#45

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):	a) has to notify to the French Notification System , b) has to notify to the Cosmetic Products Notification Portal , c) is a manufacturer of nanomaterials, d) is an importer of nanomaterials, e) is a formulator of mixtures containing 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):	C20.5.9 Manufacture of other chemical products

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	€10m to €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.

Mixtures	51 to 100

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.

Mixtures	51 to 100

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.

Mixtures	51 to 100

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	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	1
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	Nanomaterials (NMs) can be seen as any other substance. So e.g. under REACH data must be determined by industry in order to carry out risk assessments and ensure safe use of the substances and mixtures placed on the market. Consumer trust could be increased explaining to the public the process involved. Some specific sector legislation such as for cosmetics and biocides already requires information to be provided for consumers and health authorities. We want to emphasize that by providing information to consumers on products containing NMs placed on the market. This 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 is demonstrated by the implementation of the relevant regulations (REACH and/or sector-specific legislation).

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	2
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	4
f) Ensure the proportionality of the information requirements and the associated costs and administrative burden.	3
g) Protect confidential business information	4
Please provide additonal comments	We expect consumer trust can be improved by good implementation of current European legislation (even if some adaptations in the REACH annexes are needed) and a good explanation to the public. For SMEs notification would mean an administrative burden with no positive impact on consumer trust. Negative consequences on the competitiveness and innovation of the chemical industry are to 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	2
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	1
e) The establishment of national registries and notification schemes causes market fragmentation and hampers trade within the internal market	5
Please provide additional comments	There is no information on health and environmental risks by providing information on the presence of NMs in products. An effective and reliable risk assessment should be carried out for the whole life-cycle of the substance (as foreseen by REACH and product/worker/environment specific regulations). We want to emphasize that definitions of nanomaterial used in the French, Belgian, and Danish schemes are not identical; the same applies for their exemptions from notification. In addition, no standards are given as to measurement methods. As a consequence, substances could be subject to notification requirements in one Member State but not in others and/or considered as a nanomaterial or not depending on the manufacturer's/importer's understanding of the definition and method used.

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): We are aware of relevant risks and risk management measures.
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: Regulations for chemicals (REACH, CLP and sectoral legislation) are appropriate to manage potential risks from nanomaterials, as they are for other chemical substances. This legislation ensures safe use of NMs (as such, in mixtures and in articles). Hence, 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, c) Their purchasing decisions would not be affected , Please explain: We have the experience that because of the stigmatization of NMs our direct customers and consumers tend to refuse NM containing products.

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: Depending on consumer knowledge and/or understanding, nanomaterials can be interpreted as a threat or a benefit. We observed an increasing negative perception in the general public.

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: We have the experience that because of the stigmatization of NMs our direct customers and consumers tend to refuse NM containing products. That is why innovation would be hampered.
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 A notification to a register for nanomaterials would cause a burden on industry producing, importing or using such substances when competing with other non-nanomaterial substances. Furthermore the cost of such a register would probably be passed to consumers thus causing increased prices for value chains in the EU vs. non-EU markets.

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
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

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): The following information is seen as critical concerning confidentiality: - Substance name (sometimes competitors don't know that a substance can exist at the nanoscale); - Information linked to the substance identity (i.e. characterisation of the nanomaterial); - Uses; - Customers name(s).
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? Definitions of nanomaterial in the French, Belgian, and Danish schemes are not identical; the same applies for their exemptions from notification. No advice is given with regard to measurement methods. As a consequence, substances could be subject to notification requirements in one Member State but not in others or considered as a nanomaterial or not depending on the manufacturer's/importer's interpretation of the definition and measurement method applied.
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"?

ALTANA does not see, that there is a best practice model for a national notification scheme.

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.

To comply with the notification per use would be very costly especially for SMEs, due to the often large supply chains involved. As a direct result of these supply chains, this would present a large bureaucratic burden to companies to track down each and every single use.

Q29: Which actors along the supply chain should be subject to notification requirements? (tick all that apply):	Please explain: Notification of nanomaterials beyond existing legislative requirements does not make sense. This is double work and a better approach would be an Observatory – see Section IX for details on ALTANA's proposal to expand the current European Commission's JRC database.

Q30: The following should be subject to notification requirements (tick all that apply):	Please explain: We do not see a need for a register because an observatory approach would meet all stakeholder needs, especially if this were to be implemented as described in our recommendation to expand the existing Euro-pean Commission JRC database – more detail is given in Section IX.
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.) Nanomaterials notified under existing regulatory notification schemes (such as REACH, CLP, biocides, cosmetics) should be exempted. There is no need for further notification if an Observatory approach would be adopted since this would facilitate to bring together of all notifications into one database – see Section IX for details on our proposal to expand the current European Commission's JRC database.
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. However, if this would be put into force then this would cause a large bureaucratic burden on companies. So specific sectoral legislation (e.g. cosmetics, biocides etc.) should be exempt, as nanomaterials used in these sectors have already been notified. Uses leading to no exposure to human health and the environment would need to be exempted as well.

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)

a) Information from existing notification systems,

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

,

e) Information on the hazards and risks of nanomaterials

,

f) Other (please explain):
From our point of view the best way to provide the necessary information to all stakeholders, would be to expand the existing European Commission's Joint Research Centre web platform on nanomaterials and include notifications of nanomaterials to all current regulatory schemes. This ensures positive listing of nanomaterials where their safety assessment has been completely focussed on risk assessment rather than hazard. Notifications would include information on nanomaterials used in food, cosmetics, medical devices, biocidal products as well as substances submitted under REACH (once Annexes are adapted for nanomaterials) and CLP (Classification, Labelling and Packaging). Efforts should also be made to coordinate this data at the substance specific level so that it is searchable. This can then be used for risk assessment by all stakeholders including regulators to identify on a case-by-case basis if there are any data gaps and if any specific risk management controls are needed. With this in place, we thereby see no reason for establishing a separate EU register on top of existing regulatory requirements.

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

With reference to the above answer (Section IX, Q1), information on nanomaterials collected from all current regulatory schemes is already in the public domain and by bringing this together under an expanded European Commission's Joint Research Centre web platform makes this more accessible to consumers, workers and authorities. More importantly this would not only be a portal for bringing together all information, it should also be searchable by use and increase transparency of the risk assessment process for showing safe use of nanomaterials to the public. From our point of view this would satisfy all stakeholders.

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):

We do not expect any of the above deliverables can be effectively achieved from registries (EU and national) containing information on nanomaterials. Provisions are already made within existing sector European legislation that detail the requirements for appropriate risk assessment, so we therefore question the benefit of any additional register of this nature since this in its simplicity is a list that neither guarantees the safety of consumers nor workers and would very likely result in a further barrier to the commercial success of European companies. We believe this could also have a scaremongering effect on the public when they enquire about the need for traceability.

We think that the administrative burden, together with the risk of releasing confidential information and the resulting negative impact on the economy outweighs any potential positive impact of such a scheme. Indeed, no benefit from the French scheme has been identified so far, at least from a consumer perspective.

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

ALTANA supports the Observatory approach as stated in Section IX. We do not envisage a European nanomaterial registry to add any value beyond the current legislative framework for chemicals.
A register whether it be national or European is an extra regulatory burden placed on companies, especially when notification is required annually and not as a one-time action. We also have concerns that the EU would be bound to make registration requirements a bureaucratic, complicated and therefore costly process. This would also be unique to the EU with little relevance to other global regions where companies do business thereby limiting international competitiveness for EU based businesses.

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

We want to emphasize that nano per se does not impose additional risks. For certain substances nanoforms may modify some properties:

Here our most important comments:
• The definition applied has to be clear and measurable. This is not the case for the EU-definition.
• The EU-definition is by far too broad. With this definition the majority of powders have to be notified to the register.
• There are no standardized methods for measurement. Many methods are too expensive for daily use.
• There is a high administrative burden without positive effect.
• Reporting once a year increases this burden.
• Confidential information will be released.
• There will be a negative impact to innovation and competitiveness.
• With legislative approaches “Nano” as technology is stigmatized.

The only advantage of a European registry would be to get rid of the national registries. European and national registries together would be senseless!

• The understanding/implementation of some definitions (“nanomaterial”, “intentionally manufactured”, “professional users”, “distributors”…), all the more that some of them have been adapted in a national con-text without consistency with the European ones (“importer”, “distributor”);
• The problem of nanomaterials characterization and the lack of validated methods, enhancing the uncertain-ties for stating if a substance is a nanomaterial or not;
• The difficulties when communicating in the supply chain (especially with suppliers outside France that were not aware of the regulation);
• The burden for companies, especially for SMEs;
• The broad scope of the scheme: why to report on substances marketed for decades without known health and environmental impacts? Why to report on non-hazardous substances?
• The issue of so precise and low quantities to be reported;
• The frequency of the reporting (once a year);
• The public report that can provide sensitive information (like the tonnage range when only one company declares).

But besides these difficulties, the main issues that UIC wants to underline are:
• The mistrustful perception of the scheme by economic partners and consequently, the negative impact on competitiveness and innovation: indeed, the French notification system has brought uncertainties amongst economic actors towards the French market, leading, in some cases, to question marks regarding business developments and location of R&D activities in France;
• The disruption of the free movements of goods within the EU as the French system is likely to create sig-nificant obstacles to trade of substances and mixtures;
• The questionable added-value of such a scheme (especially versus REACH and existing regulations) whose objectives can appear unclear.

In the end, UIC considers that the administrative burden, the risk of releasing confidential information and the negative impact on economy outweigh the potential positive impact of the scheme.