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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:	Frauke Averbeck
Name of organisation* (if applicable):	Federal Institute for Occupational Safety and Health
Town/City:	Dortmund
Country*:	Germany
E-mail address:	

Q2: Please indicate if you are responding to this questionnaire on behalf of/as:	Other (please specify) German competent authority for REACH, CLP and Biocides
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)	5
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.	5
g) Protect confidential business information	4
Please provide additional comments	For occupational safety and health there is scientific evidence for three hazard-related categories of nanomaterials with a potential risk to human health: 1. hazards from respirable biopersistent (rigid) fibres (WHO fibres) 2. hazards from respirable granular biopersistent particles (GBP) 3. hazards covered by the criteria of the CLP regulation (human health) These hazards are not exclusively limited to nanomaterials and may arise from other materials and processes, too. Some nanomaterials may have to be assigned to more than one category (e.g. nano-silver). Currently there´s no scientific evidence for hazards exclusively related to manufactured nanomaterials only. With regard to the current state of scientific evidence it is important - to ensure the proportionality of anticipated risks for human health and information requirements - to be aware of coherence to information requirements for other substances, mixtures, articles and processes, which pose comparable hazards for human health (e.g. release of respirable biopersistent fibres from grinding of carbon-fibre reinforced plastics with "traditional" carbon fibres beyond the definition of nanomaterial) - to cover significant information gaps for materials with high scientific evidence for risks to human health (e.g. nanomaterials or advanced materials, which have a significant potential for release of respirable rigid and biopersistent fibres)

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)	4
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.	Do not know
g) Protect confidential business information	5
Please provide additonal comments	The reply is based on the current status of regulation. An ambitious amendment of REACH could improve the knowledge and transparency for the authorities. Regarding f: IR under REACH are currently not adequate to address NM. Therefore, the proportionality is not given. Regarding the JRC web platform: There are too many links instead of providing clear and easily available information.

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	4
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	4
c) The current level of available information on the presence of nanomaterials and products containing nanomaterials on the market is detrimental to consumer trust	3
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	4
Please provide additional comments	regarding e) A European regulation for a product register instead of several national registries is advantageous in sense of harmonization.

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):
There is evidence for specific env. effects caused by nanomaterials: e.g. release of toxic ions, particle effects, Trojan horse effects, depot effects, phototoxicity, ROS generation. For a couple of NM some information is available which justifies a classification. However, in normal

cases there are not enough data available to neither exclude nor justify a nanospezific env. hazard. Regarding exposure: Environmental Exposure has to be taken into account. Information on env. exposure is hardly available. However, there is evidence that environmental exposure occurs. For occupational safety and health there is scientific evidence for three hazard-related categories of nanomaterials with a relevant potential of risk to human health: 1. hazards from respirable biopersistent rigid fibres (WHO fibres): rigid types of CNT, other fibrous nano- or advanced materials, e.g. TiO2-fibres, SiC-, SiN-whiskers, potassium titanate fibres, ceramic fibres (For more information refer to the annual publication of the German MAK Commission ("fibrous dusts") and the announcements of the German Hazardous Substances Committee, e.g. TRGS 910, http://www.baua.de/en/Topics-from-A-to-Z/Hazardous-Substances/TRGS/pdf/910/910-aluminium-silicate-fibres.pdf) 2. hazards from respirable granular biopersistent particles (GBP): TiO2, Carbon Black, Al2O3, CeO2, ... released from nanomaterial or bulk material (see "TRGS 900" of the German Hazardous Substances Committee) 3. hazards covered by the criteria of the CLP regulation (human health) or by a specific OEL for the workplace, e.g. Ag, Ni particles released from nanomaterial or bulk material DNELs/PNECs/OELs: In 2014 the German Hazardous Substances Committee has announced a mandatory OEL for GBP of 1.25 mg/m³ (for a density of 2.5). Due to a 2 - 5fold higher potency for adverse effects there is a current discussion on a specific OEL for nano-GBP (T. Gebel, Small difference in carcinogenic potency between GBP nanomaterials and GBP micro materials, Arch Toxicol (2012) 86:995-1007). For Ag a mandatory OEL of 0.1 has to be applied in Germany for bulk and nano silver. German Industry recommends an OEL for (non-rigid) CNT (Baytubes) of 0.05 mg/m³ (Pauluhn, Regul Toxicol Pharmacol, 57(1) (2010) 78-89). The German statutory accidents insurances recommend an exposure limit of 10.000 F/m³ for CNT, which is also acceptance limit for asbestos (see “TRGS 910” of the German Hazardous Substances Committee) Nanospecific CLP self-classification for MWCNT (EC 231-955-3): Eye damage H319, STOT SE 3 H335. No harmonized classification is known. There are OEL's for nano-TiO2 and MWCNT by NIOSH. Hazard information for nanomaterials relies mainly on published studies.

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): There´s a current discussion on a published case of a laboratory worker suffering from long-term inhalation of nano-nickel. Nickel is a well-known and relevant sensitizer independent of its form! Working without any risk reduction measures is careless and not in accordance with the provisions of EU OSH regulation for chemical safety (98/24/EC). Obviously even the general principles acc. to art.5 of this directive were ignored. This cannot be related to specific problems with nanomaterials, but offers a glimpse on a low awareness of chemical risks in some research institutes and start-ups. Within NANOVALID, a project within the 7. EU framework program, BAuA is setting up a toolbox targeting at these problems. It will be published in 2015. Chinese workers suffering from lung diseases have been reported on the ICOH conference in South Africa in 2009. They have shovelled nano titanium oxide into bags without any ventilation or personal protective equipment. These workplace-related diseases can be related to very high exposures to biopersistent particles in the nano and in the micro scale. They are not “nano-specific”, too. Furthermore, there is the case of the "Magic Nano" spray (BfR 2006) and a case in China (Song et al. 2009) due to lack of worker protection against polyacrylate spraying, which both, however, turned out not to involve manufactured nanoparticles.
Q10: The establishment of an EU nanomaterial registry (tick the relevant box):	Would not significantly contribute to reducing the health and/or environmental risks related to the use of nanomaterials , If appropriate, please explain further: The best way to reduce the risks related to nanomaterials would be an amendment of the REACH regulation to introduce specific information requirements for nanomaterials. This would produce relevant data on the hazards of nanomaterials for human health and the environment which cannot be captured by a product register. Therefore, a product register can not significantly contribute to risk reduction. It would, however, be a useful means to get an overview which nanomaterials are on the market for which uses and in which volumes. See also: http://www.umweltbundesamt.de/publikationen/concept-for-a-european-register-of-products

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)	c) Their purchasing decisions would not be affected , d) They would search for more information, Please explain: It depends on the consumer group. It is well known that there are consumers who are pro actively interested in the ingredients/substances within the products and consumers who become interested in this information by public debate.
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

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)	b) have no significant impact on innovation
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)	c) have no significant impact on intra-EU competitiveness , d) have no significant impact on the competitiveness of European companies against extra-EU companies , Please explain Regarding d): It depends on whether the enforcement could ensure that importers of articles fulfill their requirements

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 substance based notification scheme would be considered important as it would ensure the coherence to REACH registrations and CLP notifications. However, also notification per use would be particularly valuable for better traceability and transparency along the supply chain. It would also be useful for considering the diversity of exposure situations.

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: The requirements should be addressed to the same actors as under REACH and CLP.
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: Since in all cases NM are involved which could be potentially released, all should be subject to notification.
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.) At present, no exemption should be made despite non-nanomaterial-containing articles releasing nanoparticles. The latter would be beyond the scope of "manufactured nanomaterials", though the regulatory situation here is insufficient (e.g. printer toner formulated with or w/o nano-sized pigments, both releasing nanoparticle dusts).
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.) Uses and articles for which release of NM can be excluded during the whole life cycle.

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 from existing legislation Relevant results from EU and national research programs (e.g. FP7, Horizon 2020) in the fields of nanomaterials and advanced materials. It should be considered not to limit the observatory to nanomaterials and also focus on other (advanced) ma-terials, which have a relevant potential for release of respirable biopersistent particles or fibres.

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

Suitable for the user and tailored to target groups. This includes different level of details.
With regard to occupational safety and health, the information should be addressed primarily to responsible persons in companies and consultants, who compile safety data sheets for chemical substances and mixtures. This should strengthen their responsibility for adequate information. Additional target groups are OSH professionals and occupational physicians aiming at better information and training of workers. A special focus should be given to research institutions and start-ups in material science and nanotechnology. A further development of the JRC web platform may be a way for communication.
For general use it should inform as an application for stationary or mobile use (website/app).
Two main search routes would be necessary:
a) via a substance identifier - leading to a description of the risk (as combination of exposure & hazard/concern) associated with the substance (understandable to the general public and with links to further reading, e.g. scientific literature) and naming examples of used (type of products, no brand names)
b) via a product identifier (including different trade/brand names of comparable products) - leading to a substance used, then link to a)

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)
Authorities' priority setting, consumer choice

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):

Key points are the improved database on release, exposure and hazard to be expected from information on uses and tonnages as well as traceability and transparency.
See also: http://www.umweltbundesamt.de/publikationen/concept-for-a-european-register-of-products
For occupational safety and health it is crucial, that safety data sheets provide adequate information for risk management at workplaces with nanomaterials and other chemical substances and mixtures which have a relevant potential for release of respirable biopersistent particles or fibres.

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

REACH does e.g. not deliver information on substances below 1t/a and transparency within the dossiers are too scarce, the information on NM in articles and uses are not sufficient. If the REACH regulation is amended appropriately, the added value of a nanomaterial registry would be low. If the amendment of REACH is not appropriate, a registry could deliver important pieces of information. See also:
http://www.umweltbundesamt.de/publikationen/concept-for-a-european-register-of-products

If a registry is set up, then it should be considered to also include substances with a relevant potential for release of respirable biopersistent particles or fibres. Such substances are already covered as hazardous chemical agents by EU OSH regulation (CAD, dir. 98/24/EC Art.2 (b) iii), but they are not adequately covered by CLP and REACH regulation. Currently REACH Annex 1 no. 0.6.3 exempts substances, which are not classified as hazardous, from exposure assessment and risk characterisation within a REACH registration. This leads to a significant information gap for risk management at the workplace. Especially for substances and mixtures, which release rigid and biopersistent WHO fibres, high risks for workers health are expected from current scientific knowledge.

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

An amendment of REACH for nanomaterials would be the preferred option to make information requirements obligatory for NM. The broad range from low to high risk of NM should be taken into account. Furthermore, overlaps with other regulation, in particular OSH, should be avoided.

In general, existing regulations should be used. Maybe an umbrella regulation could be used which builds on existing regulation, adapt them where necessary and brings the information on nanomaterials containing products together.

An EU-wide registry would require a harmonised definition across different legislation as well as agreement on analytical methods and instrumentation for properly estimating nanomaterials in products.

If a registry is established it should be evaluated in 2018 aiming at an integration of hazards from respirable biopersistent particles and fibres into REACH and CLP to avoid significant impacts on innovation and competitiveness in the EU.