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PAGE 2: Section I - Identification

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

Your name:	Jeremy Tager and Louise Sales
Name of organisation* (if applicable):	Friends of the Earth Australia
Town/City:	Melbourne
Country*:	Australia
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	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.	1
g) Protect confidential business information	1
Please provide additional comments	A mandatory nanomaterial register is a vital first step for regulators to determine the quantities of nanomaterials entering the environment so that basic risk assessments can be conducted. It will also provide consumers with important information regarding the nanomaterial content of products. Proactively protecting human health and the environment should be the number one priority of regulators. The need to 'maintain business competitiveness' or 'protect confidential business information' should never be used as an excuse to put in place inadequate regulation to protect human health and the environment.

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)	5
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.	1
g) Protect confidential business information	5
Please provide additonal comments	While cosmetics labelling and biocides legislation in theory provides regulation for consumers on the nanomaterial content of products, we are concerned that the lack of a stringent definition of nanomaterial means that many products that are clearly nanomaterials are excluded from labelling requirements. We are also concerned about poor levels of industry compliance with existing labelling requirements. Far too great an emphasis has been placed on maintaining industry competitiveness to the detriment of human health and the environment.

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	1
Please provide additional comments	The absence of a mandatory register of nanomaterials means that most regulators are currently unaware of the quantities of nanomaterials entering consumer products and the environment. This is completely unacceptable. While it is far preferable to ensure the safety of products before they are allowed on the market, a register is a basic first step that allows regulators to implement systems to track nanomaterials, to determine exposure pathways and to identify any impacts. The establishment of national registers and notification schemes has provided important information about nanomaterial use and has not involved the high administrative burden originally predicted by industry. Whilst national registries provide important information, a EU wide registry would provide more comprehensive and consistent information and be less of an administrative burden for industry than multiple national registries.

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): The lack of a mandatory register of nanomaterials means that many workers are unknowingly exposed to nanomaterials in their workplaces and may therefore not take appropriate precautionary measures. There is a growing body of peer reviewed literature that suggests a more precautionary approach needs to be taken with a number of nanomaterials, not only in terms of worker safety but environmental and human health issues as well. There is a general concern because of the unique characteristics and behaviour of many nanoparticles that warrants a far more careful approach to commercialisation than has been taken to date. There are also a number of studies that implicate specific nanomaterials. Nano titanium dioxide: studies have shown damage to DNA, disruption of cell, interference with the immune system, catalysing a process leading to inflammation of the gastro-intestinal tract, kidney damage. Nano titanium dioxide may be a carcinogen if inhaled. Nano titanium dioxide is widely used in foods, food supplements and cosmetics. Young children have the highest exposure levels to nano titanium dioxide; Carbon nano-tubes: MWCNTs have induced mesothelioma in rodents and are now being investigated for use in food and agriculture; Nano-silica: has been shown to accumulate in tissues and the spleen, has caused fibrosis in the livers of rodents and may be able to cross the blood brain barrier and the placenta; Nano-silver: has been shown to bioaccumulate in soil and to reduce the effectiveness of nano-silver for medical treatments. Nano-silver has become one of the most widely used nanomaterials, primarily for its anti-bacterial qualities; Nanoscale zinc oxide is toxic when ingested and leads to inflammation of the lungs when inhaled. It is used for surface coatings.
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

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: An EU nanomaterial register is a vital first step that allows quantification of the amounts of nanomaterials in the environment and levels and sources of human exposure. This is necessary in order that basic risk assessments can be conducted and appropriate regulatory regimes put in place.

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)	d) They would search for more information, Please explain: Consumers are not a uniform group. Different consumers have different motivations. For some consumers 'nano' will be a selling point - indeed some companies specifically market certain products as nano. Other consumers are concerned about the potential human health impacts of certain nanomaterials and may seek to avoid these in products. They should be provided with the information that they need to do this. If consumers believe that nanomaterials are appropriately regulated they will be more likely to accept their use in consumer products.
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: Studies suggest that the majority of consumers do not read product labels and therefore would probably not consult the information in a mandatory product register. However there are a sizeable minority that do and they should be provided with the information they need to make the purchasing decisions that they want to. In order for a mandatory register to build trust it must be part of a broader suite of measures that actually determine the safety of nanomaterials. Information is a critical - but not exclusive - step in building public trust. The information must be sufficient to allow consumers to make informed choices. This includes the nature of any risks. A register is one important step in the process of building trust.

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: Studies have shown that, rather than promote it, patents actually thwart innovation. The free sharing of information regarding the use of nanomaterials in products is therefore more likely to promote innovation than to hamper it. If the public believe that nanomaterials are being appropriately regulated they are also far more likely to use products containing them.
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 Although we believe that the impact of a nanomaterial register on industry competitiveness is likely to be negigible we also believe that this should not be a major consideration in considering the potential pros and cons of a register. The important goal of gathering information in order that basic risk assessments can be conducted, appropriate regulatory regimes devised, and adequate information provided to consumers should far outweigh the consideration of market impacts. If consumers believe that nanomaterials are appropriately regulated they will be more likely to use products containing them. In some ways these questions relating to impacts on business are misguided. Determining environment, health and safety impacts of nanomaterials, providing information that allows regulators to track and regulate nanomaterials and consumers to make informed choices will have short term costs - and these are costs that no one should question as a cost of introducing and using products containing new and poorly understood materials. However, these costs may well be offset by the impacts of precaution- including greater consumer confidence, fewer externalities and a reduced likelihood of unintended consequences.

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 will enable the tracking of nanomaterials down the supply chain. This will mean that workers will know if they are handling nanomaterials and will be able to take put in place appropriate OHS safeguards. Consumers will also know which products contain nanomaterials. A notification per use will enable public authorities to better calculate exposure pathways and levels of nanomaterials in humans and the environment.

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: Notifications from all these actors is essential to track nanomaterials along the supply chain. This will mean that workers will know if they are handling nanomaterials and will be able to take put in place appropriate OHS safeguards. Consumers will also know which products contain nanomaterials. A notification per use will enable public authorities to better calculate human exposure levels and levels of nanomaterials in different waste streams and the environment.
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: Notifications for all these articles is essential to track nanomaterials along the supply chain. This will mean that workers will know if they are handling nanomaterials and will be able to take put in place appropriate OHS safeguards. Consumers will also know which products contain nanomaterials. A notification per use will enable public authorities to better calculate human exposure levels and levels of nanomaterials in different waste streams and the environment.

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.) A comprehensive system will provide more thorough information which regulators can use to calculate exposure levels, conduct basic risk assessments and implement regulation to mitigate any potential environmental and human health impacts. It will also provide more meaningful and easily accessible information for consumers.
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.) A comprehensive system will provide more thorough information which regulators can use to calculate exposure levels, conduct basic risk assessments and implement regulation to mitigate any potential environmental and human health impacts. It will also provide more meaningful and easily accessible information for consumers.

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 , c) Information on the use of nanomaterials across Europe , d) Information concerning products containing nanomaterials , e) Information on the hazards and risks of nanomaterials

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

Information should be presented in a comprehensive online database and on product labels.

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)
More targeted research directed towards products that are most heavily used or involve the highest risk exposure pathways (eg children)

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):

Regulators are unable to conduct basic risk assessments for nanomaterials without access to data on quantities of nanomaterials produced and their uses. Likewise, if workers are unaware that they are handling nanomaterials they are unable to implement appropriate safety measures. A mandatory nano-register is a basic first step to assess the levels of nanomaterials being used by industry so that appropriate regulatory measures can be devised to protect human health and the environment. Information for each concerned product would be necessary for informed consumer purchase.

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

A European nanomaterial register will allow regulators to quantify levels of nanomaterial use and to put in place appropriate environmental and human health safeguards. It will also provide more comprehensive and accessible information for the public.

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

Transparency measures for nanomaterials on the market are essential to build public trust and to ensure nanomaterials are properly regulated.