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COMPLETE

Collector: Nano Consult - Non-Industry (Web Link)
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PAGE 2: Section I - Identification

Q1: Please provide the following details (*compulsory):

Your name:	Kathrin Schwirn
Name of organisation* (if applicable):	Federal Environment Agency
Town/City:	Dessau-Roßlau
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)	4
d) Ensure consumer trust in products containing nanomaterials	4
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.	5
g) Protect confidential business information	4

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	2
f) Ensure the proportionality of the information requirements and the associated costs and administrative burden.	1
g) Protect confidential business information	5
Please provide additonal comments	The reply bases on the current status of regulation. A ambitious amendment of REACH could improve the knowledge and transparency for the authorities. Regarding f: environment related IR under REACH is not adequate to address NM. Therefore, the proportio-nality is not given. regarding JRC web platform: There are to many links instead of providing clear and easy available 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	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	4
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
Please provide additional comments	regarding e) A European regulation of a product register instead of several national registries is advantageous in sense of harmonization.

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

,

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):
There is evidence for specific env. effects caused by nanomaterials: e.g. release of toxic ions, particle effects, Trojan horse effects, depot effects, phototoxicity, ROS generation. For a couple NM some information is available which justifies a classification regarding environmental hazard. However, in normal cases there are not enough data available to neither exclude nor justify a nanospezific env. hazard. Regarding exposure: environmental exposure has to be taken into account. Information on env. exposure is hardly available. However, there is evidence that environmental exposure occurs.

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): With respect to environmental effects: Because of the lack of appropriate analytic methods a correlation of envi. incidents and with NM is currently not possible. However, it can be assumed that for instance the wide spread use of nanosilver can significantly increase the environmental impact of silver.
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 best way to reduce the risks related to nanomaterials would be an amendment of the REACH regulation to introduce nanospecific IR. This would produce relevant data on the hazards of nanomaterials for human health and the environment which cannot be captured by a product register. The value of contribution depends on the amendment of REACH (e.g.http://www.umweltbundesamt.de/publikationen/nanomaterials-reach) However, a product register would be a useful means to get information on which nanomaterials are on the market for which uses/product groups and in which volumes. The register would be a valuable instrument to identify environmental risk and to implement appropriate risk management.: http://www.umweltbundesamt.de/publikationen/concept-for-a-european-register-of-products

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)	c) Their purchasing decisions would not be affected , d) They would search for more information, Please explain: It depends on consumer group. It is well known that there are consumers who are pro actively interested in the ingredients/substance within the products and consumers who are become interested in this information by public debate.
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

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)**	c) have no significant impact on intra-EU competitiveness , d) have no significant impact on the competitiveness of European companies against extra-EU companies , Please explain Regarding d): depends whether the enforcement makes sure that importer of articles fulfill its require-ments

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.**

The information on the extent of use and the different product groups which contains NM will help authorities for their prioritisation decisions.
Further value: transparency along supply chain, consumer information.
A substance based notification scheme would be considered important as it would ensure the coherence to REACH registrations and CLP notifications.
However, also notification per use would be particularly valuable for better traceability and transparency along the supply chain. It would also be useful for considering the diversity of exposure situations.
The added value depends on the amendment of REACH. In case the amendment is appropriate (e.g.http://www.umweltbundesamt.de/publikationen/nanomaterials-reach) the added value would be lower, if the amendment is not appropriate we propose: http://www.umweltbundesamt.de/publikationen/concept-for-a-european-register-of-products. Furthermore, a product register would be a useful means to get information on which nanomaterials are on the market for which uses/product groups and in which volumes.

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)

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 in all cases NM are involved which could be potentially released to the environment, all should be sub-ject to notification.
Q18: **Is there a need to exempt certain types of nanomaterials?**	No, all kinds of nanomaterials should be subject to notification obligations
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 and articles for which release of NM to the environment can be excluded along their whole life cycle.

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): Information from existing regulation; Relevant results from EU and national research programs (e.g. FP7, Horizon 2020) in the fields of nanomaterials and advanced materials. It should be considered not to limit the observatory to known nanomaterials but take also advanced materials into account.

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

Suitable for the user and tailored to target groups. This includes different levels of detail.

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,

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)
Authorities' prioritisation setting regading environmental hazard & risk managment; depending on the legal framework: product choice for 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: http://www.umweltbundesamt.de/publikationen/concept-for-a-european-register-of-products

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

REACH does e.g. not deliver information on substances below 1t/a and transparency within the dossiers are too low, the information on NM in articles and uses are not sufficient.

The added value depends on the amendment of REACH. In case the amendment is appropriate (e.g.http://www.umweltbundesamt.de/publikationen/nanomaterials-reach) the added value would be lower. In case the amendment is not appropriate we propose: http://www.umweltbundesamt.de/publikationen/concept-for-a-european-register-of-products

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

Existing regulations should be used. Therefore we propose an umbrella regulation which builds on existing regulation, adapt them where necessary and brings the information on nanomaterials containing products together: http://www.umweltbundesamt.de/publikationen/concept-for-a-european-register-of-products