamt.de/sites/default/files/medien/378/publikationen/texte_23_2014_assessment_of_impacts_of_a_european_register_of_products_containing_nanomaterials-schwirn.pdf
[8] RPA *et al.* (2014) Study to assess the impact of possible legislation to increase transparency on nanomaterials on the market, Evaluation report for DG Enterprise and Industry, p. viii.
[9] Elsaesser, A. & Howard, C.V. (2012) Toxicology of nanoparticles, *Advanced Drug Delivery Reviews* **64**:129–137.
[10] Umweltbundesamt (2012)
[11] http://nanodb.dk/
[12] http://www.nanotechproject.org/inventories/consumer/
[13] http://www.beuc.org/
[14] http://www.bund.net/
[15] http://www.nanowerk.com/products/products.php
[16] Umweltbundesamt (2014) Impact Assessment of a European Register of Products Containing Nanomaterials, http://www.umweltbundesamt.de/sites/default/files/medien/378/publikationen/texte_23_2014_assessment_of_impacts_of_a_european_register_of_products_containing_nanomaterials-schwirn.pdf, p.3.