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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:	Rob Buurman
Name of organisation* (if applicable):	OIVO-CRIOC
Town/City:	Brussels
Country*:	Belgium
E-mail address:	
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
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
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)	1
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	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 additional comments	To questions c), d) and g) we have answered that the respective objectives are not important at all. Please note that this doesn't mean that we feel that these aspects are not important per se (understandably, they might be for some sectors), but rather that we don't consider them to be important objectives from our perspective (consumer interests). With respect to consumer trust (question d)), however, we would like to add that we are very much in favor of transparency, and consumer trust can be gained through transparency, proper regulation and enforcement. Indeed, without better regulating NMs and continuing doubts with regard to safety and environmental issues, consumers will not have full trust into products containing NMs. Please note though that pursuing consumer trust for its own sake, is of no interests for consumers. It are businesses that profit when consumers put trust in their organisations and products, but consumers get none the wiser simply by placing trust in something.

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	1
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)	Do not know
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	1
f) Ensure the proportionality of the information requirements and the associated costs and administrative burden.	Do not know
g) Protect confidential business information	Do not know
Please provide additonal comments	The current legislative framework is insufficient because REACH does not provide for a definition for the term “nanomaterial”, the tonnage band which triggers registration requirements is currently too high and manufacturers do not declare the nano-form sufficiently in registration dossiers. REACH does not deliver data on the application of a nanomaterial and the nanomaterial concentration in articles. Hence, the current legislative base needs to be reviewed to incorporate specific requirements on nanomaterials. Even though the cosmetics regulation requires a pre-market notification and to inform the public about the use of nanomaterials in cosmetics, we regret that the Commission passed the deadline by more than half a year already to provide such information to the public. The JRC web platform is a collection of information that already exists on the internet, but does not fill existing knowledge gaps.

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	5
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	5
e) The establishment of national registries and notification schemes causes market fragmentation and hampers trade within the internal market	4
Please provide additional comments	We agree that the establishment of different national registries and notification schemes – while being useful in the absence of a mandatory EU measure - are inefficient to collect information about nanomaterials. The different approaches should be replaced with an EU-wide scheme which will be based on a mandatory EU Nanomaterial registry by application as only such a system will provide for uniform, full traceability across the supply chain. A regulatory strategy needs clear and comparable information about NMs and their use. Currently, regulators are missing information regarding the applications of nanotechnologies and nanomaterials, which products contain which kind of nanomaterials in which quantities. Furthermore, regulators are missing information on whether nanomaterials are released and if so, in what life-cycle stage of a product. Any claims made by the industry about health, safety and environment need to be scientifically substantiated.

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

,

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):
Scientific studies report frequently about health effects of nano-materials on health and/or the environment. There is evidence that carbon nanotubes may have effects on human health; and silver nanoparticles and titanium dioxide are detrimental to the environment (Emergnano, 2009 and more recently evidence of carcinogenity of TiO2 was shown in a study of the US National Institute for Occupational Safety and Health). Endocrine and cardiovascular effects among others are also observed. A new report by the Swedish Society for Nature Conservation gives an overview of these risks: Managing the unseen – Opportunities and Challenges with nanotechnology. Among the health risks stemming from nanomaterials which are already available on the market, there are however still large uncertainties. As possible uptake into the body takes place through inhalation, oral intake or dermal absorption, it has to be underlined that (long term) exposure of consumers to nanomaterials will be increasing in the coming years as nanomaterials will be used more widely. In 2012, ANEC and BEUC had monitored critically the large number of “nano silver claims” on different types of consumer products. We voiced concerns that a growing use of and exposure to nano-silver in every-day consumer products could lead to the formation of anti-microbial resistances. The recent scientific opinion from SCENIHR underlines that “Current evidence from the peer-reviewed literature raises some concern on possible health effect of continuous exposure to Ag-NP. Such concerns question the increased usage of products containing Ag-NP, in particular usage in consumer product that is not linked to justified and tangible benefits. When Ag-NP are used in consumer products, care should be taken that consumer / hygienic products release sufficient silver to be functional / effective.” http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_039.pdf In May 2014, ANSES published the study “Evaluation des risques liés aux nanomateriaux” that collected ecotoxicity data about possible effects of nanoparticles in living organisms. Among them are carcinogenic and reproductive effects, delays in growth and malformation in the development. https://www.anses.fr/fr/content/%C3%A9valuation-des-risques-li%C3%A9s-aux-nanomat%C3%A9riaux

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 , Please explain (if any, please report the events and any scientific publication): Because of lacking worker's protection, (fatal) incidents due to the use of nanomaterials have been reported to have occurred in China (see for instance http://erj.ersjournals.com/content/34/3/559.abstract).
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 , If appropriate, please explain further: More transparency on the uses and applications of nanomaterials is needed. We call for the introduction of a mandatory notification scheme of all nanomaterials that are used in products, before the products can be placed on the market and for those products already on the market. Industry also needs to provide the identification and specification of the substance, the quantity in which the substance is used, available toxicological data of the substance and relevant safety data, test methods and reasonably foreseeable exposure.

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)**	a) They would be more inclined to purchase those products , b) They would try to avoid those products, c) Their purchasing decisions would not be affected , d) They would search for more information, Please explain: More transparency on the uses and applications of nanomaterials is needed. We call for the introduction of a mandatory notification scheme of all nanomaterials that are used in products, before the products can be placed on the market and for those products already on the market. Industry also needs to provide the identification and specification of the substance the quantity in which the substance is used, available toxicological data of the substance and relevant safety data, test methods and reasonably foreseeable exposure.

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: Both A & B can apply. Just informing consumers about the presence of nanomaterials in a neutral manner should not be confused with warning labels, as is wrongly often stated by the industry and used as an argument against full transparency. Moreover, our comments with regard to the question above are also valid for this question, i.e. the purchasing decision of some consumers may be affected in favour or against products containing NM.

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) , Comments: A reporting scheme would provide for transparent information about nanomaterials in products and could thereby contribute to greater legal certainty in the market. Companies regularly indicate that legal uncertainty e.g. related to the nano-definition and the scope of certain legal requirements such as labelling requirements of cosmetic products hamper innovation. In case a nanoregister removes this uncertainty, a positive effect on innovation can be expected.
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)	d) have no significant impact on the competitiveness of European companies against extra-EU companies , Please explain To avoid negative impact on competitiveness, the EU should opt for a mandatory register per uses (Option 4 in the draft bipro/RPA consultancy report) which would require a declaration per use. Imports should be covered by such a mandatory registry.

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.

This option would allow for full traceability and provide for the highest level of transparency. It would also allow in case of emergencies a rapid intervention of public authorities at the source of the problem. It would also allow for appropriate market surveillance measures to be taken without putting burden on economic operators who are not responsible for having caused safety concerns.
An important additional reason for a database is to help authorities with understanding and monitoring exposure routes- and levels. Research is currently done to understand better what the possible hazards of certain nanomaterials are, but without knowing to which nanomaterials the public is exposed, and in which way that happens, authorities are seriously hampered in understanding the risks. This is also a pivotal reason that supports a type of database for which each use of a nanomaterial substance needs to be registered.

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: As mentioned above, every new use of a NM should be declared in the mandatory reporting scheme. Retailers have to be included in case they sell products which contain nanomaterials which have not yet been reported in the reporting scheme before. This is in particular important for imported products for which downstream users have not yet made a declaration for the end product.
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: The EU Commission Recommendation for the term nanomaterial should be the basis for notifying a nanomaterial. However, it has to be pointed out that for the exposure of consumers and the environment it is irrelevant whether the release of nanomaterials is intended or occurs accidentally. Moreover, the “intention” of a manufacturer to release NMs is difficult to proof. Hence, all articles containing nanomaterials should be notified. We do therefore not support an exemption of all “incidental” materials as has been discussed in the draft bipro/RPA consultancy report.

Q18: Is there a need to exempt certain types of nanomaterials?	No, all kinds of nanomaterials should be subject to notification obligations , If yes, which types should be exempted and why? (in terms of specific properties, available knowledge, absence of hazards, etc.) Exempting NMs from reporting because of a lack of knowledge about their properties is not acceptable based on the precautionary principle. If a manufacturer is unable to proof the absence of harm before marketing, such materials and mixtures should not be commercially available. We accept to exclude only certain liquid nanoparticles such as micelles in mayonnaise. However, in case nanostructures are created to deliver a certain function, such as liposomes which carry encapsulated NPs, these should be covered by reporting obligations. Today, the different national nano registers have different exemptions. An EU wide solution should provide consistency here with regard to exemptions to make sure that reporting obligations will not differ in different EU countries. All exemptions must be limited to a few groups of substances with proper justification.
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.) All manufactured NMs should be notified. To illustrate: excluding nanomaterials in paints from registration means that authorities will lack important information on exposure to many nanomaterials. Exclusions on the base of 'use' is nonsensical from a risk-perspective where authorities want to get information on exposure. The reporting should also cover materials where NMs are present as a by-product of the production process even though the manufacturer intended to produce a material larger than the nanosize (e.g. above 100 nm).

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)	f) Other (please explain): We do not support a Nanomaterials Observatory as we need a proper regulatory information provision.

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

A Nanomaterial Observatory is not our preferred option as it is an insufficient measure to provide transparency about the use of nanomaterials to consumers. If this option will be implemented, consumers in each EU country should have access to information about which types of nanomaterials have been used for what purpose in which consumer products. They should also find information whom to contact in case of safety concerns, such as addresses of market surveillance authorities. The following reporting parameters are key: Quantities of NMs produced and used per application. Information about possible exposure about accidents/ safety concerns, i.e. collecting information about incidents related to NMs.

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

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):

As mentioned above, we believe that the option 4 should be realised, i.e. an indication of concrete substances and mixtures per use. To allow consumers to take transparent purchase decisions full traceability throughout the supply chain has to be ensured from the manufacturers of the raw materials up to the final consumer product.
In 2011, BEUC analysed the functioning of the consumers' right to know (http://www.beuc.eu/publications/2011-09794-01-e.pdf). It has been found that very often retailers did not know which hazardous chemicals were contained in their products and that they were unable to provide such information to consumers because of a lack of information from the manufacturers. We could demonstrate this through asking in each letter for information on three different products of the same category (e.g. 3 different toothbrushes) sold by the same retailer. In some cases, we only received information about one or two but not all three products. This shows that there is a lack of cooperation in the supply chain. For this reason, all manufacturers, downstream users and importers / retailers should make entries in such a nano-register to ensure that there will not be loopholes with regard to the information provision.

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

As outlined above (see Section III question 2), REACH does not ensure consistent reporting about the use of nanomaterials in consumer products. Per definition, REACH is only about Registration, Evaluation and Authorisation of Chemicals and not about informing consumers about chemicals unless they are Substances of Very High Concern. Moreover, article 33 of REACH is only allowing consumers to ask for information rather than requiring manufacturers to provide this type of information proactively. REACH would not help in understanding in which ways and in which quantities consumers are exposed to different nanomaterials. Registration for each use of a nanomaterial substance is necessary to help authorities understand the actual exposure, and consequently be able to perform risk assessments and intervene more effectively when necessary.
As there is still little information about the safety of nanomaterials available to consumers, a European nanomaterial registry will fill an important information gap and will facilitate informed decision making.

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

Please note that most of our comments are identical to ANEC's and BEUC's comments as we work together with these organisations. On a few occassions, our opinions are slightly different though.