#34

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:	Federal Institute for Risk Assessment
Name of organisation* (if applicable):	Federal Institute for Risk Assessment
Town/City:	10589 Berlin
Country*:	Germany
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)	1
d) Ensure consumer trust in products containing nanomaterials	5
e) Ensure the availability of relevant information on the presence of nanomaterials or products containing nanomaterials on the market	5
f) Ensure the proportionality of the information requirements and the associated costs and administrative burden.	1
g) Protect confidential business information	1
Please provide additional comments	Questions c, f, g are beyound BfR`s (Federal Institute for Risk Assessment) scope

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	2
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	2
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.	Do not know
g) Protect confidential business information	Do not know
Please provide additonal comments	Answers relate to REACH/CLP and Biocides

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	4
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	4
c) The current level of available information on the presence of nanomaterials and products containing nanomaterials on the market is detrimental to consumer trust	3
d) The available information on the presence of nanomaterials and products containing nanomaterials on the market is presented in an incoherent or ineffective way	4
Please provide additional comments	Question 3.e is related to business strategy and out of the scope of a regulator`s perspective.

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 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 aware of 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): The answers need to consider the weak dataset on hazards and exposure for nanomaterials based on the few nanotmaterial-specific REACH registration dossiers available (< 10) and the poor differentiation between bulk and nanoform in other dossiers. Nanospecific CLP self-classification for MWCNT (EC 231-955-3): Eye damage H319, STOT SE 3 H335. No harmonized classification is known. There are OEL's for nano-TiO2 and MWCNT by NIOSH. Hazard information for nanomaterials relies mainly on published studies.
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): The only human incidents I am aware of is the case in China (Song et al. 2009) due to lack of worker protection against polyacrylate spraying and the "Magic Nano" spray (BfR 2006), both of which, however, turned out not to involve manufactured nanoparticles.
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: A registry would provide a useful means to get reliable information on uses and volumes of nanomaterials in production, processes and on the market, allowing more robust exposure estimates and thus adequate risk assessment, the primary instrument for risk reduction.

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)	d) They would search for more 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)	b) have no significant impact

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)
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)	a) stimulate intra-EU competitiveness, b) enhance the competitiveness of European companies against extra-EU companies , Please explain Stimulating the intra-EU competitiveness should be regarded positively as a driver for innovation (e.g. triggering safe-by-design approaches), which in the long run may even become a competitive advantage against extra-EU companies.

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.

A notification system based on uses appears to be superior as it allows better traceability and transparency. This would be particularly useful for considering the diversity of exposure situations. However, a combination with a "per substance registry" is most effective for balancing production/import volumes with uses, thus also considering the substance-based tonnage-triggers in REACH.

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) , e) Distributors to consumers (e.g. retailers), Please explain: Issues on labelling, packaging and release (e.g. sprays) may trickle down even to retailers
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: Since all cases contain nanomaterials, which could be potentially released, all should be subject to notification.
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.) At present, no exemption should be made despite non-nanomaterial-containing articles releasing nanoparticles. The latter would be beyond the scope of "manufactured nanomaterials", though the regulatory situation here is insufficient (e.g. printer toner formulated with or w/o nano-sized pigments, both releasing nanoparticle dusts).
Q19: **Is there a need to exempt certain uses of nanomaterials?**	If yes, which uses should be exempted and why? (in terms of specific exposure scenarios, available knowledge, absence of hazards, etc.) Uses can be exempted, where the absence of release has been adequately demonstrated (e.g. closed production/processing, certain composite materials).

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)

a) Information from existing notification systems,

b) Information from market studies on nanomaterials and products containing nanomaterials

,

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):
This sort of observatory understood as a "nanovigilance" system is most effective in addition to a registry as long as there is a high uncertainty regarding the safety of nanomaterials for humans and the environment (re. long-term effects in particular). It is not recommended to install it as a substitute for a nanoregister.

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

No comment since it is not desirable as a stand-alone measure.

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,

d) Development of strategies to ensure the safe use of nanomaterials

,

e) Informed purchasing decisions by consumers

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):

See answers and comments in Section III and IV.

Key points are the improved database on release, exposure and hazard to be expected from information on uses and tonnages as well as traceability and transparency.

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

As mentioned above, this could indeed become a driver for innovation, which may turn into a competitive advantage against non-EU countries with regard to nano- and advanced materials technologies. Furthermore, trust in (precautionary) EU decisions is greatly increased in general, due to increased transparency and choice for the consumer.

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

An EU-wide registry would require a harmonised definition across different legislation as well as agreement on analytical methods and instrumentation for properly estimating nanomaterials in products. All these developments should be accelerated in parallel.