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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:	Dr. Axel Dorenbeck
Name of organisation* (if applicable):	Bavaria State Ministry of the Environmental and Consumer Protection
Town/City:	Munich
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)	5
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	4
f) Ensure the proportionality of the information requirements and the associated costs and administrative burden.	5
g) Protect confidential business information	5
Please provide additional comments	In the registration process under regulation 1907/2006 (REACH) "substance identity" turned out to be a problem, because many substances to be registered were not characterised unambiguously. Because the characterisation of nanomaterials appears to be even more difficult, communications of risks of certain nanomaterials have to express clearly for which nanomaterial the information applies.

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	3
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.	Do not know
g) Protect confidential business information	Do not know
Please provide additonal comments	The information provided by the jrc and the legislative framework are not useable for consumers. The risk information needs to be prepared and presented in a user friendly way focused on the relevant risk and appropriate risk management option. Therefore an easy accessible and well promoted website is needed. Research results should be regularly monitored and assessed by a competent and trustworthy organisation.

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	4
e) The establishment of national registries and notification schemes causes market fragmentation and hampers trade within the internal market	5

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 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): 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): PEC/PNEC-ratio for Nano-Ag indicates a potential hazard for cleaned wastewater. PNECs for 5 nanomaterials in the aquatic environment were estimated in Environ. Toxicol. Chem. 32, 1278-1287 (2013) For consumers as well as workers several uses of nanomaterials exist in which a contact with nanomaterials may occur or is foreseen. Using in this context the term “significant exposure” which is defined in the occupational health and safety legislation might be inappropriate.
Q9: With regard to the past and current use of nanomaterials (tick the relevant box):	I am not aware of any health and/or environmental incidents which have occurred
Q10: The establishment of an EU nanomaterial registry (tick the relevant box):	Would not significantly contribute to reducing the health and/or environmental risks related to the use of nanomaterials , If appropriate, please explain further: If appropriate, please explain further: A nanomaterial registry won’t contribute to reducing the risks. It could serve as a basis for consumer information and for a risk management of the authorities. The risk reduction itself will mainly occur within the regulatory framework of REACH (risk management measures) especially if the ongoing discussion information requirements for nanomaterials will be implemented in a useful way.

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 , Please explain: Please explain: Information about the presence of nanomaterials alone won't have any measurable effect on the consumer behaviour. A minority of the consumer may avoid those products as well as a minority may search for more information. In general the consumption behaviour of products containing nanomaterials with health concerns is comparable to products containing substances of concern or of very high concern.
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, Comments: Comments: See the answer to the question 1 of section V. In case of additional information to hazards there might be negative effects on the market for products with potential hazardous nanomaterials and a positive effects for products with hazard free nanomaterials.

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)	c) hamper innovation in the EU (e.g. through concerns about confidential business information or through additional costs related to providing information) , Comments: Comments: There might be a small positive effect on the innovation due to small changes of the consumption behaviour, see question 1 section V. Basically it has to be distinguished between an additional notification obligation for nanomaterials for the industry or a registry which collects and summarizes existing data, see section IX question 1. A notification duty will hamper the innovation in the EU due to additional compliance costs.

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 , Please explain Please explain: As already stated in question 1 there are several options of a nanomaterial registry with different consequences. An additional notification obligation may hamper the competitiveness of European companies against extra-EU companies, depending on how the non-EU companies will be affected by the notification duty. A registry based on existing data will have no significant impact on intra-EU competitiveness and maybe a small positive effect on the competitiveness of European companies against extra-EU companies. Based on the uncertain impact of a registry it is strongly recommended to first analyse the outcomes of the nanomaterial registrations under REACH within the next years. The collection of data has just started and will be adapted soon.

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.

Such notifications would lead to a lot of additional communication containing huge amounts of information with unknown reliability and relevance [The REACH framework provides sufficient information through material safety data sheets (MSDS) if handled appropriately]. The resulting confusion would be detrimental for consumer's believe in the safety of the nanomaterial-products available in the market. Moreover the costs for the industry as well as the enforcement authorities would be disproportionate to the added value.
Therefore information on nanomaterials should be collected only under the framework of the REACH regulation. These and further existing information would be the basis for a nanomaterial registry/nanomaterial observatory which we prefer.

Q16: Which actors along the supply chain should be subject to notification requirements? (tick all that apply):	Please explain: Please explain: The registration and communication requirements under REACH are sufficient. There should be no further notification requirements.
Q17: The following should be subject to notification requirements (tick all that apply):	Please explain: Please explain: The registration and communication requirements under REACH are sufficient. There should be no further notification requirements.
Q18: Is there a need to exempt certain types of nanomaterials?	If yes, which types should be exempted and why? (in terms of specific properties, available knowledge, absence of hazards, etc.) If yes, which types should be exempted and why? (in terms of specific properties, available knowledge, absence of hazards, etc.) The prescriptions/exemptions of the REACH regulation are fully appropriate.

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.) If yes, which uses should be exempted and why? (in terms of specific exposure scenarios, available knowledge, absence of hazards, etc.) According the REACH Regulation registrants have to communicate risk management measures for every registered use.

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): If other, please explain or add any comment: Other: Any useful information. This includes information from existing legal and labelling requirements, e.g. information from REACH registration or labelling requirements for cosmetics, foods and biocides (see also part 2 of the answer in Section VIII number 1).

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

As stated in the answers of section V and in the first sentence of section IX, the relevant information has to be presented in a clear and consumer-friendly way. The website needs a manageable web address and promotion by the EU and MS.

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 , g) Other purposes (please specify) After a preparation of the relevant information for consumers it can be also used for information (e) or education (f).

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):

There is a need of information about each nanomaterial concerning hazards, risk management, product lines….
The additional value for listing each product on the market seems very small compared to costs and administrative burden.

Q24: What would be the added value of a European nanomaterial registry beyond the current framework of chemicals legislation, including REACH registration?	*Respondent skipped this question*
Q25: Please provide any other comments that you would like to share regarding transparency measures for nanomaterials on the market.	*Respondent skipped this question*