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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:	Jaydee Hanson
Name of organisation* (if applicable):	International Center for Technology Assessment
Town/City:	Washington DC
Country*:	United States
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	4
b) Provide consumers with relevant information on products containing nanomaterials on the market	5
c) Maintain competitiveness and innovation of businesses bringing nanomaterials or products containing nanomaterials to the market (including SMEs)	5
d) Ensure consumer trust in products containing nanomaterials	5
e) Ensure the availability of relevant information on the presence of nanomaterials or products containing nanomaterials on the market	5
f) Ensure the proportionality of the information requirements and the associated costs and administrative burden.	3
g) Protect confidential business information	2
Please provide additional comments	It is important that the registry include potential health and safety effects. Companies should not be allowed to exclude these effects from the registry as "confidential business" information. In order to build consumer trust there needs to be greater transparency of nano containing products on the market through labelling and a greater focus on health risks from regulatory authorities.

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	2
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	5
Please provide additonal comments	REACH information available to public authorities, citizens and consumers is still extremely limited. REACH considers many nano materials to be indentical to the bulk material. Manufacturers should be required to submit separate data for nano-scale chemicals as part of complying with the requirement that all uses of the chemical are to be identified. 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. This is a significant problem and the weight limits need to be reduced in order to capture more data on nanochemicals.

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	National registries and notification schemes could have needed flexibility that an EU wide scheme would not and should not be discouraged. We need registries that include products that are claimed to contain nanomaterials by their manufacturers, products that have been tested by compentent testing authorities and found to contain nanochemicals, and also registries that would include products with broader definitions of nano than might be included in an EU wide registry (such as the US FDA definition that asks for information on nano products using nanochemicals up to 1000 nm.) Such diversity of information will help consumers. This information deficit is not removed by existing product registers on the national level (e.g. Switzerland, Norway, Denmark or Sweden). These registers do not sufficiently provide an overview on the market with nanomaterials as they focus on dangerous substances/ mixtures and not on consumer products.

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

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I am aware of specific nanomaterials that are classified as hazardous under Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures

,

I am aware of 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):
Our comments raising concern about the US EPA's conditional registration of the NanoSilva nano-silver texile treatment highlights many of the problems of nano chemicals. As with nanomaterials most generally, there is a lack of research on the human health and environmental safety of nano-silver and especially with a composite product like Nanosilva that the company plans to use more extensively than any existing nano-silver products, indeed it plans more extensive use than any existing bulk silver products. Among other things, Nanosilva is proposed to be incorporated into textiles, plastic films, sheets, slabs, and molded parts, meaning it can end up in consumer products such as footwear, sportswear, uniforms, and auto parts, floor coverings, outdoor furniture, decking, and house siding. To our knowledge, no other silver pesticide product registrations cover floor coverings, plastic films, slabs, and molded parts as would be found in outdoor furniture, decking and house siding. EPA’s SAP Report specifically acknowledged “data gaps about potential exposures and hazards related to nanosilver are broad,” noting that “there is very little information about nanosilver in the environment related to fate, transport and transformation.” Further, EPA’s Decision Document admits that there are “no fate or ecotoxicity studies available for Nanosilva,” which required EPA to estimate the fate and ecotoxicity using existing studies in the scientific literature. In its Decision Document, EPA acknowledged the existence of many gaps in scientific knowledge with regard to nano-silver’s effects on health and the environment. These gaps include: • no intermediate- or long-term human or environmental toxicity studies available for Nanosilva or for the nanosliver released from products incorporating Nanosilva • no studies in the scientific literature that investigate carcinogenicity of nano-silver • no subchronic or chronic oral or dermal toxicity studies available for Nanosilva or on the nano-silver that might break away from products incorporating Nanosilva • no acceptable studies on the reproductive and developmental toxicity for nano-silver • inadequate information to assess mutagenic and carcinogenic potential of nano-silver due to differences in results between in vitro studies and in vivo studies, and limitations of the only available in vivo study • insufficient information on aggregate exposures to other nano-silvers currently in the market place. Yet

the absence of data cannot replace the agency's burden to show, based on substantial evidence, that there will be no unreasonable impacts on the environment. 7 U.S.C. § 136a(c)(7)(C). Studies have raised significant red flags about nano-silver pesticides. As with some other nanomaterials, due to its small size, the toxicity of nano-silver is greater than that of silver in bulk form; furthermore, nano-silver is more toxic then other metal nanoparticles. The EPA's SAP concluded: Nanoscale particles including nanosilver have been shown to be capable of penetrating biological barriers such as cell membranes and can enter into the cells themselves. Nanoparticles are able to attach to cell membranes, producing changes in membrane permeability, redox cycling in the cytosol, intracellular radical accumulation, and dissipation of the proton motive force for ATP synthesis. Each of these has been reported as a possible mechanism for nanoparticle toxicity. Evidence from scanning transmission electron microscopy also shows that smaller particles (< 10 nm) may enter the cell directly to inhibit microbial growth. Among documented potential harms to human health, in vitro (test tube) studies demonstrate that nano-silver is toxic to mammalian liver cells, stem cells and even brain cells. One 2009 study discovered that absorption of nano-silver may interfere with the replication of DNA molecules, potentially creating genetic mutations. Two other studies have demonstrated that exposure to nano-silver can reduce mitochondrial function. The number of diseases associated with mitochondrial malfunction is increasing and includes Parkinson's, Alzheimer's and Huntington's disease. Beyond the issue of toxicity, nano-silver may also create a public health burden by producing antimicrobial resistance. The Centers for Disease Control and Prevention (CDC) recently acknowledged antimicrobial resistance as one of the world's most serious health threats, in part because of the use and overuse of antibiotics in medicine and food production. As with antibiotics, the overuse of nano-silver may promote resistance to important antimicrobials, which should be addressed before it is too late. Nano-silver is also toxic to a variety of aquatic and terrestrial organisms. Even in its bulk form, silver is extremely toxic to fish and other aquatic species. At the nano-scale, however, nano-silver can be many times more toxic. Swiss researchers recently modeled the environmental concentrations of several commercially available nanomaterials and predicted that nano-silver emissions may already pose risks to aquatic organisms. See also ER 42 (concluding that exposure to AGS-20 nanosilver, a similar product, "may result in adverse effects to aquatic species"). Further, the same property that makes these nanoparticles attractive to manufacturers—their highly enhanced antimicrobial properties—can be highly destructive to ecosystems, by threatening the bacteria-dependent processes that underpin these natural systems

that underpin these natural systems. Microorganisms are the foundation of all ecosystems and provide key environmental services ranging from primary productivity to nutrient cycling and waste decomposition. Early studies show that nano-silver can reduce the activities of microbes employed in treating wastewater. Widespread use of household products that release nano-silver into the sewage system could adversely affect waterways, exacerbated by the inability of public utilities and water treatment plants to properly treat the substance. Increased nano-silver concentrations in treatment-plant discharges could lead to adverse effects such as bioaccumulation in fish and the killing of aquatic life. Another potential post-treatment harm is the spreading of sewage sludge and the decomposition of nano-silver in landfills, whereby nano-silver can contaminate agricultural fields. In 2009, as a result of these and other potential adverse impacts on the environment, EMERGNANO, the first global review of environmental, health, and safety studies examining the risks of nanotechnology exposure, found that there is “sufficient evidence to suggest that silver nanoparticles may be harmful to the environment and therefore the use of the precautionary principle should be considered in this case.” A number of studies have also shown significant problems with other nanochemicals: 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 invivo 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

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 by a Duke University team confirm this as they show adverse responses of plans and micro organisms to low doses of silver nanoparticles applied in mesocosyms simulating field experiments via a likely route of exposure, sewage sludge application (Colman et al., 2013). Studies have also shown that carbon nanotubes can induce cell death in plants (Cong-Xian Shen, et al, Public Consultation – Non-Industry Stakeholders – Page 8 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 metals build up in the ecosystem. The researchers also showed uptake of zinc nanoparticles.

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):
Two Chinese women at a chemical plant are believed by Chinese researchers to be the first documented deaths from nano chemicals. See this article in the European Respiratory Journal: Eur Respir J. 2009 Sep;34(3):559-67. doi: 10.1183/09031936.00178308. Epub 2009 Aug 20.

Exposure to nanoparticles is related to pleural effusion, pulmonary fibrosis and granuloma. Song Y1, Li X, Du X. Author information Abstract Nano materials generate great benefits as well as new potential risks. Animal studies and in vitro experiments show that nanoparticles can result in lung damage and other toxicity, but no reports on the clinical toxicity in humans due to nanoparticles have yet been made. The present study aimed to examine the relationship between a group of workers' presenting with mysterious symptomatic findings and their nanoparticle exposure. Seven young female workers (aged 18-47 yrs), exposed to nanoparticles for 5-13 months, all with shortness of breath and pleural effusions were admitted to hospital. Immunological tests, examinations of bacteriology, virology and tumour markers, bronchoscopy, internal thoracoscopy and video-assisted thoracic surgery were performed. Surveys of the workplace, clinical observations and examinations of the patients were conducted. Polyacrylate, consisting of nanoparticles, was confirmed in the workplace. Pathological examinations of patients' lung tissue displayed nonspecific pulmonary inflammation, pulmonary fibrosis and foreign-body granulomas of pleura. Using transmission electron microscopy, nanoparticles were observed to lodge in the cytoplasm and caryoplasm of pulmonary epithelial and mesothelial cells, but are also located in the chest fluid. These cases arouse concern that long-term exposure to some nanoparticles without protective measures may be related to serious damage to human lungs. USA: Nanomaterial causes workplace illness A US worker is reported to have developed an acute allergy as a result of exposure to nanomaterial containing nickel, a known sentitiser. The 26-year-old chemist was unaware that she was working with nickel nanoparticle powder at work and no arrangements were made to protect her from exposure. American Journal of Industrial Medicine abstract • Risks 656 Hazards news, 31 May 2014 It is unclear whether other occupational diseases have already been caused by nano chemicals, Many major companies working with nano particles are doing little or nothing to protect their staff - and some are using “safety” measures that are making matters worse, new research suggests. Researchers from the University of California, Santa Barbara (UCSB) surveyed 78 international companies working with nanoparticles and found many are unsure about the right way to protect those handling the materials, or how to dispose of them. New Haven Independent • Risks 523 Hazards news, 17 September 2011

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 establishment of an EU nanomaterial registry would greatly contribute to reducing the risk related to the use of nanomaterials only IF the registry contains full information on those risks in a way that is useful to manufacturers, workers and consumers.

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 just beginning to understand nanomaterials and what they can do to bring value to products they need more information to make informed decisions.
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)	b) have no significant impact, Comments: Lack of information is currently making some consumers wary of nano materials, but a recent survey in the US by Peter Hart Associates found that when consumers get more information, they mostly want nanotechnologies to be better regulated, not banned.

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: It may be that companies themselves will have a better idea of what can be done using nanotechnologies if there is a registry that captures most of the manufactured 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)

d) have no significant impact on the competitiveness of European companies against extra-EU companies

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Please explain
Another kind of registry suggests that the large electronics companies are already the biggest source of nanotechnology patents each year. In the EU, Philips and ASML, electronics and photolithography giants, account for the most nanotechnology patents. In the US, IBM is currently receiving the most patents. Big companies already know what their competitors are doing in these fields. Small companies, consumers, and the governments will be the beneficiaries of a nano registry.

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.

As long as the company notifies the registry of all of the uses of its products. This would be similar to the requirements in US Toxic Substances Control Act that the EPA would be notified on new commercial uses of chemicals and engineered microorganisms.

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:
As nano materials are incorporated into various products, it will be necessary to have information on all of the products in the supply chain. 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. Regulators will also be better served.

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: 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. Also, many of these materials will be recycled resulting in unintended releases of the chemicals.
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.) All engineered nanomaterials should be included in the registry.
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)**	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 , f) Other (please explain): Information about potential health and environmental impacts as well as environmental fate of the material

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

It should be in a searchable data base so that consumers, workers and regulators can find out what is being done nearby. Ideally, a map locating physical sites of manufacturing facilities would be included.

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)
Safe use and recycling of nanomaterials.

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 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 with other manufacturers.

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

REACH does not include all chemicals. Nanochemicals mostly slip through REACH. Moreover, polymers and monomers are exempt from registration and evaluation under REACH. A nanomaterial database should include polymers and monomers used in nanoapplications as a way of closing this gap.

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

Transparency is essential for consumer trust. One of the mistakes that the producers of GMOs have made in the US is to insist that labeling is not needed for GMOs. A nano registry can go a long way toward convincing consumers that goverments want them to have adequate information. Refusing to make this information available would show contempt for the concerns of the consuming public.