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COMPLETE

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PAGE 2: Section I - Identification

Q1: Please provide the following details (*compulsory):	
Your name:	
Name of organisation* (if applicable):	
Town/City:	
Country*:	United Kingdom
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 but should be kept anonymous
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	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.	5
g) Protect confidential business information	5
Please provide additional comments	All of these are in principle very important. However they are worded in a very general way which is perhaps inevitable in a questionnaire such as this. In particular, objectives b) and e) turn on the meaning of “relevant”, and both must be informed through meeting objective a), which itself raises the question of what is “appropriate” and the terms in which it is to be decided.

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	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	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.	3
g) Protect confidential business information	4
Please provide additonal comments	There is not actually a single answer to any of these questions which applies to all nanomaterials. To the extent (incomplete, of course) that nanomaterials are covered by REACH, then objective a) should be largely met. Cosmetics, biocides and foods are largely covered in respect of objectives b) and e). The “scoring” here attempts to reflect these and other differentials. However, even where specific requirements in respect of provision of information exist, access to and interpretation of the information may be daunting for casual enquirers from the public. Here again, “relevant” and “appropriate” need detailed consideration according to circumstance.

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	2
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	1
d) The available information on the presence of nanomaterials and products containing nanomaterials on the market is presented in an incoherent or ineffective way	3
e) The establishment of national registries and notification schemes causes market fragmentation and hampers trade within the internal market	3
Please provide additional comments	a) is far too general a proposition to merit any agreement. What can be said is that there is a range of “levels of information available”, in part driven by product-specific legislation. Similarly, b) and c) cannot be supported over the whole range of nanomaterials and furthermore do not explore what “informed consumer choice” or “consumer trust” actually mean in practice. Statement d) is plainly true in the sense that levels of information are not coherent across the range of nanomaterials – but that is not to say that lack of coherence is ineffective. What matters is the level of information is appropriate to the risk-based need. Evidence to support e) is lacking, although it would be surprising if there were no effect on market trade or (notably absent from the question) innovation.

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 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

	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): Hazardous effects of many chemicals are observable in laboratory studies, regardless of particle size. However, the issue to be addressed is the practical risk to human health or the environment which results from the manufacture, use and eventual disposal or recycling of chemicals, whether or not they are nanomaterials. Graphene (CAS 1034343-98-0) is listed in ECHA's classification and labelling (C+L) inventory and is self classified by suppliers as an eye and respiratory tract irritant. The entry states that data are lacking for other endpoints. Fullerenes with the following CAS numbers (115383-22-7, 131159-39-2, 150493-27-9, 150493-29-1, 153218-95-2, 155116-19-1, 155679-97-3, 155679-98-4, 159717-72-3, 160848-21-5, 925673-03-6, 99685-96-8) are also listed in the C+L inventory. These are also self classified as eye and respiratory tract irritants and in some cases skin irritants. The entries state that data are lacking for other endpoints. However, it is possible that these self classifications have been made by the suppliers as a precautionary measure and they are not underpinned by data. ECHA's dissemination site indicates multiwalled carbon nanotubes (EC no. 936-414-1) have been registered. A DNEL for long-term exposure of 0.05 mg/m3 has been established. The registrants have not identified a need to classify this material. The aggregated tonnage band for this registration is 100 – 1000 tpa. Looking elsewhere, NIOSH has set a recommended exposure limit (REL) of 0.001 mg/m3 (8-hr TWA), for carbon nanotubes and carbon nanofibres (http://www.cdc.gov/niosh/docs/2013-145/). This has been set to reduce the risk of pulmonary inflammation and fibrosis and represents the lowest currently measurable level. NIOSH has also set a REL of 0.3 mg/m3 (10-hr TWA) for ultrafine (including engineered nanoscale) TiO2 (http://www.cdc.gov/niosh/docs/2011-160/pdfs/2011-160). This has been set on the basis of animal lung cancer data. Generally when people try to measure workplace exposure to manufactured nanomaterials, it is very difficult to detect the nanomaterial of interest above background concentrations. On this basis, I am not aware of any "significant" worker exposure to specific nanomaterials/types of nanomaterials.
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):	I do not know

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)**	Please explain: Evidence is lacking and it is not appropriate for the Department to speculate at this stage.
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)**	Comments: Evidence is lacking and it is not appropriate for the Department to speculate at this stage.

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)**	Comments: Evidence is lacking and it is not appropriate for the Department to speculate at this stage.
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)**	Please explain Evidence is lacking and it is not appropriate for the Department to speculate at this stage.

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.**

Notification per use would certainly add to administrative burdens and produce a large and potentially unwieldy body of information adding little or no value and potentially detracting from the usefulness of a register.

Q16: **Which actors along the supply chain should be subject to notification requirements? (tick all that apply):**	a) Manufacturers of nanomaterials, b) Importers of nanomaterials, c) Downstream users (e.g. re-formulators, manufacturers of products containing nanomaterials) , Please explain: “Notification requirements” should not necessarily mean requirements prescribed in legislation, but should also encompass voluntary approaches. It is in that wider sense that this question has been answered.

Q17: The following should be subject to notification requirements (tick all that apply):	a) Substances, b) Mixtures containing nanomaterials, c) Articles with intended release of nanomaterials , Please explain: Here again, “notification requirements” is taken to include voluntary approaches. It is in that wider sense that this question has been answered.
Q18: 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 subject to REACH should be exempted on the basis that information will already be available in that way. Nanomaterials used in research or pre-production trials not involving the public should be exempt. Consideration also should be given to exempting nanomaterials which have demonstrably been in use for many years. “Nanomaterials” is taken here, as throughout this questionnaire, to mean manufactured or engineered nanomaterials, not those which occur naturally.
Q19: 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.) Consideration should be given to exempting uses where releases (including at the end of life of products) are demonstrably insignificant. Medicinal uses should also be exempt, in view of the regulatory requirements regarding testing and labelling which already apply.

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,

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):
The observatory would need to be easily searchable, with rapid links to other systems where necessary. As far as possible, it should be a “one stop shop” for information on the nature and use of nanomaterials. It should operate in “real time”, that is to say, with new or updated material appearing as soon as it is input, subject to an appraisal process to confirm the reliability of the information. Detailed views on how he appraisal should be done, how the observatory should operate and what it should contain would need to be obtained from the full range of stakeholders before setting up the observatory as such.

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

It should be presented in conformance as far as possible with the wishes of those groups and of “civil society”.

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

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):

The prime purpose of a registry is to hold information which can be used, according to need, in risk assessment or risk management. The other uses listed above are all ultimately about risk assessment/management (for example, “general education of the public” is about managing the risk of uninformed, damaging campaigns against the use of nanomaterials) and can be serviced as required from a properly structured and searchable register.

Q24: What would be the added value of a European nanomaterial registry beyond the current framework of chemicals legislation, including REACH registration?

Depending on how it is operated, some form of registry could cover nanomaterials which are not subject to REACH if that were shown to be desirable – although evidence is lacking that it would be. Some form of registry – in particular, a “nano observatory” – might also enable easier access to REACH information.

Q25: Please provide any other comments that you would like to share regarding transparency measures for nanomaterials on the market.

Depending on how it is operated, some form of registry could cover nanomaterials which are not subject to REACH if that were shown to be desirable – although evidence is lacking that it would be. Some form of registry – in particular, a “nano observatory” – might also enable easier access to REACH information.