#39

COMPLETE

Collector: Nano Consult - Industry (Web Link)
Started:
Last Modified:
Time Spent:
IP Address:

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 , c) is a manufacturer of nanomaterials, d) is an importer of nanomaterials, e) is a formulator of mixtures containing nanomaterials , f) is a manufacturer of articles containing nanomaterials without intended release , h) is a distributor of nanomaterials and/or 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):	20xy
Secondary business sector (NACE 4 digit code):	21xy
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
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.	*Respondent skipped this question*
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.	*Respondent skipped this question*
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.	*Respondent skipped this question*
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).	*Respondent skipped this question*

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	3
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	Nanomaterials (NMs) should be regarded as any other substance. In that context, as required by REACH for instance, data should be gathered by industry in order to perform risk assessments and ensure safe use of the products that are placed on the market. By this way, with relevant explanation on the process provided to the public, consumer trust could be increased. Specific legislation covering sensitive products containing nanomaterials, like cosmetics or biocides, already require information for consumers and health authorities. Also via the ECHA dissemination consumers have access to nanomaterials registered under REACH and potential application. An inventory is not the right tool for consumer communication. On the contrary, providing to consumers information on products containing NMs that are placed on the market could lead to a stigmatisation of NMs, with a negative effect on consumer trust, 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	3
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	Do not know
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.	4
g) Protect confidential business information	4
Please provide additonal comments	Merck believes that, as for any other chemical, consumer trust can be increased by a good implementation of the current European legislative framework (even if some adaptations in the REACH annexes are needed), provided that it is well explained to the public. Additional requirements would constitute an administrative burden for companies with no guaranty of a potential positive impact on consumer trust. Negative consequences on the competitiveness and the 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	3
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 adequate response to health and environment risks is not linked to the information on the presence of NMs in products but to an effective and reliable risk assessment carried out for the whole life-cycle of the substance (as foreseen by REACH and product-specific regulations).

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): DNELS and reference values are existing for TiO2 and carbon nanotubes (under REACH and NIOSH)
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 , Please explain (if any, please report the events and any scientific publication): No unexpected incidents in our company or with products from our company. Health and environmental incidents only happen with substances for which the hazardous potential is already known for the non-nanoform (e.g. Nickel).
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: Merck believes that risks can be controlled by the implementation of the current European regulatory framework (REACH, CLP and sectoral legislation), even if we acknowledge that amendments of REACH Annexes may be needed. Indeed, this framework foresees hazards identification requirements, risk assessment methodologies and ensures safe use of NMs that are placed on the market (as such, in mixtures and in articles). Moreover, for hazardous NMs, traceability can be ensured via the Safety Data Sheet as regards industrial and professional users. Hence, the added value of an EU registry as regards risks control is questionable.

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, d) They would search for more information
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, nanomaterials can be interpreted as a threat or a benefit. Generally outside professional users, there is poor knowledge about nanomaterials in products and the benefit they bring. This could lead to a priori negative feeling 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: The implementation of the French national registry system led to a mistrustful perception from economic partners and consequently, to a 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)	f) hamper the competitiveness of European companies against extra-EU companies , Please explain There is no reason a priori to consider that a register is needed for nanomaterials: they are not more or less hazardous than any other chemical. Asking for a register would create a burden on that specific industry producing, importing or using nanomaterials when competing with other non nano substances. In addition the cost of such register would most probably be borne by consumers so entailing increased prices for value chains in 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
c) with respect to articles with intended release of the nanomaterials	3
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)	4
Please explain:	As chemical industry, an EU notification would mainly impact substances and mixtures. However nanomaterials are sometimes already embedded in a matrix at production level and so in this case could be considered as part of articles.

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): Indeed, several confidential information could be disclosed with such a notification scheme: - The name of the substance itself as sometimes competitors don't know that a substance can exist at nanoscale - The information linked to the substance identity (characterisation of the NM) - The uses - The quantities put on the market - The name of the customers

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? Diverging notification obligations increase the workload for companies not only for filling the notification but also to ensure adequate compliance in schemes that diverge from each other.

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"?

- Transmission of the notification numbers along the supply chain in order to minimize the burden for companies and protect confidential information
- Consider as much as possible information as CBI in order not to hamper more competitiveness and innovation

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.

For workers and downstream users, the best information should be found in safety data sheets and is then related to a substance/mixture notification.
A substance notification (as practice under REACH and CLP) is a good start for a NM Observatory.

Q29: Which actors along the supply chain should be subject to notification requirements? (tick all that apply):	Please explain: Notification systems are already, and in Merck's opinion to a sufficient degree, in place (see answers to question 1)
Q30: The following should be subject to notification requirements (tick all that apply):	Please explain: Notification systems are already, and in Merck's opinion to a sufficient degree, in place (see answers to question 1)
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.) Notification systems are already, and in Merck's opinion to a sufficient degree, in place (see answers to question 1)
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.) Notification systems are already, and in Merck's opinion to a sufficient degree, in place (see answers to question 1)

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 , c) Information on the use of nanomaterials across Europe , e) Information on the hazards and risks of nanomaterials

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

For consumers, market studies would be of greater values. For workers and authorities, more detailed information from ECHA dissemination would be useful.

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):

f) General education of the public,

g) Other purposes (please specify)
Risk assessment and risk management should continue to be subject to horizontal and sectoral frame work, as REACH, CLP and the food, cosmetics and biocides Regulations, and not be linked to a product registry.

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):

Merck 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. 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?

No added value identified so far. It seems nice to have in case of a potential problem would occur. However this can be said for any substances or products put on the market. Nanomaterials are not more dangerous per se as any other chemicals.

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

Respondent skipped this question