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PAGE 2: Section I - Identification

Q1: Please provide the following details (*compulsory):	
Your name:	Carine Gorrebeeck
Name of organisation* (if applicable):	Coordination Committee for International Environmental Policy - Belgium (CCIEP/BE)
Town/City:	Brussels
Country*:	Belgium
E-mail address:	
Q2: Please indicate if you are responding to this questionnaire on behalf of/as:	b) a public authority/public administration
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	4
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	4
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.	4
g) Protect confidential business information	5
Please provide additional comments	We believe objectives (a) and (e) are most important, as these objectives will stimulate the objectives (b) and (d). The importance of protecting confidential business information has to be taken in consideration also. (f) We completely agree that the proportionality is an important objective and that the balance between information requirements versus costs and burden must be kept in equilibrium. On the other hand, the value of information which can help to reduce possible health or environmental risks cannot be overestimated. Hence, in our opinion, the introduction of a compulsory registration of nanomaterials cannot be considered disproportionate.

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	2
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	2
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.	3
g) Protect confidential business information	5
Please provide additonal comments	(b) + (d) We believe that consumers have a strong need for – and the right to - objective information. Information about (the presence of) nanomaterials can be nuanced for commercial purposes. Due to a lack of legislation, labels for example can incorrectly claim the presence of nanomaterials, or vice versa. This is very confusing for a consumer, and will definitely have a negative influence on the consumers trust in nanomaterials. (e) the information is not there or is not relevant enough – for example, only few nanomaterials are registered in REACH, and for these few registered, the nanospecific information is insufficient.

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	4
e) The establishment of national registries and notification schemes causes market fragmentation and hampers trade within the internal market	1
Please provide additional comments	(a) Currently, there is not enough information available about the supply chain. This is a major problem when there is an urgent need to react in case of a problem. (b) and (c): A lack of objective information may cause distrust against nanomaterials and the products containing them. The same situation occurred for example with GMO's. (e) Please note that these are two questions put together. We believe that the establishment of a European registry can avoid market fragmentation. We don't believe that a registry will hamper trade within the internal market.

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):
Health hazards: According to the SAICM report “Nanomaterials: Applications, Implications and Safety Management in the SAICM context (2012)”, there are four mechanisms of toxicity for nanoparticles. As a solid particle, nanomaterials could: 1. Pose a hazard due to physical shape (e.g. toxicity of long, rigid fibers); 2. Elicit immunological responses (e.g. foreign body reaction leading to fibrosis); 3. Act as carriers due to high adsorptive properties, delivering hazardous chemicals present in the environment to biological compartments which would otherwise be inaccessible to those chemicals; 4. Exert biological activity through chemical entities present on the surface as a result of the manufacturing process (intended and unintended surface functionalization) and through deposition in biological environments (e.g. protein corona). Example: silica (nano)particles can have double (geminal) and single hydroxyl groups on the surface. It has been shown that geminal silanols bind strongly to phospholipids of cell membranes, with the destruction of cell membranes of red blood cells as a result. Furthermore, there are clear indications of adverse health effects (lung, cardiovascular) of ultrafine particles, which are currently put on the priority list of IARC.
Environmental hazards: Environmental exposure has been addressed by the report “Engineered Nanoparticles: Review of Health and Environmental Safety (ENRHES)”. The main conclusion is that more research needs to be done to get full insights in to the environmental safety of nanomaterials, particularly in the mechanisms of toxicological action. It also identifies a lack of knowledge about degradation and accumulation of nanomaterials, and also no studies are as yet available to support extrapolation of effect levels from laboratory tests to environmental scenarios. Classification: IARC lists carbon black and TiO2 as group 2B carcinogens (possibly carcinogenic to humans). The classification is not a classification of the “pure” nano-product, but in the criterion documents, the nano-components are mentioned. (Carbon Black: “Aggregate dimension ranges from tens to a few hundred nanometers”; TiO2: “Studies that used ultrafine or nanosize titanium dioxide showed enhanced toxicity relative to the fine particles used in earlier studies”). OELs: Due to a lack of (toxicology, epidemiology, …) data, only provisional OELs could be defined so far. As they are provisional, one cannot expect a full protection when they are applied. Further research is needed. Examples: - the Dutch NRV (nanoreference values): for fibers, biopersistent granular material with density > 6000 kg/m3, biopersistent granular material with density < 6000 kg/m3 and non-biopersistent granular material) - recommended exposure limits (REL) for nano-TiO2 and CNT by NIOSH - benchmark exposure limits (IFA) - benchmark exposure limits (BSI) As for the questions about classification and effect levels, we would like to add that it seems that the classic testing

	protocols may not be suitable for nanomaterials. Even the preparation of relevant samples from nanomaterials is still under discussion. Moreover, classification of nanomaterials should be specifically decided for them. We believe that the classification of a bulk material is not suitable per se for the nanoform of this material. The form (nano) should be specified for classification purposes.

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):
Worker Illness After Nanomaterial Exposure Examined in First U.S. (http://onlinelibrary.wiley.com/doi/10.1002/ajim.22344/abstract) A U.S. worker suffered adverse health effects after handling nickel nanoparticles, according to a published case study that appears to be the first of its kind. A chemist developed throat congestion with postnasal drip, flushing of the face and skin sensitivity to metals within a week of exposure to nickel nanoparticles, according to a case study published May 8 in the online version of the American Journal of Industrial Medicine. Exposure consisted of periodically weighing out 1 to 2 grams of nickel nanoparticles without using protective measures. The chemist eventually moved to another lab that had no metal chemistry work, and her symptoms improved, the study said. Despite animal and cell research indicating that exposure to some nanomaterials might cause adverse health effects, there's a dearth of reports on exposed workers getting sick. Available research has supported the National Institute for Occupational Safety and Health's recommended exposure limit for carbon nanotubes and nanofibers and the Interna-tional Agency for Research on Cancer's designation of nano-sized titanium dioxide as a possible human carcinogen. Tip of the Iceberg? Although individual case studies linking worker exposure and adverse health effects are valuable because they alert re-searchers to potential problems, they should be treated with caution in terms of drawing causal relationships, said Andrew Maynard, professor and director of the University of Michigan's Risk Science Center. “They give the ability to start asking questions, but really don't answer any,” Maynard told Bloomberg BNA May 13. A 2009 case study of seven workers in China whose adverse health effects were blamed on nanoparticle exposure has been widely cited, but any causal link in it is “pretty much entirely speculative,” Maynard said. The case study of the U.S. chemist's exposure to nickel nanoparticles underscores the need to use protective measures in the absence of conclusive toxicity data, lead study author W. Shane Journeay told Bloomberg BNA May 13. “This is a modest example, but it shows that in the modern workplace in the United States it can and did happen,” said Journeay, who heads Nanotechnology Toxicology Consulting & Training. “It's really just the tip of the iceberg.” Furthermore, there are clear indications of adverse health effects (lung, cardiovascular) of ultrafine particles, which are currently put on the priority list of IARC.

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: The registry itself will not directly reduce the risks related to the use of nanomaterials or solve the specific problems met when working with nanomaterials, but it will facilitate matters. The EU registry would at least provide in information • to make it possible to react appropriately when a negative impact on health or environment has been confirmed • which can make it possible to correlate some epidemiological occurrences with the presence of nanomaterials (or show the lack of these correlations) • to provide in answers to the questions consumers may be posing • to contribute to an estimation of exposure and waste.

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: We believe that consumers have the right to know what they are consuming. People who are concerned, will try to find out more about nanomaterials. The absence of relevant data, on the other hand, might have a negative effect on the trust of consumers.
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: The absence of information might have a negative effect on consumers trust, as it may seem that information is kept hidden for them. On the other hand, the availability of information can increase trust among consumers, but will not stop the concern about possible 'unsafe' products. The added value of a registry will be that there are guarantees that the given information is objective. By processes such as market surveillance, the government can validate the information given in the registry and thus reduce the risk of inaccurate information.

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: We believe that the establishment of a nanomaterial registry in itself will have a positive impact on innovation, as innovation is driven by factors such as potential markets for the new product. Collecting data in a registry can be a good opportunity to show consumers that the manufac-turers know very well what they are working with, and that the manufacturers have taken important aspects such as risks for health and environment into consideration. This will generate trust among consumers and thus result in an increase in the potential markets. The establishment of a registry will be a win/win situation for all stakeholders.
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)	b) enhance the competitiveness of European companies against extra-EU companies , c) have no significant impact on intra-EU competitiveness , Please explain Due to the establishment of a EU registry on nanomaterials, EU companies will be working with well characterized nanomaterials. This will help them in promoting the product or improving their manufacturing process. The establishment of a EU registry will thus increase trust among consumers and open more potential markets.(cfr. Question 1)

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.

We believe that the registration of the substance in nanoform is a very important registration, since it gives a good idea about the properties of the substance.
However, when a substance is used in a mixture or incorporated in an article, the properties might change, for example the agglomeration- or aggregation state can change, and thus the specific surface or other properties of the nanosubstance.
As mentioned under section IV – question 1, nanoparticles can act as carriers due to their high adsorptive properties and thus deliver hazardous chemicals present in the environment to biological compartments which would otherwise be inaccessible to those chemicals.
In order to have a good idea about the nanomaterials on the market, we believe it is necessary to register the substances as well as the use of them in mixtures or articles. This can be done in a simplified manner, for example by referring to the properties of the substance already registered and only explaining the way it is used in the specific mixture or article. Only then it will provide in enough information to answer to the objectives of the registry (amongst which traceability throughout the supply chain).

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) , Please explain: In order to get a good idea about the supply chain, it is necessary that all actors in the supply chain register. It is, however, not necessary that every actor provides in all the data. If the manufacturer has already registered a nanomaterial, the next actors in the chain can refer to this previous registration and only provide in information about what they do with the nanomaterial. It may not be necessary to provide in registration by non-professional users, as they usually work with small amounts of the material. The administrative burden would be too high compared to the possible impact.
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: As discussed above (question 1), we believe it is necessary to register substances as well as mixtures and articles. We also believe that both types of articles (intended and not intended release) should be regis-tered, as at the end of the life cycle, when the article has become waste, there is still a possibility that nanomaterials will be released. Articles containing nanomaterials (with or without intended release) can thus cause exposure. It may also be difficult for enforcement to distinguish between intended/not intended release.

Q18: Is there a need to exempt certain types of nanomaterials?	Yes, certain types of nanomaterials should be exempted from a notification system , If yes, which types should be exempted and why? (in terms of specific properties, available knowledge, absence of hazards, etc.) In order to keep the administrative burden in balance with the information requirements and the possible impact of the nanomaterial, the exemption of some nanomaterials may be considered, for example the types of nanomaterials already covered by EU legislation which provides in equivalent information. This is very much related to the use of the nanomaterial (cfr. next question).
Q19: Is there a need to exempt certain uses of nanomaterials?	Yes, certain uses of nanomaterials should be exempted from a notification system , If yes, which uses should be exempted and why? (in terms of specific exposure scenarios, available knowledge, absence of hazards, etc.) Nanomaterials included in articles, and for which it can be foreseen that, under normal conditions of use throughout the whole lifecycle (including waste!),they will not release (intended or not intended) more than 0.1% (m/m) nanomaterials, could be exempted. Nanomaterials which are, for a specific type and for a specific use, already covered by EU legislation which provides in equivalent information, could be exempted.

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):
We believe that this option may be a good way to centralize data about nanomaterials. However, we feel it cannot really replace the option of a mandatory registry. It is not clear who will be responsible for the correctness and/or the completeness of the information. In our view, nobody can guarantee that the information given is correct, complete and not nuanced (either positively or negatively). Furthermore, we see a problem in the uniformity of the data. For different types of nanomaterials, different data may be presented, which can result in confusion among the consumers or other stakeholders. Where the observatory will group a lot of generally available information, the registry should also contain comprehensive and objective information, which is necessary to react adequately in case of problems with a nanomaterial.

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

The Observatory can be seen as a sort of library, and present the information classified according to the category of information (research, legislation, press article,…). It can be sorted by date and contain key words such as the nanomaterial(s) concerned, health or environment related, type of product, type of uses etc.
It should also mention if the information has been validated (and by whom) and who is responsible for the content of the information. It can contain links to other websites, documents etc.
Most important would be that the Observatory disposes of a very strong search engine, which makes it easy for a user to find the information he is looking for in an efficient way.
Another option to present the data can be the development of an app, which allows the consumer to scan the label of the product and thereby showing all the information available. But also here, the same remarks as mentioned in question 1 arise.

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)
The information from registries will be particularly helpful in: - Provide decision makers, regulatory authorities and professional users with enough information that allows for an appropriate response to health and environmental risks of specific nanomaterials; - Provide consumers with relevant information on products containing nanomaterials on the market; - Provide the necessary information that employers need to comply with OSH regulations: i.e. to perform a proper risk analysis and define preventive measures to protect their workers from the risks of nanomaterials (currently it often happens that downstream users don't even know that there are nanomaterials in the products they are using); - Provide traceability; - It will increase competitiveness of companies, and stimulate innovation. (f) The registry may be too specific to be used for the general education of the public, but it will contribute to it in an indirect way, as more information about nanomaterials becomes available.

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):

In order to answer the above mentioned objectives, we believe that registration is necessary for substances, as well as for mixtures and articles.
We think that the following data are indispensable in order to reach the objectives:
- Characterization of the nanomaterial
- Who puts the nanomaterial on the market
- The form in which it is placed on the market
- The quantities of the nanomaterial placed on the market (per year, in grams)
- Use of the substance, the mixture or the article
- To whom the product is delivered.
Furthermore, it would be very interesting to collect information about the possible changes in the characterization of the nanomaterials during waste treatment (wastewater treatment, incineration, recycling, landfilling).

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

- It would cover all the nanomaterials, including the large fraction not yet covered by other legislations.
- REACH registration starts from only 1 ton/y, which is very high for nanomaterials. Furthermore, up to now, REACH proved to be highly ineffective for nanomaterials. Adapting the annexes won't solve all of the current problems. As it is not yet clear whether the actual testing protocols in CLP and REACH can be used also for nanomaterials, it is not yet clear how they can be classified (alone, bulk) and thus registered in these legislations.
- It can provide in extra information and traceability, such as flow of nanomaterials through the supply chain
- It would lead to an improved worker protection, due to an improved downstream transfer of nano-specific information that is needed to comply with OSH-regulations.
- Information to allow for consumers' decision.

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

Respondent skipped this question