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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:	marie kranendonk
Name of organisation* (if applicable):	Women In Europe for a Common Future - Netherlands
Town/City:	Utrecht
Country*:	The Netherlands
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)	4
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.	3
g) Protect confidential business information	3
Please provide additional comments	Building consumer trust is the most essential priority. Otherwise innovation and development of nanotechnologies will fail in the future. To build consumer trust there needs to be a prioritised focusby regulatory authorities on health risks from nanomaterials applied in consumer products and from environmental pollution by nanomaterials and - production processes . This should be combined with greater transparency of nano containing products on the market through labelling and accessible information and communication to the general public as well as in educational materials for schools.

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	2
c) Maintain competitiveness and innovation of businesses bringing nanomaterials or products containing nanomaterials to the market (including SMEs)	2
d) Ensure consumer trust in products containing nanomaterials	1
e) Ensure the availability of relevant information on the	1

presence of nanomaterials or products containing nanomaterials on the market	
f) Ensure the proportionality of the information requirements and the associated costs and administrative burden.	1
g) Protect confidential business information	5
Please provide additonal comments	Several years after the beginning of REACH implementation, and after the first two registration deadlines, information available to public authorities, citizens and consumers is still extremely limited. ECHA's analysis of information provided through REACH registration of nanomaterials concludes that the information provided is extremely limited, and inadequate. One important hurdle for data submission in REACH and subsequently for data which is available for decision makers and competent authorities is the registration-threshold of 1 t/a and per manufacturer/importer for a substance in REACH. If a nanomaterial together with a chemically identical bulk material is manufactured or imported in quantities of 1 t/a or more, information on the nanomaterial should be available, too, even if the quantity of the registered nanomaterial is less than 1 t/a. This is due to the fact that all identified uses of a substance have to be registered (see Art. 10 (a) (iii) REACH), which includes uses below 1 t/a. However, if a nanomaterial is not chemically identical with a bulk material (e.g. carbon nanotubes with carbon), the nanomaterial itself must be manufactured or imported in quantities of 1 t/a or more in order to be registered. In any case REACH will not deliver data on: • the application of a nanomaterial as the usage categories in REACH are very broad, • the nanomaterial concentration in the respective product, and • manufactured or imported tonnage bands of the nanomaterial(s) when registered together with the chemically identical bulk material.

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	4
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	2
Please provide additional comments	Consumer trust is not just depending on sufficient information about the presence of nanomaterials in products. Consumers expect in the first place that the authorities will protect their health and environment by adequate policy measures. But the authorities cannot take those measures without sufficient and clear, understandable information about the properties and type of nanomaterials in products and about the health and environment risks. If the EU does not take appropriate health protection measures and does not put health protection as a priority above economic interests of companies, then members states have the obligation to protect their citizens by national registration and notification schemes.

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
Q9: With regard to the past and current use of	Please explain (if any, please report the events

nanomaterials (tick the relevant box):

and any scientific publication):
The increasing use of nanomaterials has raised concerns about their potential risks to human health. Recent studies have shown that nanoparticles can cross the placenta barrier in pregnant mice and cause neurotoxicity in their offspring. They show that silica and titanium dioxide nanoparticles with diameters of 70 nm and 35 nm, respectively, can cause pregnancy complications when injected intravenously into pregnant mice. The silica and titanium dioxide nanoparticles were found in the placenta, fetal liver and fetal brain. Mice treated with these nanoparticles had smaller uteri and smaller fetuses than untreated controls. Risks of Nanomaterials in personal care products Personal care products may contain SiO2, ZnO or TiO2 nanoparticles. Risk estimates regarding these nanoparticles have so far proven elusive due to data gaps. More is known about nanoparticulate hazard to humans. The ability to generate reactive oxygen species is a major determinant of this hazard, but there are presumably also other determinants such as the ability of nanoparticles to change the structure of cellular components leading to loss of functionality. There is scope for hazard reduction by substitution and by suppressing the ability of nanoparticles to generate reactive oxygen species. Options for hazard reduction are not reflected in current legislation regarding personal care products in the USA and the European Union. Current widespread application of nanomaterials in consumer products without proper knowledege about their physicochemical properties and biological responses, and without adquate testing methods and legislation and control;, is a great cause for concern both among indepemdent researchers and citizens. The necessary precautionary approach is neglected by industry and authorities. CONSUMERS ARE not aware or POORLY INFORMED ABOUT HEALTH hazards of NMs that are published by researchers. Research information indicates that further studies of the relation between physicochemical properties of NMs and biological responses are needed for the development of safer forms of NMs. In the meantime a good registration system should be put in place in the EU for nanomaterials. (Ciel) Other health hazards and risks Evidence of Carcinogenicity: A study done on the impacts of nano sized titanium dioxide on rats showed a significant increase in malignant lung tumours following chronic inhalation of the nanomaterial (Heinrich et al., 1995). The US National Institute for Occupational Safety and Health (NIOSH, 2011) also determined the same result. More recent research by NIOSH has also showed the potential for multi wall carbon nanotubes to increase the risk of cancer in mice exposed to a known carcinogen (Castranova et al., 2013). Evidence of pulmonary effects: Animal studies have linked inhalation of carbon nanotubes to inflammation in the nasal cavity, larynx and trachea as well as alveolar lipoproteinosis (deposition of surfactant like material in the alveoli) (Ma-Hock et al,.

2009).Other in vivo studies have linked single wall carbon nanotubes to pulmonary toxicity, namely granulomas in the lungs (Larn et al., 2004). The severity of these effects is concentration dependent (Ma-Hock et al., 2009). The danger of pulmonary disease is inversely proportional to the size of the particle, smaller the particle, the greater the danger (Poland et al., 2008). Several studies have found that multi wall carbon nanotubes can have a significant impact on biological activity (Muller et al., 2009). One study showed that long multi wall carbon nanotubes produced length dependent effects on a surrogate for the protective lining that covers many internal organs of the chest cavity (Poland et al., 2008). Effects include inflammation, foreign body giant cells, and granulomas. Other in vivo studies found that long exposure to nanosilver particles via inhalation produced an inflammatory response and alterations to lung function (Sunget al., 2008). These findings are similar to others showing pulmonary effects of other nanomaterials (aluminium oxide, titanium dioxide, zinc oxide, copper oxide and nickel oxide (Cho et al., 2010). Endocrine effects: Several studies have observed effects of quantum dots on reproductive dysfunction, thyroid hormone signaling, estrogen receptor activation, and endocrine disrupting activity. Other studies have shown that metal and metal oxide nanoparticles may exert endocrine-associated toxicities. Reproductive toxicity: It has been demonstrated in vivo rats that nano titanium dioxide cross the blood-testes barrier and cause lesions in the testis and spermatogenesis (Gau et al., 2013). This study showed changes in gene expression and hormone levels. Studies have that pre pubertal males exposed to nano silver resulted in delayed puberty and the males had lower sperm concentrations and a higher frequency of abnormal sperms, changes in the morphology of the seminiferous epithelium, as well as changes to cell membrane integrity and mitochondrial activity (Mathias et al., 2014, Sleiman et al., 2013 and others). Trans generational effects have also been demonstrated in a study where mice were exposed prenatally to nano carbon, lower sperm counts were found in the second generation (Oraby et al., 2013). Environmental toxicity: The impacts of nanomaterials has also been shown to impact on the environment. There is evidence of silver nanoparticles causing harm to aquatic invertebrates under low concentrations (Aitken et al., 2009). Other studies confirm this as they show adverse responses of plans and micro organisms to low doses of silver nanoparticles applied in field experiments via a likely route of exposure, sewadge sludge application (Colman et al., 2013). Studies have also shown that carbon nanotubes can induce cell death in plants (Cong-Xian Shen et al., 2010). Recently, a research team has determined that some metalic nanopoarticles can enter the food chain (Hernandez-Viezcas., 2013). Cerium oxide can be taken up by food crops when present in the soil, this is then an accumulative process as these

this is then an accumulative process as these metals build up in the ecosystem. The researchers also showed uptake of zinc nanoparticles.

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:
Public authorities/agencies and governments will gain a comprehensive overview of nanoproducts available on the market across all sectors affected, enabling them to draw various conclusions, e.g. on the amount of special nanomaterials used in products in various sectors or the possible exposure pathways for those nanomaterials. Subsequently, governments and public agencies can use such information to improve their law enforcement as well as to develop new or adjust existing research programs for eco- and humantoxicology tailored to the nanomaterials on the market and their possible exposure pathways. Companies would benefit from the ENPR by gaining more knowledge about the use of NMs throughout the product chain. Traceability of nanomaterials throughout the production chain is an important part for risk management for both producers and authorities. That way, all players are enabled to remove products containing nanomaterials from the market if they prove to be unsafe after all based on latest scientific findings. The instrument enables producers to duly perform their producer responsibility. Consumers would have the choice between products containing NMs and without NMs. In addition, increased transparency could retain trust in NM technologies. The ENPR would also be beneficial in that it will limit the distortion of the European markets from different parallel registers at national level. An ENPR which is built on present substance and product related regulations would cost notifiers (manufacturers, distributors etc.) significantly less than multiple independent registers potentially creating duplicate obligations.

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)	a) generate trust among consumers and the broad public, and thus have a positive effect on the market for the concerned products , Comments: Availability of information on the presence will also include information on the health and environment aspects - and public awareness will help to steer production and use of nanomaterials in the necessary safe and sustainable direction.

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)
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 , Please explain The need for health and environment protection and for sustainable development is regarded as an essential basis for development and the costs of negelcting these are increasingly recognised. A healthy workforce and reduction of health care costs are basic to increased competetiveness.

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.

A notification per use of a mixture/article would allow for full traceability across the supply chain, which would be beneficial for supply chain information, relevant to downstream users and distributors, as well as for workers and consumers. If a product is labelled with a product-specific notification number and additionally nanomaterials are named on the label of the product, the chances that consumers and regulators will be able to track nanomaterials containing products is likely to be higher than in the other options.
It will also help to keep tabs on new nanoproducts entering the market, which is of key importance when trying to measure the total exposure and potential environmental and health impacts of nanomaterials. Moreover it will help improving knowledge on substances in products along the supply chain as currently many organisations/suppliers are unsure as to whether their products/ semi-row materials contain nanomaterials or not.
The notification per substance present in multiple products is useful for regulators, and research agencies but isn't sufficient in allowing informed consumer choice. The process needs to be clear, effective and provide consumers and down-stream suppliers with robust information to gain consumer and civil society’s confidence on the nano-market.

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: Full traceability across the supply chain is needed therefore notification requirements are going to be necessary from all actors involved in the production and distribution of a nano containing product. This is the best way of creating a market that encourages consumer choice by making them aware of the health impacts that nanomaterials may have. If the use of a notification system 'per substance' is introduced then there should be no issue in all actors providing the notification scheme to downstream users. A VAT system to track this would be effective as shown by the French system.
Q17: The following should be subject to notification requirements (tick all that apply):	b) Mixtures containing nanomaterials, c) Articles with intended release of nanomaterials , d) Articles containing nanomaterials without intended release , Please explain: If the product contains nanomaterials as defined by the EC definition then they should be required to have a notification as that is the reason the nano registry has been devised. All information about nano containing products has to be provided to consumers to allow for an informed choice. The question of release also relates to the life cycle phase considered. The registration is necessary if there are releases anticipated at any stage of the life cycle of the product. Furthermore, even when no release is foreseen, information about this material/product would still be relevant to workers in order to implement workplace risk management measures.
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.) It will be necessary for the regulators to have an accurate picture without exemptions.

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

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

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If yes, which uses should be exempted and why? (in terms of specific exposure scenarios, available knowledge, absence of hazards, etc.)
All uses need to be included to avoid hidden risks for health and environment

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

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d) Information concerning products containing nanomaterials

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e) Information on the hazards and risks of nanomaterials

,

f) Other (please explain):
In general, a Nanomaterials Observatory can only provide added value beyond existing studies on nanomaterials on the EU market if the following information is publicly available: • Application of the nanomaterial, • Functionality of the nanomaterial(s) employed, • Characterisation of nanomaterial(s), • Nanomaterial concentration in the respective product, and • Manufactured or imported tonnage bands of the nanomaterial(s).

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

We need to generate statistical data on these products.
A good way could be to set up a visual tool that works like google map (you can zoom-in and out) and you can, by region, find out the amount of nanomaterial containing products are produced, sold and disposed. Data should be easily aggregated and exported via a public available website.

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

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d) Development of strategies to ensure the safe use of nanomaterials

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e) Informed purchasing decisions by consumers,

f) General education of the public,

g) Other purposes (please specify)
Safe disposal, reuse and recycling of products containing NMs. Enhance the acceptance of the safe use of nanomaterials in products.

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):

A notification scheme based on the use of substances would be more useful in the context of risk assessment scenario. A life cycle assessment of each product also needs to be carried out in order to evaluate the risk of nano containing products over their whole life cycle, especially in the manufacturing and disposal phase. Information should support regulatory authorities in developing legislation to protect workers (who are generally exposed to higher concentrations of nanomaterials for extended periods of time). Regulators will also be able to develop strategies assessing the use of nanomaterials in greater detail, this will only serve to enhance the safe use of nanomaterials in the market. A registry of products will ensure that companies know exactly what is present in their products, this information will be transparent and will therefore drive companies to promote the safe use of nanomaterials in their products in order to compete in the market. A nano registry provides consumer choice of products allowing them to choose nano, non-nano or different nanomaterials ensuring a greater control from consumers, which is one of the main aims of the registry. Increased information in relation to nanoproducts will undoubtedly increase awareness of the market thereby improving education of the public about the matter at hand.

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

As described in various legal studies such as “just out of REACH, how reach is failing to regulate nanomaterials and how it can be fixed”, or the ECHA analysis of nano registration so far, REACH contains gaps and loopholes when it comes to nanomaterials, and as a result, REACH has not so far delivered any meaningful information on nanomaterials. Such a register would address this issue. It would furthermore achieve traceability of all NMs in products arriving to the EU. Finally, a nanomaterial registry could be a good control tool to verify the correct registration of nanomaterials according to REACH requirements.

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

the ENPR as a precautionary instrument and this makes a comparison of costs and benefits rather difficult. The costs of preventive actions are usually tangible, clearly allocated and often short term, whereas the costs of failing to act are less tangible, less clearly distributed and usually longer term, posing particular problems of governance. (see “late lessons from early warning 2: Science, precaution, Innovation” in particular section C, available @ http://www.eea.europa.eu/publications/late-lessons-2