#15

COMPLETE

Collector: Nano Consult - Industry (Web Link)
Started:
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Time Spent:
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PAGE 2: Section I - Identification

Q1: Please provide the following details (*compulsory):	
Organisation*:	
Town/City:	
Country*:	Germany
Contact name:	
E-mail address:	
Q2: 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 but should be kept anonymous
Q3: We might need to contact you to clarify some of your answers. Please state your preference below:	I am available to be contacted
Q4: Did your organisation participate in the online survey (undertaken by RPA/BiPRO for the European Commission in early 2014) on the administrative burden of the notification schemes?	No

PAGE 3: Section II - Organisation Information

Q5: Please indicate which of the following applies to you or your members (tick all that apply):	a) has to notify to the French Notification System , c) is a manufacturer of nanomaterials
Q6: Please indicate the four-digit NACE code of your primary and secondary business sector (if applicable). If you require information regarding NACE codes, please visit the European Commission Competition webpage at http://ec.europa.eu/competition/mergers/cases/index/nace_all.html	
Primary business sector (NACE 4 digit code):	2012
Q7: Please indicate the number of employees.	≥ 250 employees
Q8: Please indicate the approximate annual turnover of your organisation and the annual turnover which relates to nano-related products (where these include nanomaterials as well as mixtures and articles containing nanomaterials).	
Annual turnover	€10m to €50m
Nano-related annual turnover	≤ €250k

Q9: Please indicate the number of nano-related products (where these include nanomaterials as well as mixtures and articles containing nanomaterials) that you place on the national market.

Nanomaterials	less than 6

Q10: Please indicate the number of nano-related products (where these include nanomaterials as well as mixtures and articles containing nanomaterials) that you place on the EU market.

Nanomaterials	less than 6

Q11: Please indicate the number of nano-related products (where these include nanomaterials as well as mixtures and articles containing nanomaterials) that you place on the global market.

Nanomaterials	less than 6

Q12: Please indicate the number of customers and, if applicable, number of suppliers for all your nano-related products combined (where these include nanomaterials as well as mixtures and articles containing nanomaterials).

Number of customers	less than 6
Number of suppliers	less than 6

PAGE 4: Section III – Problem definition and objectives

Q13: 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	4
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	5
e) Ensure the availability of relevant information on the presence of nanomaterials or products containing nanomaterials on the market	3
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	It needs to be defined what is meant by “relevant information”. The information of nanomaterials being present in a product is not of much use without knowing the specific function or impact of that material, and it might not be a "relevant" informationat all if the nanomaterial is not released during the life cycle of the product.

Q14: 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	5
b) Provide consumers with relevant information on products containing nanomaterials on the market	4
c) Maintain competitiveness and innovation of businesses bringing nanomaterials or products containing nanomaterials to the market (including SMEs)	2
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	4
f) Ensure the proportionality of the information requirements and the associated costs and administrative burden.	2
g) Protect confidential business information	2
Please provide additonal comments	to g) There might be different interpretations by industry and legislators on "confidential business information", leading to a different perception .

Q15: 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	1
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	1
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	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	The accentuation of nanomaterials compared to other substances mightevokes the consumer's fear of potential hazards and thus is detrimental to consumers trust. The national registers already in place have different scopes, leading to incoherent collection and presentation of data. Experience with the French Nano-Register shows that there is a high burden, especially for SMEs, national registers would multiply these burdens and thus hamper trade within the (internal) market.

PAGE 5: Section IV – Health and environmental aspects

Q16: **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 aware of 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): There are national schemes to set OELs for nanomaterials , e.g. the German TRGS 527. We are of course aware of possible worker and also consumer exposure to nanomaterials, but the term "significant" needs to be defined, and it has to be stated that exposure can be intentional such as in cosmetics or for food additives. Nanomaterials are no more hazardous substances than other chemicals. (SCENIHR, Risk Assessment of Products of Nanotechnologies (2009): “The hypothesis that smaller means more reactive and thus more toxic cannot be substantiated by the published data. In this respect nanomaterials are similar to normal substances in that some may be toxic and some may not.”).
Q17: **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
Q18: **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: The existing regulations, especially REACH, are sufficient/suitable for controlling risks.

PAGE 6: Section V – Consumer trust

Q19: In case information on the presence of nanomaterials in your products were made available, what impact do you think this would have on your clients? (Please tick all that would apply)	b) They would try to avoid those products, Please explain: Discussions with different industries (e.g. food, cosmetic, automotive supplier and automotive industry) show a growing demand for nano-free products at the end of the supply chain. The reasons for this are the additional efforts and costs in these companies or the additional labelling requirements.
Q20: 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)	c) generate insecurity or stigmatise such products, and thus have a negative effect on the market for the concerned products , Comments: see Section V Q1

PAGE 7: Section VI - Innovation and competitiveness

Q21: 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: see Section III Q2
Q22: 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)	e) hamper intra-EU competitiveness, f) hamper the competitiveness of European companies against extra-EU companies , Please explain see also Section IV, Q1; Nanomaterials are not necessarily more (or less) dangerous than other, non-nano-chemicals; so there is no extra benefit in establishing specific register only for nanomaterials. Therefore register for nanomaterials are a disadvantage for European producers and users of nanomaterials compared to producers and users of other chemicals.

PAGE 8: Section VII – Possible impact of a registry on your company/members of your association

Q23: Overall, how would a possible obligation to notify nanomaterials at the EU level affect your company/the members of your association, assuming that no exemptions were to be made from 1 (no impact) to 5 (significant impact):

a) with respect to nanomaterials on their own	5
b) with respect to nanomaterials in mixtures	5
c) with respect to articles with intended release of the nanomaterials	5
d) with respect to articles containing nanomaterials in general (i.e. in case also articles without an intended release of nanomaterials were to be covered)	5
Please explain:	see Section III, Q3 (e)

Q24: Would disclosure of the notified information conflict with the confidentiality of business information?	Yes, there would be a conflict with business information confidentiality , If yes, please elaborate; you may differentiate according to the different information that may be required in a notification scheme (e.g.: if a notification is only per substance and general use, or if the exact use needs to be disclosed): see Section III, Q2; Information on e.g. distribution, quantities of substances used in different sectors, formulation and name of customers would highly conflict with the confidentiality of business.
Q25: Do you experience or expect any significant barriers for your company/members of your association from diverging registration obligations in the schemes in France/Belgium/Denmark?	Yes, we foresee significant barriers, If yes, please describe these barriers? The differences in notification schemes and definition of nanomaterials lead to a lot of extra workload; keeping it up to date every year means an unnecessary but considerable burden.
Q26: Is the market for your nanomaterials/products containing nanomaterials significantly different from Member State to Member State?	No, there is not any significant difference in the national markets for our products

Q27: In case the European Commission were to recommend a best practice model for national notification schemes based on the experiences in France, Belgium and Denmark, which elements of these systems can be considered as "best practice"?

In our opinion, REACH is already an established register for chemical substances which includes information on nanomaterials.
An alternative implementation for a notification scheme might be the Norwegian approach, being an additional tool to the existing chemical notification legislation.
If there is to be a special nano-register, then the Danish scheme is the most suitable one for communication to the target audience, namely the consumer, as its scope is focussed on consumer products.

PAGE 9: Section VIII – Possible options and exemptions

Q28: 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.

None, the notification per use would bring no extra benefit in comparison to already existing regulations, as the information for downstream users are already covered by the safety data sheets, which are also commonly issued by the chemical industry for non-hazardous substances. Regarding consumer products sufficient regulation is already established (e.g. cosmetics , food, biozides).

Q29: Which actors along the supply chain should be subject to notification requirements? (tick all that apply):	Please explain: No separate nanomaterial registry is required as sufficient regulation/notification systems already exist (see Section VIII Q1.)
Q30: The following should be subject to notification requirements (tick all that apply):	Please explain: Sufficient regulation/notification systems already exist (see Section VIII Q1.)
Q31: 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.) Sufficient regulation/notification systems already exist (see Section VIII Q1.)
Q32: 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.) see Section VIII, Q1.+ Q2

PAGE 10: Section IX – Nanomaterials Observatory

Q33: If a Nanomaterials Observatory is established instead of an EU-wide registry, what type of information should be collected? (please tick all that apply)	f) Other (please explain): Sufficient information is provided by existing regulations.

Q34: How should the information in a Nanomaterials Observatory be presented in order to reach the consumers, workers and authorities?

Sufficient information is provided by existing regulations.

PAGE 11: Section X - Potential use and benefits of a nanomaterial registry

Q35: In what ways could the information on nanomaterials from registries be potentially useful (tick all that apply):	*Respondent skipped this question*

Q36: 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):

Sufficient information is provided by existing regulations.

Q37: What would be the added value of a European nanomaterial registry beyond the current framework of chemicals legislation, including REACH registration?

none, see Section VIII Q3.

Q38: Please provide any other comments that you would like to share regarding transparency measures for nanomaterials on the market.

Due to the extremely broad definition of nanomaterial applied very many materials will have to be considered as “nano”. Thus the focus is lost and there will be no differentiation in new nanomaterials (where hazards need to be identified and controlled, if present) and materials with small particle sizes known and safely used for many decades.