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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:	Monita Sharma
Name of organisation* (if applicable):	PETA International Science Consortium, Ltd.
Town/City:	London
Country*:	UK
E-mail address:	
Transparency Register ID number (if applicable):	83485908659-40
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	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	3
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

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	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

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	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	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	1
e) The establishment of national registries and notification schemes causes market fragmentation and hampers trade within the internal market	3

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 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):
Human inhalation exposure studies Exposure assessments were conducted at six representative primary and secondary manufacturers of carbon nanotubes and carbon nanofibres. Sampling of personal breathing zones at the sites mostly suggested a dose below the recommended exposure limit (REL) of 7 mg/m-3 as proposed by the US National Institute for Occupational Safety and Health (NIOSH) except for the secondary sites that used the nanomaterials for commercial applications (Dahm, Evans et al. 2013). A similar study showed the airborne concentration of carbon nanotubes generated during handling to be 53µg/m3 or below (Maynard, Baron et al. 2004). This study also quantified the possible dermal exposure to carbon nanotubes by quantifying the concentrations on the gloved hands (0.2 mg and 6 mg per hand) and speculating exposure to less protected areas. Human oral exposure studies Recent studies evaluated oral exposure of silver nanoparticles in human subjects (18-80 years of age). Exposure to commercial nanoscale silver NP solutions (63 ± 19 nm) with an average ingestion of 100 µg/day or 480 µg/day for 14 days did not cause any clinically important changes. Detectable silver was found in serum but not in urine (Munger, Radwanski et al. 2014; Smock, Schmidt et al. 2014) References: Dahm, M. M., D. E. Evans, et al. (2013). Occupational exposure assessment in carbon nanotube and nanofiber primary and secondary manufacturers: Mobile direct-reading sampling. Annals of Occupational Hygiene 57(3): 328-344. Maynard, A. D., P. A. Baron, et al. (2004). Exposure to carbon nanotube material: aerosol release during the handling of unrefined single-walled carbon nanotube material. J Toxicol Environ Health A 67(1): 87-107.

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):
Examples of human case studies related to clinical implications after occupational/accidental exposure to nanomaterials A few case studies have assessed the toxicity of nanomaterials after inhalation exposure in humans. Recently, a case study of a 26-year-old female chemist was published in which clinical symptoms were linked to occupational exposure to nickel nanoparticles (Journeay and Goldman 2014). The chemist developed nickel sensitization when working with nickel nanoparticles, and her symptoms included throat irritation, nasal congestion, post-nasal drip, facial flushing, and new skin reactions to her earrings and belt buckle. An investigation into this case revealed that engineering controls such as working with nanoscale nickel under a hood, in a glove box, or wearing personal protective equipment were not used during material handling. Apart from the workforce directly handling nanomaterials, there is evidence of exposure from the products that the nanomaterials are incorporated into. In the case of a 33-year-old female working in an open plan office, weight loss and diarrhea were linked to exposure to carbon nanoparticles from toner dust used in laser printers (Theegarten, Boukercha et al. 2010). Laparoscopy followed by biopsies done for suspected endometriosis based on the clinical symptoms revealed the presence of dark spots in the peritoneum. Scanning electron microscopy and energy dispersive x-ray analysis confirmed the size (31 to 67 nm) and carbon composition of the dark spots in the peritoneum. Transmission electron microscopy revealed localization of these carbon aggregates in the phagolysosomes of macrophages. In this case, the transport of carbon nanomaterials and their submesothelial deposition was assumed to occur via lymphatic and blood vessels after inhalation exposure to toner dust. Another study reported that seven female workers (aged 18 to 47 years) were exposed to nanoparticles for 5 to 13 months and all had clinical symptoms such as shortness of breath and pleural effusions (Song, Li et al. 2009). References: Journeay, W. S. and R. H. Goldman (2014). Occupational handling of nickel nanoparticles: A case report. American Journal of Industrial Medicine. Theegarten, D., S. Boukercha, et al. (2010). Submesothelial deposition of carbon nanoparticles after toner exposition: case report. Diagn Pathol 5: 77. Song, Y., X. Li, et al. (2009). Exposure to nanoparticles is related to pleural effusion, pulmonary fibrosis and granuloma. European Respiratory Journal 34(3): 559-567.

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

Respondent skipped this question

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)	*Respondent skipped this question*
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)	*Respondent skipped this question*

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)	*Respondent skipped this question*
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)	*Respondent skipped this question*

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.	*Respondent skipped this question*
Q16: Which actors along the supply chain should be subject to notification requirements? (tick all that apply):	*Respondent skipped this question*
Q17: The following should be subject to notification requirements (tick all that apply):	*Respondent skipped this question*
Q18: Is there a need to exempt certain types of nanomaterials?	*Respondent skipped this question*
Q19: Is there a need to exempt certain uses of nanomaterials?	*Respondent skipped this question*

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 , d) Information concerning products containing nanomaterials , e) Information on the hazards and risks of nanomaterials , f) Other (please explain): The Nanomaterials Observatory should include information from the existing literature regarding physico-chemical characterization and life cycle transformations of nanomaterials in addition to their potential impact on biological and ecological systems. Information regarding the potential exposure to nanomaterials, based on published case studies, should also be reported.
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, d) Development of strategies to ensure the safe use of nanomaterials , f) General education of the public, g) Other purposes (please specify) Decrease or eliminate duplication of studies

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):

Registries such as the Nanomaterial Registry are intended to provide information regarding the physico-chemical properties of nanomaterials in addition to their biological and environmental interaction. Such information is critical for risk assessment and management. Furthermore, the registries provide information on the physical form (powder or solution) of the nanomaterial when it is manufactured or used in the development of other products, which is useful in exposure monitoring. Accurate assessment of the exposure will help in implementing appropriate engineering controls to ensure worker protection. Inclusion of data regarding the biological and environmental interaction of nanomaterials, as provided by the registries, will provide information regarding the toxicity potential of nanomaterials and be useful in making informed decisions regarding the safe use of nanomaterials.

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

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