Nanotechnology Industries Association

05 August 2014

NIA Comments on the EC Consultation on Transparency Measures for nanomaterials on the market

Introduction

On 16 May 2014, the European Commission Directorate-General on Enterprise and Industry (DG ENTR) has announced that, 'as part of the Communication on the Second Regulatory Review on Nanomaterials, **the European Commission [...will develop] an impact assessment to identify and develop the most adequate means to increase transparency and ensure regulatory oversight on nanomaterials**'. In order to support the development of this assessment, a public consultation has been run 'to obtain stakeholder views on the currently available information on nanomaterials on the market, the problem definition that forms the basis of the impact assessment, as well as the positive and/or negative impacts of [...] policy options'.

The consultation aimed at 'companies, public authorities, academia, associations, consumers and all other interested stakeholders'. A draft working document has been made available that highlights the first chapters of the Impact Assessment report. The consultation is being carried out by external organisations on behalf of DG ENTR, who have created two separate one: one for industrial stakeholders, and one for all other stakeholders. DG ENTR also informs readers that it will be running a validation workshop on the topic, and that there are several documents already available that can act as reference points.

The draft working document, which was discussed in detail during the 12th CASG-Nano meeting held in March 2014, where NIA was represented, will make up the beginning of the eventual Impact Assessment report; it consists of:

- The regulatory and political context of the assessment
- The 'problem definition' around the topic
- Objectives of the assessment (including general, specific and operational policy objectives)
- Policy Options, that consist of:
    - 'Baseline scenario
    - Recommendation on how to implement a "best practice model" for Member States wishing to establish a national system (soft law approach)
    - Structured approach to collect information ("Nanomaterials Observatory")
    - Regulation creating an EU nanomaterial registry with one annual registration per substance for each manufacturer/importer/downstream user/distributor
    - Regulation creating an EU nanomaterial registry with one annual registration per use (including substances, mixtures and articles with intended release)'

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Together with the draft version of the first chapters of a corresponding Impact Assessment report(link is external), two questionnaires (for industry and non-industry respondents) about the impacts of a potential nanomaterial registry at EU level have now been made available to the public. The public consultation was closed on 5 August 2014.

NIA replied to the public consultation on behalf of its Members.

EC-mandated Questionnaire

Section III - Problem definition and objectives

1. Please rate the importance of the following objectives on a scale between 1 and 5 (1-not important at all / 5-very important).

	1	2	3	4	5
a) Provide decision makers, regulatory authorities and professional users with information that allows for an appropriate response to health or environmental risks of nanomaterials					X
b) Provide consumers with relevant information on products containing nanomaterials on the market					X
c) Maintain competitiveness and innovation of businesses bringing nanomaterials or products containing nanomaterials to the market (including SMEs)					X
d) Ensure consumer trust in products containing nanomaterials					X
e) Ensure the availability of relevant information on the presence of nanomaterials or products containing nanomaterials on the market					X
f) Ensure the proportionality of the information requirements and the associated costs and administrative burden.					X
g) Protect confidential business information					X

Please provide additional comments:

The phrasing of this question is not optimal; all indicated objectives are certainly important, but the means on how to achieve them are not considered. None of the objectives is achieved through a nanomaterial registry alone, and to some of the objectives, a nanomaterial register might prove detrimental (cf. the French Mandatory Reporting scheme has not led to consumer trust).

It is unclear what the word 'relevant' means in the objective e): 'Ensure the availability of relevant information on the presence of nanomaterials or products containing nanomaterials on the market'; also, this data is already in the possession of the suppliers of the product.

NIA is of the view that the regulatory framework in EU is very suitable and functional to give regulatory authorities and professional users required information to respond to potential EHS

risks of nanomaterials. Appropriate consumer information is already provided in sectors where ingredient lists are required; regulatory authorities know that the mandatory provision of such information needs to go hand-in-hand with information by regulators on the purpose of the information requirement, as well as public reporting on the authorisation of specific listed ingredients. Additional administrative burdens for industry will not enhance EU innovation and competitiveness, and only increase the economic burden for industry, as well as for the public administration. Also, the current issues and uncertainties related to EC Recommendation on the Definition of Nanomaterial 2011/696/EU and its foreseen review need to be addressed before any additional measure based on this Recommendation is developed.

2. To what degree (from 1 - not at all to 5 - fully) do the current legislative framework (including the REACH and CLP Regulations and product-specific legislation) and the currently available databases (including the JRC web platform[1]) meet the following objectives?

	1	2	3	4	5	Don't know
a) Provide decision makers, regulatory authorities and professional users with information that allows for an appropriate response to health or environmental risks of nanomaterials					X	
b) Provide consumers with relevant information on products containing nanomaterials on the market				X		
c) Maintain competitiveness and innovation of businesses bringing nanomaterials or products containing nanomaterials to the market (including SMEs)				X		
d) Ensure consumer trust in products containing nanomaterials				X		
e) Ensure the availability of relevant information on the presence of nanomaterials or products containing nanomaterials on the market					X	
f) Ensure the proportionality of the information requirements and the associated costs and administrative burden.				X		
g) Protect confidential business information					X	

Please provide additional comments:

NIA considers that the existing REACH and CLP regulation provide an appropriate framework for nanomaterials. The phrasing of this question is nevertheless misleading: REACH, CLP and product-specific legislations were not necessarily designed to reach the above listed objectives; furthermore, and as outlined in answer 1. above, none of the objectives is achieved through a registry/regulation alone: for example, objective d): ensuring consumer trust in products containing nanomaterials, can be achieved only if an authority (or any other form of 'trusted organisation') creates and communicates 'information' from 'raw data'.

Nanomaterials are already being registered in the REACH regulation and additional measures

[1] http://ihcp.jrc.ec.europa.eu/our_databases/web-platform-on-nanomaterials

would hamper the competitiveness of innovative European companies.

Nevertheless, NIA considers that the requirements for registering nanomaterials under REACH will be improved following suitable and appropriate modifications of the REACH Annexes, ECHA guidance, and that intensified information campaigns could be of value for registrants, especially for SMEs.

3. To what extent do you agree with the following statements from 1 (strongly disagree) to 5 (strongly agree):

	1	2	3	4	5
a) The current level of available information on the presence of nanomaterials and products containing nanomaterials on the market is insufficient for an adequate response to health and environmental risks	X				
b) The current level of available information on the presence of nanomaterials and products containing nanomaterials on the market is insufficient for informed consumer choice	X				
c) The current level of available information on the presence of nanomaterials and products containing nanomaterials on the market is detrimental to consumer trust	X				
d) The available information on the presence of nanomaterials and products containing nanomaterials on the market is presented in an incoherent or ineffective way		X			
e) The establishment of national registries and notification schemes causes market fragmentation and hampers trade within the internal market					X

Please provide additional comments:

Similarly to other substances, nanomaterials are going through testing and risk assessment procedures in order to address potential health and environmental risks. There is no reason for nanomaterials to be addressed with different procedures than conventional chemical substances.

To date, the multiple proposed or enforced national registries for nanomaterials refer to diverse definitions of nanomaterials and require an important financial investment from companies. Industries having activities in a country that has set up a registration scheme have to abide by a supplementary nano-specific regulation; thus internal barriers to trade arise.

The wording: an 'adequate response' to a risk, in statement (a) is unclear.

Section IV - Health and environmental aspects

1. With regard to health and environmental hazards and risks of specific nanomaterials/types of nanomaterials, please tick the relevant boxes:

I am aware of health and/or environmental hazards of specific nanomaterials/types of	

nanomaterials	
I am not aware of any health and/or environmental hazards of specific nanomaterials/types of nanomaterials	
I am aware of specific nanomaterials that are classified as hazardous under Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures	
I am not aware of any classified nanomaterials	
I am aware of DNELs/PNECs/OELs[2] set for specific nanomaterials/types of nanomaterials	X
I am not aware of any DNELs/PNECs/OELs set for specific nanomaterials/types of nanomaterials	
I am aware of significant exposure of workers/users/consumers to specific nanomaterials/types of nanomaterials	X
I am not aware of any significant exposure of workers/users/consumers to specific nanomaterials/types of nanomaterials	

Please explain your responses below (if any, please report the nanomaterials, the health and/or environmental hazards, any relevant classification, any DNELs/PNECs/OELs, any exposure and in which condition):

In a 2009 Opinion on: Risk Assessment of Products of Nanotechnologies, the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) of the European Commission stated that 'nanomaterials are similar to normal chemicals/substances in that some may be toxic and some may not'; it would hence be wrong to state that there are not any health and/or environmental effects linked to conventional chemicals and specific nanomaterials alike. Over ten years of detailed investigation have not yielded new toxicology endpoints or new health effects that are induced by nanomaterials only and that are not also induced by conventional chemicals. Studies that had originally been linked to nanomaterial effects have all been corrected to show that the nano-size of the material used was not the culprit.

NIA Members are aware of safety measures applying to specific nanomaterials and are proactively engaging in, e.g. workers safety and ensuring that consumer exposure is following specifications from authorities, e.g. in relation to cosmetics and packaging material.

2. With regard to the past and current use of nanomaterials (tick the relevant box):

I am aware of health and/or environmental incidents which have occurred	
I am not aware of any health and/or environmental incidents which have occurred	X

Please explain (if any, please report the events and any scientific publication):

Accidental exposure to nanomaterials, just as for conventional substances may give risk to hazardous exposures. Like other substances, working with nanomaterials requires adherence to safety rules and wearing protective equipment etc. . A case was published in May 2014 when a worker suffered an intoxication to nickel nanoparticles (Iafolla, 2014). Importantly, this health incident was not related to the nanoparticulate nature of the substance: it incident was

[2] **DNELs:** Derived No Effect Levels, exposure levels below which hazardous substances are expected to have no effect on human health; **PNECs:** Predicted No Effect Concentrations, exposure levels below which hazardous substances are expected to have no effect on the environment; and **OELs:** Occupational exposure limits

caused by the absence of use of worker protection. In addition it is worth noting that the toxicity of nickel is well known and documented, it can hence be expected that nickel nanoparticles exhibit similar toxicity.

Iafolla, R. 2014, 'Worker Illness After Nanomaterial Exposure Examined in First U.S. Case Study on Issue' BNA, 15 May. Available at: http://www.bna.com/worker-illness-nanomaterial-n17179890489/,
Personal notes and articles on emerging technologies, responsible innovation, science communication and the University of Michigan Risk Science Center, from Center Director Andrew Maynard. 2020 Science, Available at: http://www.riskscience.umich.edu/2020-science/

3. The establishment of an EU nanomaterial registry (tick the relevant box):

Would significantly contribute to reducing the health and/or environmental risks related to the use of nanomaterials	
Would not significantly contribute to reducing the health and/or environmental risks related to the use of nanomaterials	X
I do not know	

If appropriate, please explain further:
A registry would not improve safety; it would only increase the stress on SMEs which would have to dedicate significant funds to the registration process. On top of creating administrative burden for both the authorities and the industries, such a register would create a negative public perception of nanotechnologies and increase the stigmatisation. The societal benefits of nanotechnology, as a key enabling technology, run the risk of not materialising.

Section V - Consumer trust

1. In case information on the presence of nanomaterials in specific products were made available, what impact do you think this would have on consumers? (Please tick all that would apply)

a) They would be more inclined to purchase those products	
b) They would try to avoid those products	X
c) Their purchasing decisions would not be affected	
d) They would search for more information	

Please explain:
Due to the bad press that has recently been given to nanomaterials (caused by unreliable toxicology studies and a constant association of nanotechnologies to risk-related issues), making available information on the presence of nanomaterials in products will only give credit to the conveyers of these negative views. In the absence of any scientific basis to

support the need for such information, providing it would negatively impact the market penetration of products containing nano-objects. Taking into account the fact that nanomaterials have already been used in consumer products for decades without harm the provision of information on their presence in products would only confuse the consumer.

2. Do you believe that the public availability of information on the presence of nanomaterials in products would be likely to… (choose one of the following answers)

a) generate trust among consumers and the broad public, and thus have a positive effect on the market for the concerned products	
b) have no significant impact	
c) generate insecurity or stigmatise such products, and thus have a negative effect on the market for the concerned products	X
Comments: See replies to questions IV.3 and V.1.	

Section VI - Innovation and competitiveness

1. With regard to innovation, do you believe that information on nanomaterials and products containing nanomaterials that could be gathered in a nanomaterial registry would:

a) stimulate innovation (e.g. through increased consumer trust, increased awareness on nanomaterials)	
b) have no significant impact on innovation	
c) hamper innovation in the EU (e.g. through concerns about confidential business information or through additional costs related to providing information)	X
Comments: Information on products would impact the way products containing nanomaterials would be seen and would stigmatise them. It would therefore hamper nanotechnology innovation in the EU. In addition, such a registry might also impact decisions of companies on manufacturing location in or outside the EU, and might therefore stimulate research and development outside of the European Union.	

2. With regard to competitiveness of EU companies manufacturing nanomaterials or products containing nanomaterials, do you believe that information on nanomaterials and products containing nanomaterials that could be gathered in a nanomaterial registry would (tick all that apply):

a) stimulate intra-EU competitiveness	
b) enhance the competitiveness of European companies against extra-EU companies	
c) have no significant impact on intra-EU competitiveness	

d) have no significant impact on the competitiveness of European companies against extra-EU companies	
e) hamper intra-EU competitiveness	
f) hamper the competitiveness of European companies against extra-EU companies	X

Please explain:
A nanomaterial registry would result in a severe disadvantaging of EU companies: EU industries would have to register their nanomaterials at all stages of development and processing. Extra-European companies would only have to register their products once they would enter the EU-market and would thus have a reduced administrative burden compared to EU companies.

Competitiveness may already be hampered by existing schemes such as the French mandatory reporting scheme which is already showing severe threat to confidential business information, i.e. confidentiality settings are not automatically forwarded to other declarations using the same declaration number, and registrants asking for confidentiality must therefore ensure that all the industrial users of their product also ask for confidentiality.

Section VIII - Possible options and exemptions

Different nanomaterial registries are under consideration. Firstly, an annual notification requirement per substance for each manufacturer/importer/downstream user/distributor (this would imply that a downstream user using one substance in multiple mixtures or articles would only submit one notification) or an annual notification requirement per use of a nanomaterial across the supply chain (e.g. for each mixture or article).

1. What would be the added value of a notification per use (i.e. for each mixture/article) compared to a notification per substance? – Please consider the usefulness of the information for public authorities, downstream user companies, workers and consumers.

It is not clear from the question who would provide the information in the 'notification per use'. It is expected that the 'notification per use' would require a very large additional administrative burden and resources, compared with 'notification per substance'.

2. Which actors along the supply chain should be subject to notification requirements (tick all that apply):

a) Manufacturers of nanomaterials	
b) Importers of nanomaterials	
c) Downstream users (e.g. re-formulators, manufacturers of products containing nanomaterials)	
d) Distributors to professional users (e.g. wholesalers)	
e) Distributors to consumers (e.g. retailers)	

Please explain: It is not clear if the question refers to 'notification per substance' or 'notification per use'. If used, the requirements should be equally applicable as the current REACH requirements.

3. The following should be subject to notification requirements (tick all that apply):

a) Substances	X
b) Mixtures containing nanomaterials	
c) Articles with intended release of nanomaterials	
d) Articles containing nanomaterials without intended release	
Please explain: Several regulatory frameworks already require notifications, most notably REACH, but also e.g. the cosmetics regulation. The notification refers to substances, and a change of procedure to notify e.g. mixtures or articles is not warranted.	

4. Is there a need to exempt certain **types** of nanomaterials?

Yes, certain types of nanomaterials should be exempted from a notification system	
No, all kinds of nanomaterials should be subject to notification obligations	
If yes, which types should be exempted and why? (in terms of specific properties, available knowledge, absence of hazards, etc.) Nanomaterials should not require additional registration than is already provided for following the EU regulatory framework.	

5. Is there a need to exempt certain **uses** of nanomaterials?

Yes, certain uses of nanomaterials should be exempted from a notification system	X
No, all uses of nanomaterials should be subject to notification obligations	
If yes, which uses should be exempted and why? (in terms of specific exposure scenarios, available knowledge, absence of hazards, etc.) If such a scheme had to come into force, R&D use of nanomaterials would have to be exempted in order to safeguard the innovative potential of Europe.	

Section IX - Structured approach to collect information *("Nanomaterials Observatory")*

A Nanomaterials Observatory is intended to be a structured approach to collect information on nanomaterials on the market and to present it in a clear and user-friendly way.

1. If a Nanomaterials Observatory is established instead of an EU-wide registry, what type of information should be collected? (please tick all that apply)

a) Information from existing notification systems	X
b) Information from market studies on nanomaterials and products containing nanomaterials	X
c) Information on the use of nanomaterials across Europe	
d) Information concerning products containing nanomaterials	
e) Information on the hazards and risks of nanomaterials	
f) Other (please explain)	X
If other, please explain or add any comment: If a Nanomaterials Observatory is established, the collected information should be used with care; while regulators may see a need to ask information on the use of nanomaterials across Europe (c) and information concerning products containing nanomaterials (d) such data should be kept confidential. No external user should be able to 'derive' this information from supply-chain partners that do not tick the 'confidentiality'-box.	

2. How should the information in a Nanomaterials Observatory be presented in order to reach the consumers, workers and authorities?

This question is formulated too broadly to allow a useful reply. Information should be provided in a structured way, suitably presented to the intended target groups(s).

Section X - Potential use and benefits of a nanomaterial registry

1. In what way could the information on nanomaterials from registries be potentially useful (tick all that apply):

a) Risk assessment and/or risk management	
b) Enforcement of worker protection	
c) Promotion of safe use of nanomaterials in products	
d) Development of strategies to ensure the safe use of nanomaterials	
e) Informed purchasing decisions by consumers	
f) General education of the public	
g) Other purposes (please specify below)	X
A registry for nanomaterials is not required, nor desired, to provide the information suggested in the question. EHS and worker safety aspects are already covered under the current EU regulatory framework. Strategies for ensuring safe use of nanomaterials are developed within industry and downstream users following regulatory requirements. General education to the public is not achieved with based on information from a registry, but best executed in targeted approaches.	

2. Please give a justification for your views (presented in the previous question) and describe which data would be necessary to allow the desired use (e.g. would information on substances alone be enough for informed consumer purchase decisions, or would this require information for each concerned product):

NIA do not believe that a nanomaterial registry would help address any of the concerns addressed above. On the opposite, it might be detrimental to consumer confidence in nanotechnology and could hamper innovation and job creation in Europe.

3. What would be the added value of a European nanomaterial registry beyond the current framework of chemicals legislation, including REACH registration?

NIA believes that the existing regulatory requirements already provide a significant amount of information to the public authorities and that there is no need for additional registration.

4. Please provide any other comments that you would like to share regarding transparency measures for nanomaterials on the market.

Nanomaterials should not be discriminated against based on the sole factor of their size (1-100 nm). Any transparency measure that would come on top of the existing regulatory framework is therefore inappropriate.

The Nanotechnology Industries Association

Formed in 2005 by a group of companies from a variety of industry sectors including healthcare, chemicals, automotive and consumer products, the Nanotechnology Industries Association (NIA) creates a clear single voice to represent the diverse industries in the multi-stakeholder debate on nanotechnologies. NIA provides a purely industry-led perspective, derived from the views of the collective membership and forms an interface with government, acting as a source for consultation on regulation and standards, communicating the benefits of nanotechnologies and interacting with the media to ensure an on-going advancement and commercialization of nanotechnologies.

For further information visit http://www.nanotechia.org or contact us on enquiries@nanotechia.org.

The NIA, Nanotechnology Industries Association, is the sector-independent, responsible voice for the industrial nanotechnologies supply chains; it proactively supports the ongoing innovation and commercialisation of nanotechnologies and promotes their safe and reliable advancement.

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