#68

COMPLETE

Collector: Nano Consult - Industry (Web Link)
Started:
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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?	Do not know

PAGE 3: Section II - Organisation Information

Q5: Please indicate which of the following applies to you or your members (tick all that apply):	c) is a manufacturer of nanomaterials, d) is an importer of nanomaterials, e) is a formulator of mixtures containing nanomaterials , k) Not sure whether we deal with 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):	C20 - Manufacture of chemicals and chemical products C25 - Manufacture of fabricated metal products, except machinery and equipment
Secondary business sector (NACE 4 digit code):	C20.1.2 - Manufacture of dyes and pigments; C20.1.2 - Manufacture of dyes and pigments; C25.5 - Forging, pressing, stamping and rollforming of metal; powder metallurgy

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	≥ €50m
Nano-related annual turnover	≥ €50m

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	over 1,000
Mixtures	over 1,000

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	over 1,000
Mixtures	over 1,000

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	over 1,000
Mixtures	over 1,000

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	more than 100
Number of suppliers	6 to 15

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	2
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	2
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	Information on consumer products should include relevant safety precautions if necessary and required. Only the presence of nanomaterials in products should not qualify for labelling and adding the information that nanomaterials are included. A large amount of materials that are nano according to the broad EU definition has been on the market for decades without any known risks for consumers' and workers´ health and safety. The most relevant information for the supply chain is whether a product is safe and how it can be handled safely. This information is already required by the REACH regulation. Providing information to consumers on products containing NMs placed on the market could lead to a stigmatisation of NMs resulting in a negative effect on consumer trust. This may still be the case even if safe use has been demonstrated and the nanomaterial substance is not harmful.

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)	3
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.	2
g) Protect confidential business information	1
Please provide additonal comments	Different definitions for nanomaterials on a global scale, diverging implementations in nanoproduct registers and a lack of suitable and commonly available, reliable and repeatable measuring methods provoke intricacies when dealing with nanomaterials. The uncertainty not only detracts consumer trust, it also hampers innovation processes and competitiveness in the industry. It is known that non-European companies profit from information published on the ECHA-website. Safety and informational content should be well balanced to protect consumers' and workers´ safety and confidential business information equally. For the complete industry and for SMEs in particular additional requirements would constitute an administrative burden with no guarantee of a potential positive impact on consumer trust. Negative consequences on the competitiveness and innovation capacity of the chemical industry can nevertheless be expected.

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	2
d) The available information on the presence of nanomaterials and products containing nanomaterials on the market is presented in an incoherent or ineffective way	2
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 current level of information is adequate regarding the requirements of the REACH regulation. Further obligations triggered by registries and notification schemes require increased efforts and hinder the industry. The accentuation of nanomaterials compared to other substances in various sectors evokes the consumers' fear of potential hazards and thus is detrimental to consumers' trust.

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 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 Scientific Committee on New and Emerging Health Risks stated that “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 chemicals/substances in that some may be toxic and some may not, yet specific nanomaterials and specific uses of these nanomaterials may carry specific health and environmental risks.” Risk Assessment of Products of Nanotechnologies (2009). We are aware of relevant classifications and of the risks of substances we manufacture and we comply with the relevant legislation.
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: Existing regulations are sufficient and suitable for controlling risks and providing customer information. The added value of an EU registry as regards to controlling potential risks is negligible.

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: Experiences have shown that various industries in the end of the supply chain request for nano-free products. The reasons for this are the additional efforts and costs in these companies or the additional labelling requirements. This might evoke the consumers' wish to avoid nanomaterial.
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: As explained in section VQ1. Depending on consumer knowledge and/or understanding, nanomaterials can be interpreted as a threat or a benefit. Generally non-professional users have a poor knowledge about nanomaterials in products and the benefit they bring. This could lead to miss-informed negative perception in the general public. One negative report or information about one specific hazardous or supposedly hazardous nanomaterial will surely be turned over to the complete group of nanomaterials.

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 Q 2, increased effort and costs, administrative burden, negative impact on competitiveness and innovation
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 Nanomaterials are not more or less dangerous than other chemicals, so there is no reason for establishing a specific register only for nanomaterials. A register for nanomaterials would cause an additional burden for industry. Therefore it is a disadvantage for producers and users of nanomaterials compared to producers and users of other chemicals and a disadvantage for European industry compared to non-European competitors.

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:	Pigments and fillers, considered as nanomaterials according to the current EU-definition, are present in nearly every product and article of our daily life. Therefore nearly every product/article would have to be registered if there was no exemption. Investigations on finished products like coatings and plastics containing pigments and fillers show that there is no release of nanomaterials if they are bound in a matrix. (see D. Göhler, A. Nogowski, P. Fiala, M. Stintz, J. Phys.: Conf. Ser. 2013, 429, 012045.) So there is no scientific justification for a registration of articles mentioned under d).
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): Information on e.g. substance identity, uses, particle size distribution, quantities of substances used in different sectors, formulations and names 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 national notification schemes and worldwide definitions of nanomaterials mean a lot of extra workload for the companies; keeping it up to date every year means an unnecessary but considerable burden especially for SMEs. The broadness of the definitions themselves, as they are morphology based and not risk based.
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"?

We cannot recognize best practice in any notification scheme. REACH is already an established kind of register for chemical substances and therefore also already covers nanomaterials.

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 user companies and workers are already covered by the safety data sheets, which are also common for non-hazardous substances This would also mean enormous costs and burden for all downstream users. Regarding consumer products sufficient regulation is already established (cosmetic regulation, food information/regulation, biocides regulation).

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.
Q30: The following 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.
Q31: Is there a need to exempt certain types of nanomaterials?	Yes, certain types of nanomaterials should be exempted from a notification system , If yes, which types should be exempted and why? (in terms of specific properties, available knowledge, absence of hazards, etc.) Non-hazardous nanomaterials and nanomaterials bound in a matrix like pigments and fillers should be exempted because no risk has been observed. One dimensional nano-materials (platelets) should be excluded from the scope of the nano definition due to negligible nano risk. (German Advisory Counsil on the Environment [1]) [1] Vorsorgestrategie für Nanomaterialien; Sachverständigenrat für Umweltfragen, Sondergutachten; Juni 2011
Q32: 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.) We do not support such a scheme. But uses leading to no exposure to human health and the environment need to be exempted.

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?

As part of the implementation of the new European chemicals legislation REACh substances are subjected to extensive toxicological and eco toxicological studies. So there will be no added value by a nanomaterial registry.

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 are “nano”. Thus the focus is lost and differentiation into relevant, new or hazardous nanomaterials and materials with small particles known and used for many decades is not possible.
A risk based approach considering hazards and exposure is needed for nanomaterials instead of a morphology based approach.
The lack of suitable and commonly available measuring methods should be solved preliminarily.