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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:	Steve Suppan
Name of organisation* (if applicable):	Institute for Agriculture and Trade Policy
Town/City:	Minneapolis
Country*:	United States of America
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)	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.	3
g) Protect confidential business information	3
Please provide additional comments	The above questions are answered relative to the purpose of the consultation, i.e. the establishment of an EU wide nanomaterials registry. The Institute for Agriculture and Trade Policy has petitioned the U.S. Environmental Regulatory Agency to establish a mandatory nanomaterials registry, following several years of failure to elicit industry cooperation in a voluntary nanomaterials stewardship program. It is impossible to carry out realistic environmental fate studies, e.g. of nano-silver in treated waste water, without specific and detailed knowledge of which nanomaterial is being produced/used, where, how and by whom.

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)	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	2
f) Ensure the proportionality of the information requirements and the associated costs and administrative burden.	1
g) Protect confidential business information	Do not know
Please provide additonal comments	As we understand REACH, it has a volume of production requirement for chemicals registration that is of little relevance to the vast surface to volume exposures of nanomaterials. Save for the dozen or so most widely used nanomaterials, our understanding is that REACH fails to require development of nano-toxicological reference values for most nano-materials in commercial use. We do not believe that it is possible to develop sustainable markets for nanomaterials and nanotechnologies on the basis of voluntary guidance to industry.

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	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	3
Please provide additional comments	If the Commission fails to establish an EU wide nanomaterials registry, national registries will at least provide not only a data base for environmental studies within the national territory, but also a lesson on what and what not to do when other member states and/or the Commission establish registries. Market fragmentation is not the result of regulation in one member state but not in another, but rather the result of the lack of industry support for an EU wide nanomaterials registry.

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): I am aware of dermal exposure and oral exposure for children to sunscreens containing nano-titanium dioxide. I am aware of a Dutch study that reports 4-33% of silicon dioxide is nano-sized in processed foods from supermarket shelves and tested for the study. Presumably there is gastro-intestinal exposure to nano silicon dioxide in those foods.
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): Anecdotally, in my home state of Minnesota, I know of spillage of nanomaterials that were "cleaned up" using a protocol for cleaning up blood because there is no industrial hygiene protocol for cleaning up nanomaterials.
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 most immediate health and environmental impacts of a nanomaterials registry would be to inform both member states authorities and the Commission about the likely origins of contamination of natural ecosystems by nanomaterials, e.g. on soil and watersheds in close proximity to nanomaterials fabrication sites. Nanomaterials registries could also help local authorities develop safe and effective response plans in the event of nanomaterials accidents or contamination incidents

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: Labeling is an entry point for a broader information campaign that would 1)distinguish soluble and excreted nanomaterials from bio-accumulative ones; 2) explain reference values for chronic and acute exposure to bio-accumulative nanomaterials; 3) explain agglomeration and encapsulation of nanomaterials; 4) explain the uses the Commission and member states authorities would have for a nanomaterials registry; 5) explains the benefits and risks of the use of nanomaterials in specific products, e.g. nano-titanium dioxide in food packaging materials.
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: If the information only concerns the presence of nanomaterials, consumer response will be product specific. Where there is very little likelihood of consumer exposure to the nanomaterials, e.g. those used in the production of electronic components, there is likely to be a positive or insignificant effect. For products that are intended to be inhaled, ingested or rubbed on the skin, a great deal of information will have to be provided, not just risk assessment information, but information about why the use of nanomaterials is necessary or at least advisable.

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: There are numerous studies, e.g. by the (U.S.) Union of Concerned Scientists to show that after initial and sometimes massive resistance, most industries respond to regulation by innovation, even if they have to pass on the costs of innovation to consumers or down the supply chain. The locus classicus is the seat belt, where the U.S. auto industry engaged in burglarly, character assassination and other crimes to prevent mandatory adoption of the seat belt, but then discovered that it could profit by selling safety.

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 , Please explain It is difficult to know the impact of a naomaterials registry on the intra-EU competitiveness of any particular product. European risk assessment and risk management are generally regarded as more stringent than that of other countries, though this regulatory brand value is in danger of being eroded as the EU develops U.S. style cost-benefit risk management criteria under the TTIP and other FTAs.

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.

The greatest added value of per use notification would be for worker safety. A laboratory reference value for a substance used in a nano-coating is very unlikely to be the same as a reference value for a substance in an industrial setting. Per use notification would also be of great value to environmental regulators and public health authorities. Per use notification in consumer products could be done with less granularity for categories of products, e.g. a food packaging materials would presumably have a very similar chemical reactivity whether it came into contact with a fruit or a vegetable.

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) , Please explain: Notifications should extent to downstream users. Wholesales and retailers require more categorical guidance, e.g. concerning storage and worker handling requirements for products incorporating nanomaterials.
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 effect of nano-silver in a pesticide applied to a plant and the effect of a nano-material plated part in a landfill certainly pose different kinds of risks, but the kinds and perhaps even the degree of risk are not dependent on the intention of the manufacturer but on the interaction of the nanomaterials with its 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.) Until peer-reviewed science determines that a nanomaterial, as used alone or with other nanomaterials in industrial manufacturing, poses negligible risk, whether for acute or chronic exposures, all nanomaterials should be subject to notification requirements. For example, some nano-sized materials, such as clays, likely do not pose hazards. However, as used in combination with other nanomaterials, they should be notified.
Q19: Is there a need to exempt certain uses of nanomaterials?	No, all uses of nanomaterials should be subject to notification obligations

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)	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 , f) Other (please explain): If the Observatory is to be a systematic platform for regulatory analysis, rather than a compilation of information, information in existing notification systems may be difficult to integrate.

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

A Nanomaterials Observatory should be developed after an EU nanomaterials registry is established for regulatory purposes. That registry could serve as an information basis for a more broad-based observatory that itself would not be a regulatory tool.

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

,

g) Other purposes (please specify)
Member state governments need to develop materials and processes for informing local authorities about nanomaterials and nanotechnologies, e.g. for permitting, industrial zoning decisions, and emergency worker training. The registry would be an important information source.

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):

Because the nanomaterials registry would ideally be both substance and use based, it could provide necessary baseline information for risk assessment and risk manageement. Because the registry would be site specific, it could be useful for ensuring that any new uses of nanomaterials at one manufacturing site would be transmitted with lessons learned for worker safety, as well as for industrial process (subject to trade secret exemptions not affecting worker safety or public health).

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

Nanomaterials produced and used at volumes below REACH thresholds could be assessed and managed, with appropriate lessons learned for manufacturers, workers and regulators before manufacture and use of a given nanomaterial was scaled up.

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

The Commission has the opportunity to become the leader in developing standards and practices for effective an nanomaterials registry, whose systematic data base, updated as new uses and substances came on line, could become a model for other jurisdictions. The Commission should disregard threats of lawsuits or trade disputes to impede development of this essential regulatory tool.