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COMPLETE

Collector: Nano Consult - Non-Industry (Web Link)
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PAGE 2: Section I - Identification

Q1: Please provide the following details (*compulsory):

Your name:	Vito Buonsante
Name of organisation* (if applicable):	ClientEarth
Town/City:	Brussels
Country*:	Belgium
E-mail address:	
Transparency Register ID number (if applicable):	96645517357-19

Q2: Please indicate if you are responding to this questionnaire on behalf of/as:	d) a consumer organisation/trade union/environmental organisation/non-governmental organisation
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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 under the name indicated
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Q4: We might need to contact you to clarify some of your answers. Please state your preference below:	I am available to be contacted
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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) | 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 | 2 |

Please provide additional comments

Building citizens' trust in new technologies is key enabling factor to spur innovation. Further, greater transparency is needed to allow citizens to understand how new technologies are applied and to allow them to decide whether or not they want to make use of these technologies. Transparency enables citizens to make informed choices about the products they buy.

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 | 2 |
| 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) | 3 |
| d) Ensure consumer trust in products containing nanomaterials | 1 |
| 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 additional comments

Due to the low level of compliance with REACH in general and the lack of specific information requirements for nanomaterials, REACH is not providing the necessary information to public authorities and citizens. Further the Commission has decided not to implement within the legally foreseen timeframe its obligation to publish the catalogue of nanomaterials in cosmetics therefore information on the uses of nanomaterials is not sufficient to build trust in the technology.

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 | 5 |
| 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 | 4 |
| c) The current level of available information on the presence of nanomaterials and products containing nanomaterials on the market is detrimental to consumer trust | 5 |
| d) The available information on the presence of nanomaterials and products containing nanomaterials on the market is presented in an incoherent or ineffective way | 4 |
| e) The establishment of national registries and notification schemes causes market fragmentation and hampers trade within the internal market | 3 |

Please provide additional comments	We believe that authorities should have a complete picture of the uses of nanomaterials in order to understand the routes of exposure and, when needed take the necessary measures. Further authorities need to understand in which products nanomaterials exist on the market to take measures for the correct disposal of waste containing nanomaterials.
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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

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I am not aware of any classified nanomaterials,

I am not aware of any DNELs/PNECs/OELs set for specific nanomaterials/types of nanomaterials

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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):

Please explain your responses below (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): Several scientific studies both independent and in some cases carried out by public institutions such as the US National Institute for Occupational Safety and Health, have highlighted hazards related to nanomaterials: these studies have discovered, among others effects of carcinogenicity, pulmonary effects, endocrine disrupting effects and reproductive toxicity. The impacts of nanomaterials have also shown environmental effects in particular in relation to nano silver, carbon nanotubes and cerium oxide.

Q9: With regard to the past and current use of nanomaterials (tick the relevant box):

I am aware of health and/or environmental incidents which have occurred

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Please explain (if any, please report the events and any scientific publication):

Please explain (if any, please report the events and any scientific publication): Although health related incidents have been reported in literature (the most recent case relating to the use of nickel in nano form, the need for information on nanomaterials is not necessary only due to acute effects and incidents related to their use. The goal of chemicals legislation is to document latent effects which are much more difficult to prevent and to document. As some nanomaterials have been shown to behave like asbestos, it is worth reminding that asbestos can show its effects on human health after many decades from the exposure. A register of nanomaterials is needed also to understand the uses of certain materials that may have such latent effects.

Q10: The establishment of an EU nanomaterial registry (tick the relevant box):

Would significantly contribute to reducing the health and/or environmental risks related to the use of nanomaterials

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If appropriate, please explain further:
We believe that it is obvious that knowledge about the uses of materials that may be hazardous could increase the ability of public authorities to prevent harmful effects.

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)

c) Their purchasing decisions would not be affected

,

d) They would search for more information,

Please explain:

The consumer behaviour is largely unaffected by the labels. However citizens would welcome further transparency about the composition of the products they use. We believe that there is no reason to hide to citizens what products, substances, materials they are being exposed to and that it is not ethical to force consumers to buy products containing substances they may want to avoid on a precautionary basis.

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)

a) generate trust among consumers and the broad public, and thus have a positive effect on the market for the concerned products

,

Comments:

Citizens would welcome innovative uses of nanotechnologies that brings benefits to them as long as there is little or no risks from the use of these substances in the products they buy.

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)

a) stimulate innovation (e.g. through increased consumer trust, increased awareness on nanomaterials)

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Comments:

Certainty for all operators is clearly a better environment for business and innovation. The uncertainty about the hazards, about the risks, about the legal requirements is detrimental to all parties. Consumers have less trust in nanomaterials, companies are not motivated to invest due to the uncertainties. The EU is an important market that could spur the way for innovative solutions that are also safe for citizens and the environment. Years of discussions with the only aim of delaying regulatory action in relation to nanomaterials have not had a positive impact on the development of this technology. In addition it further adds to the lack of confidence that citizens have towards European institutions.

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)

a) stimulate intra-EU competitiveness,

b) enhance the competitiveness of European companies against extra-EU companies

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Please explain

A European wide nanomaterials register would encourage safe innovation and thus greater investment in a technologies that also has potential to deliver many benefits for the environment. No detrimental effects could be foreseen in extra-EU competition, particularly due to the size of the EU market.

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 benefit traceability in the supply chain of the use of nanomaterials and it would also be coherent with the need to estimate exposure per use of the substance. A notification system based on substances only would give a limited picture of the uses and would not be sufficient to allow consumers' choice.

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)
- ,
- d) Distributors to professional users (e.g. wholesalers)
- ,
- e) Distributors to consumers (e.g. retailers),

Please explain:

Traceability in the whole supply chain would make it necessary that all actors in the supply chain are involved in the notification requirements. if any of the actors in the supply chain are exempted then the flow of in-formation would not allow effective information to consumers.

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
- ,
- d) Articles containing nanomaterials without intended release
- ,

Please explain:

All actors should be included in the notification requirements; there is no reason to exempt any. An exemption of articles without intended release would create also legal uncertainty in the interpretation of what is intended release and unintended.

Q18: Is there a need to exempt certain types of nanomaterials?

No, all kinds of nanomaterials should be subject to notification obligations

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If yes, which types should be exempted and why? (in terms of specific properties, available knowledge, absence of hazards, etc.)
There is no reason to exempt any type of nanomaterial. The fact that a substance has been on the market for a long time does not mean that it is safe or that its safety is proved or that there is no need of transparency about its uses.

Q19: Is there a need to exempt certain uses of nanomaterials?

No, all uses of nanomaterials should be subject to notification obligations

,

If yes, which uses should be exempted and why? (in terms of specific exposure scenarios, available knowledge, absence of hazards, etc.)
 There is no reason to exempt any use of nanomaterials unless full traceability is already possible through other regulatory regimes applicable in the EU. Further, use specific exemptions could create a lot of legal uncertainties.

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,

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

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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):
 We believe that a system that doesn't create legally binding obligations could not solve the problem of lack of information on the uses and safety of nanomaterials on the market.

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

Respondent skipped this question

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,
- b) Enforcement of worker protection,
- c) Promotion of safe use of nanomaterials in products
- ,
- d) Development of strategies to ensure the safe use of nanomaterials
- ,
- e) Informed purchasing decisions by consumers,
- f) General education of the public,
- g) Other purposes (please specify)
- Safe disposal of waste containing nanomaterials.

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):

We believe that a notification scheme based on the uses of nanomaterials that covers the entire supply chain would be the best tool. Also the full coverage of the supply chain would allow companies to understand well what substances are included in their products. Citizens would be able to make an informed choice and, pending full assessment of the hazards and risk of nanomaterials decide whether the potential risks from a nanomaterials is outweighed by its benefits.

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

The shortcomings of REACH in relation to nanomaterials have been mentioned above. To a certain extent they can be addressed through a better implementation of REACH and through better enforcement. However the powers of member states in the enforcement of REACH in relation to registration have not been fully explored, thus member states have not fully exploited the possibility of using enforcement to address the lack of information on nanomaterials.

However REACH has many shortcomings in relation to nanomaterials especially in relation to information in articles for consumers' use and in relation to lower volumes of nanomaterials.

See ClientEarth's ideas on how to review EU laws on chemicals in relation to nanomaterials here: <http://www.clientearth.org/reports/high-time-to-act-on-nanomaterials.pdf>

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

Respondent skipped this question