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PAGE 2: Section I - Identification

Q1: Please provide the following details (*compulsory):	
Your name:	Rolf Packroff
Name of organisation* (if applicable):	BAuA - 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:	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
c) Maintain competitiveness and innovation of businesses bringing nanomaterials or products containing nanomaterials to the market (including SMEs)	5
e) Ensure the availability of relevant information on the presence of nanomaterials or products containing nanomaterials on the market	4
f) Ensure the proportionality of the information requirements and the associated costs and administrative burden.	5
g) Protect confidential business information	3
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 (physico-chemical e. g. …, 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	4

appropriate response to health or environmental risks of nanomaterials	
b) Provide consumers with relevant information on products containing nanomaterials on the market	Do not know
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	Do not know
e) Ensure the availability of relevant information on the presence of nanomaterials or products containing nanomaterials on the market	4
f) Ensure the proportionality of the information requirements and the associated costs and administrative burden.	4
g) Protect confidential business information	4
Please provide additonal comments	The EU CLP inventory covers the hazard data of all chemical substances on the EU market, which are registered under REACH and/or are classified as hazardous acc. to the CLP criteria. Nanomaterials, which are classified as hazardous, are covered by the inventory for every production volume. Workers are informed by the corresponding labelling with pictograms, signal word, H- and P-phrases. Nanomaterials, which are not classified as hazardous, but have a relevant potential for release GBP or WHO fibres, are not covered by current labelling and CLP inventory. But they are covered by EU OSH legislation in the chemical agents directive 98/24/EC as hazardous chemical agents acc. to art. 2 (b) iii leading to a series of obligations for employers for the protection of workers health. Safety data sheets acc. to Annex II of REACH provide information on hazards and risk reduction measures for professional users of chemical substances and mixtures, which are classified as hazardous acc. to the CLP criteria or which are registered under REACH. For nanomaterials, which release GBP or WHO fibres, which are not classified as hazardous due to their chemical composition and which are not registered under REACH, the SDS is provided by the supplier on a voluntary basis. While the above cited regulations will not cover nanomaterials which are not classified, an additional nanoregister would doublicate information received under the registers created in the context of implementation of to Art. 45 of CLP “Information relating to emergency response” which has to be provided for mixture. . According to this draft regulation (14. CARACAL-Meeting - follow-up - CA/06/2014 Harmonisation of information for poison centres) ingredients of mixtures including any nanomaterials shall be

	indicated starting from o,1% or 1% respectively. a) mixture components classified as hazardous on the basis of their health or physical effects; if those components are present in concentrations lower than 0.1% the submission can be limited to the identified components; b) mixture components not classified as hazardous on the basis of their health or physical effects, if those components are present in concentrations equal to or greater than 1%.

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	2
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	There is no scientific evidence for a direct relationship of "nanomaterial" and "hazard for human health". Some nanomaterial pose a risk for workers, others not. Legal information requirements must take this into account.

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

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I am aware of DNELs/PNECs/OELs set for specific nanomaterials/types of nanomaterials

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I am aware of significant exposure of workers/users/consumers to specific nanomaterials/types of nanomaterials

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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):
For occupational safety and health there is scientific evidence for three hazard-related groups 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 bulkmaterial (see "TRGS 900" of the German Hazardous Substances Committee) 3. hazards covered by the criteria of the CLP regulation (physico-chemical, human health) or by a specific OEL for the workplace, e.g. Ag, Ni particles released from nanomaterial or bulk material For DNELs/PNECs/OELs there is an recommended OEL to CNT (Baytubes) of 0.05 mg/m³ (Pauluhn, Regul Toxicol Pharmacol, 57(1) (2010) 78-89). A collection of recommended exposure limits contains the NIOSH Current Intelligence Bulletin (CIB) 65 pp. 37-45 (http://www.cdc.gov/niosh/docs/2013-145/pdfs/2013-145.pdf).

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 sensitiser independent on 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-up. Within NANOVALID, a project from the 7. EU framework program, BAuA is setting up a toolbox targeting at these problems which will be published in 2015. Some cases of Chinese workers suffering from lung diseases have been reported on the ICOH conference in South Africa. 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.
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 most promising way to reduce risks is the integration of hazards for respirable biopersistent particles and fibres into the CLP and/or REACH regulation For industrial and professional users CLP labels and safety data sheets are the most important legal sources for information on risk reduction measures, which ensure safe handling of chemical substances and mixtures. It is questionable, that employers and OSH professional will use additional information sources, which only cover a small portion of chemicals at the workplace.

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)	*Respondent skipped this question*

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)	*Respondent skipped this question*

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)**	c) hamper innovation in the EU (e.g. through concerns about confidential business information or through additional costs related to providing information) , Comments: Identified hazards groups and the corresponding risks for workers health are not limited to nanomaterials. The handling of other chemical substances and mixtures and some processes, e.g. grinding or welding, may lead to comparable risks. Limiting information requirements to nanomaterials leads to an incoherent, addi-tional burden for importers, producers and suppliers of nanomaterials which may hamper innovation in the EU. There are several negative experiences from the former EU notification scheme for new chemical sub-stances acc. to dir 67/548/EC. As a consequence, a complete redesign of chemical safety legislation in EU was starting point for REACH in 2006 aiming at coherent legal demands for all new and existing chemical sub-stances on the EU market after a “phase-in” until 2018. Specific notification demands for nanomaterials may be a barrier to this.
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)**	e) hamper intra-EU competitiveness, f) hamper the competitiveness of European companies against extra-EU companies , Please explain ./.

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.**

There is no added value of an annual notification for each mixture and article with nanomaterials. This would lead to an unmanageable stream of information, which was one of the main reasons for the failure of the former EU existing chemicals regulation (793/93/EEC). Extended legal information requirements weaken the self-responsibility of producers, importers and suppliers on the one hand but cannot strengthen the governmental supervision to the same extent on the other. Experience from the French registration procedure for nanomaterials demonstrate a high portion of fragmentary information, which bond extensive personal capacities in the competent authorities of ECHA and member states with a very limited benefit for risk assessment and management. This is contrary to the objectives mentioned under Sec. III.

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 notification requirements should be addressed to the same actors in the supply chain as for other chemical products under the CLP and REACH regulation. This should offer the opportunity for an integration of the specific notification requirements into CLP and REACH to avoid fragmentation of EU chemical safety legislation.
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 , Please explain: There is sufficient scientific evidence, that inhalation of particles is the most important exposure route for workers, which handle nanomaterials.
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.) From the viewpoint of workers safety and health the inventory should focus on nanomaterials, which have a high potential of risk for human health and which are not yet covered by EU chemical safety legislation. To be coherent and to avoid double-regulation the following nanomaterials should be exempted from the notification requirements: 1. nanomaterials, which are classified as hazardous substances acc. to EC regulation 1272/2008 (CLP) 2. other nanomaterials which are highly soluble in water and/or have a low potential for release of particles or fibres 3. mixtures and articles containing nanomaterials acc. to No. 1 and 2.

Q19: Is there a need to exempt certain uses of nanomaterials?

Yes, certain uses of nanomaterials should be exempted from a notification system

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If yes, which uses should be exempted and why? (in terms of specific exposure scenarios, available knowledge, absence of hazards, etc.)
From the viewpoint of occupational safety and health all uses can be excluded, which do not lead to relevant exposure of workers against respirable particles and fibres.

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

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f) Other (please explain):
Relevant results from EU and national research programs (e.g. Horizon 2020) in the field of nanomaterials and advanced materials. In general the observatory should not be limited to nanomaterials and also focus on other (advanced) materials, which have a relevant potential for release of respirable biopersistent particles and fibres.

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

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, than 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

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d) Development of strategies to ensure the safe use 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):

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.
With regard to the STOP principle in OSH safety-by-design is the best way for protection of workers from particle-related diseases. A notification procedure for dust-generating materials and an obligation to provide information on dustiness in safety data sheets, which is not limited to nanomaterials, can be a driver for the development of low-emission substances, mixtures and articles or appropriate techniques.

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

European nanomaterial registry would have no additional benefit. On the contrary, it would delay that the known and relevant regulatory measures be taken. Research performed on nanomaterials clearly indicates that new risks will predominantly appear in the context of respirable biopersistent particles or fibres and that the REACH and CLP regulation need amendmenst in this context.
Substances with a relevant potential for release of respirable biopersistent particles or fibres are already covered as hazardous chemical agents by EU OSH regulation (dir. 98/24/EC Art.2 (b) iii), but they not adequately covered by CLP and REACH regulation. Currently REACH Annex 1 no. 0.6.3 exempts substances, which not classified as hazardous, from exposure assessment and risk characterisation within 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. An European registry, which mainly focuses on this issue can provide important experience for future amendments of the CLP and REACH regulation targeting at a harmonisation of demands for "hazardous chemical agents" in both, the EU OSH and the chemical safety legislation, to provide relevant substance-related information to employers and OSH professionals.

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

Currently there´s no scientific evidence for a need of additional chemical safety regulations, which are targeted to the whole group of nanomaterials. For workers safety and health nanomaterial pose a broad range from no or low to very significant risks.
A nanomaterial registry will result in a misbalance of coherence in EU chemical safety legislation compared to other chemical substances and mixtures with currently unknown or incompletely clarified risks for human health.
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. For a sector or product specific regulation only a scientifically sound presumption of risk (from hazard and exposure) can justify additional requirements for placing on the market going beyond the demands from CLP and REACH. This is currently not foreseeable for nanomaterials.