#19

COMPLETE

Collector: Nano Consult - Non-Industry (Web Link)
Started:
Last Modified:
Time Spent:
IP Address:

PAGE 2: Section I - Identification

Q1: Please provide the following details (*compulsory):	
Your name:	Lisa Anfält
Name of organisation* (if applicable):	Swedish Chemicals Agency
Town/City:	Stockholm
Country*:	Sweden
E-mail address:	
Q2: Please indicate if you are responding to this questionnaire on behalf of/as:	b) a public authority/public administration
Q3: Received contributions may be published on the Commission's website, with the identity of the contributor. Please state your preference with regard to the publication of your contribution:	My contribution may be published under the name indicated
Q4: We might need to contact you to clarify some of your answers. Please state your preference below:	I am available to be contacted

PAGE 3: Section III – Problem definition and objectives

Q5: Please rate the importance of the following objectives on a scale between 1 (not important at all) and 5 (very important).

a) Provide decision makers, regulatory authorities and professional users with information that allows for an appropriate response to health or environmental risks of nanomaterials	5
b) Provide consumers with relevant information on products containing nanomaterials on the market	5
c) Maintain competitiveness and innovation of businesses bringing nanomaterials or products containing nanomaterials to the market (including SMEs)	4
d) Ensure consumer trust in products containing nanomaterials	3
e) Ensure the availability of relevant information on the presence of nanomaterials or products containing nanomaterials on the market	4
f) Ensure the proportionality of the information requirements and the associated costs and administrative burden.	4
g) Protect confidential business information	3
Please provide additional comments	Proportionality is of course very important but it should be recognized how important information is for appropriate response to health or environmental risks. The information is therefore proportional to a relatively high cost. Consumer trust is ensured not only by providing information to consumers but ensuring consumers that the authorities responsible have the information available to mitigate consumer risk. This is a reaction from consumers contacting the Swedish Chemicals Agency, they wish for the authority to make sure sufficient security measures are in place – not necessarily more information in all cases. Regarding option e) it is unclear to whom the information should be available. If the option includes information to the general public it is important for transparency reasons (i.e. ensure trust) and to give possibility for consumers to make informed choices.

Q6: To what degree (from 1 - not at all to 5 - fully) does the current legislative framework (including the REACH and CLP Regulations and product-specific legislation) and the currently available databases (including the JRC web platform, see http://ihcp.jrc.ec.europa.eu/our_databases/web-platform-on-nanomaterials) meet the following objectives?

a) Provide decision makers, regulatory authorities and professional users with information that allows for an appropriate response to health or environmental risks of nanomaterials	1
b) Provide consumers with relevant information on products containing nanomaterials on the market	2
c) Maintain competitiveness and innovation of businesses bringing nanomaterials or products containing nanomaterials to the market (including SMEs)	Do not know
d) Ensure consumer trust in products containing nanomaterials	1
e) Ensure the availability of relevant information on the presence of nanomaterials or products containing nanomaterials on the market	1
f) Ensure the proportionality of the information requirements and the associated costs and administrative burden.	1
g) Protect confidential business information	Do not know
Please provide additonal comments	Regarding a) This is also true since there is a lack of requirement to provide relevant nanomaterial specific information in the REACH registrations. Regarding b) information is available only for cosmetic and food. Regarding f) The information requirements are disproportionate considering that the tonnage levels are generally not adequate for nanomaterials which lead to a lack of relevant/necessary information.

Q7: To what extent do you agree with the following statements from 1 (strongly disagree) to 5 (strongly agree):

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	5
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	5
c) The current level of available information on the presence of nanomaterials and products containing nanomaterials on the market is detrimental to consumer trust	5
d) The available information on the presence of nanomaterials and products containing nanomaterials on the market is presented in an incoherent or ineffective way	5
e) The establishment of national registries and notification schemes causes market fragmentation and hampers trade within the internal market	5
Please provide additional comments	Presently there is a lack of information on potential exposure – a register would be an important source of information e.g. types of use, annual and time-trend quantities to characterise exposure.

PAGE 4: Section IV – Health and environmental aspects

Q8: 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 classified nanomaterials, I am not aware of any DNELs/PNECs/OELs set for specific nanomaterials/types of nanomaterials , I am not aware of any significant exposure of workers/users/consumers to specific nanomaterials/types of nanomaterials , Please explain your responses (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): We are aware of problems with bulk forms where even nanomaterials exist, for example titanium dioxide, carbon nano tubes, but with a restricted search of 5 minutes by a non-nanomaterial expert which included scrutiny of EU inventories, secondary regulatory review, net available information we were not able to categorically and easily find clear and definitive answers to all the above – demonstrating e.g. lack of transparency.
Q9: 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 , Please explain (if any, please report the events and any scientific publication): Journeay and Goldman 2014 a case of Nickel allergy. It can be argued that this could have been avoided by appropriate safety measures. However, to be able to take such safety measures in workplaces today they need to be aware of that they are working with nanomaterial which a registry could provide. http://www.ishn.com/articles/98650-published-report-nano-worker-developed-allergic-sensitization-breathing-problems-and-rash?v=preview
Q10: 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 , If appropriate, please explain further: The register in itself would not reduce risks but the information it could contain would make it possible to respond to known risks and risks that may occur in the future. The information is vital for mitigating risk but does not in itself do so.

PAGE 5: Section V – Consumer trust

Q11: 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, c) Their purchasing decisions would not be affected , d) They would search for more information, Please explain: All boxes could be ticked for different consumer groups. What we know previously has created distrust is the impression of consumers that something is being hidden from them. Studies have shown that acceptance of a risk is related to if you voluntarily are exposed to it and you can clearly asses the benefits, this is why we for instance eat candy although we are aware of the risk of consuming sugar. The contrary is also true, even though the risk is small if it is being hidden this makes it less easy to accept. Communication about risk is complicated however it is necessary to in the long run ensure consumer trust - lack of communication will never ensure consumer trust in the long run. Generally, it may not be helpful for the consumer to receive the raw technical data from a registry system but authorities could process the data and provide useful information to consumers to achieve the set objectives of consumer trust and consumer information.
Q12: 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 , Comments: Transparency and awareness of occurrence, risks and benefits will increase public understanding and trust and so enable informed choice/decisions. In the long run not giving the public access to information will always create more concern.

PAGE 6: Section VI - Innovation and competitiveness

Q13: With regard to innovation, do you believe that information on nanomaterials and products containing nanomaterials that could be gathered in a nanomaterial registry would…(choose one of the following answers)	a) stimulate innovation (e.g. through increased consumer trust, increased awareness on nanomaterials) , Comments: In the long run, transparency and governance are crucial to avoid a similar situation to GMO's in the EU.

Q14: 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)	b) enhance the competitiveness of European companies against extra-EU companies , c) have no significant impact on intra-EU competitiveness , Please explain The same requirements would be on all companies and therefore not affect intra-EU competitiveness. Trust in European companies compared to extra-EU companies could enhance the competitiveness of the European companies, i.e. if the origin is marked on the products (http://www.europarl.europa.eu/news/en/news-room/content/20140411IPR43453/html/MEPs-push-for-mandatory-made-in-labelling-to-tighten-up-product-safety-rules

PAGE 7: Section VIII – Possible options and exemptions

Q15: 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.

This would allow for:
- traceability which is crucial in risk mitigation to provide information on use, use trends and potential exposure and better allow for Life Cycle Analysis
- development of Risk Assessment methods/models

Q16: 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) , Please explain: If the registry would be incorporated in REACH only a), b) and c). If it would be in a separate legislation a), b), c), and d).

Q17: The following should be subject to notification requirements (tick all that apply):	a) Substances, b) Mixtures containing nanomaterials, c) Articles with intended release of nanomaterials , d) Articles containing nanomaterials without intended release , Please explain: Articles* with expected/possible release along the lifecycle should be notified. Intended release does not cover all relevant cases. The end-of-life/waste sector would likely risk exposure even for articles without intended use. *Including treated articles.
Q18: Is there a need to exempt certain types of nanomaterials?	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.) Exemptions should only be allowed based on scientific and technical guarantees of safe use
Q19: Is there a need to exempt certain uses of nanomaterials?	Yes, certain uses of nanomaterials should be exempted from a notification system , If yes, which uses should be exempted and why? (in terms of specific exposure scenarios, available knowledge, absence of hazards, etc.) Uses for research and development should be exempted, similar to how it is in REACH, not to hamper innovation. Only include nanomaterials placed on the market.

PAGE 8: Section IX – Nanomaterials Observatory

Q20: If a Nanomaterials Observatory is established instead of an EU-wide registry, what type of information should be collected? (please tick all that apply)	*Respondent skipped this question*

Q21: How should the information in a Nanomaterials Observatory be presented in order to reach the consumers, workers and authorities?

-

PAGE 9: Section X - Potential use and benefits of a nanomaterial registry

Q22: In what ways 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)
- Effects resulting from the use of nanotechnology might arise as a result of the chemical composition of the nanoparticles, the characteristics of the products made from them, or aspects of the manufacturing processes that are used to generate them. In order to make it possible to develop adequate methods and models (including validation of these methods/models), for the estimation of potential health or environmental effects and exposure from manufactured nanomaterials, the information from registries are considered crucial. - For g) for appropriate management of waste/end-of-life stage. - Better, more knowledge based, legislation. - Traceability.

Q23: 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):

a) Use and quantity information for e.g. exposure assessment and mitigation
b) To identify national/EU responsible parties for occupational compliants
c) Promotion by meaningful and informed communication/dialogue
d) Information is always essential for efficient and effective strategies
e) Will provide the possibility of informed decision - public/consumers will mainly be educated/informed by competent authorities assessing the data.
f) The public/consumers will mainly be educated/informed by competent authorities assessing the data
g) Essential information for appropriate management of waste/end-of-life stage.
Basic characterisation of the substance, use(s), quantities etc.

Q24: What would be the added value of a European nanomaterial registry beyond the current framework of chemicals legislation, including REACH registration?

REACH does not give information on presence of nanomaterials in articles which is necessary to ensure traceability and information to downstream users. REACH does not register nanomaterials separately and thus does not create the equivalent of a nanomaterial registry.

A registry would also have a lower starting point (100g) than REACH which would provide information about additional nanomaterials.

Q25: Please provide any other comments that you would like to share regarding transparency measures for nanomaterials on the market.

Downstream information: Many companies that today carry the main responsibility for legislation concerning workers health, the environment and the safety of products does not have access to information on the presence of nanomaterials in the products they are manufacturing and selling. They risk carrying a large cost if risks are discovered because of their lack of knowledge. Apparent risks, for instance to workers health, that could have been easily avoided by appropriate safety measures are not being taken due to lack of information. This incurs both unnecessary cost and suffering to both individual companies but also society at large.

Information on nanomaterials is also necessary for process and product development. Information on the raw material that are being used in theses process is necessary for them to make choices and assess how to handle a nanomaterial with perhaps unknown risks.

Governmental bodies and agencies need the information to prioritise measures for risk reduction but also investments.

In a democratic society consumers should be able to make informed decisions.

An overview of nanomaterials on the market and transparency on products containing nanomaterial is important to support a positive development of nanotechnology and nanomaterials. It has both practical and psychological benefits. Such an overview would in the long run also contribute to a balanced approach in legislation adapted in relationship to the actual situation and knowledge based.

Free movement of goods on the internal market need to be ensured. Differentiated systems in the Member States prevent the free movement of goods - a harmonised registry in EU would promote free movement. A registry is also necessary to give a more accurate picture of the actual flow since products containing nanomaterials could have a high mobility on the internal market.

It is not sufficient with a Nanomaterials Observatory alone. It would not give a full picture of which nanomaterials and which products that are on the market and therefor fail to deliver reliable information for companies, agencies and consumers to act on. The same risks for companies further down the supply chain with responsibility for workers safety and the environment would remain since they would not receive all information needed. If the information is incomplete there is a risk of creating a biased system for regulatory decision making and governmental measures. It is also unclear how such a Nanomaterials Observatory would be financed and if the cost would be proportional to the limited benefits.

We welcome this impact assessment and believe that a registry at an European level would be of great benefit.