#13

COMPLETE

Collector: Nano Consult - Industry (Web Link)
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PAGE 2: Section I - Identification

Q1: Please provide the following details (*compulsory):	
Organisation*:	Euroalliages - European Silica Fume Committee
Town/City:	Brussels
Country*:	Belgium
Contact name:	Nadia Vinck
E-mail address:	
Transparency Register ID number (if applicable)	19153965510-75
Q2: 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
Q3: We might need to contact you to clarify some of your answers. Please state your preference below:	I am available to be contacted
Q4: Did your organisation participate in the online survey (undertaken by RPA/BiPRO for the European Commission in early 2014) on the administrative burden of the notification schemes?	No

PAGE 3: Section II - Organisation Information

Q5: Please indicate which of the following applies to you or your members (tick all that apply):	j) None of the above
Q6: Please indicate the four-digit NACE code of your primary and secondary business sector (if applicable). If you require information regarding NACE codes, please visit the European Commission Competition webpage at http://ec.europa.eu/competition/mergers/cases/index/nace_all.html	
Primary business sector (NACE 4 digit code):	C.24.1.0
Q7: Please indicate the number of employees.	1-9 employees
Q8: Please indicate the approximate annual turnover of your organisation and the annual turnover which relates to nano-related products (where these include nanomaterials as well as mixtures and articles containing nanomaterials).	*Respondent skipped this question*

Q9: Please indicate the number of nano-related products (where these include nanomaterials as well as mixtures and articles containing nanomaterials) that you place on the national market.	*Respondent skipped this question*

Q10: Please indicate the number of nano-related products (where these include nanomaterials as well as mixtures and articles containing nanomaterials) that you place on the EU market.

Nanomaterials	less than 6

Q11: Please indicate the number of nano-related products (where these include nanomaterials as well as mixtures and articles containing nanomaterials) that you place on the global market.	*Respondent skipped this question*
Q12: Please indicate the number of customers and, if applicable, number of suppliers for all your nano-related products combined (where these include nanomaterials as well as mixtures and articles containing nanomaterials).	*Respondent skipped this question*

PAGE 4: Section III – Problem definition and objectives

Q13: 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	2
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	4
f) Ensure the proportionality of the information requirements and the associated costs and administrative burden.	5
g) Protect confidential business information	5
Please provide additional comments	The messages, positions that nanos equal danger should not be circulated. The consequence will be mistrust in nanos while there is no evidence of such statement. Only relevant and factual information should be given without emotional or ideological messages. The existing national inventories are not harmonized leading to conflicting information submitted by the companies.

Q14: 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	3
b) Provide consumers with relevant information on products containing nanomaterials on the market	3
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	2
f) Ensure the proportionality of the information requirements and the associated costs and administrative burden.	3
g) Protect confidential business information	2
Please provide additonal comments	So far there is no binding definition, which makes the inventory exercise difficult. Nanos do not mean hazardous. No evidence can be put forward for such statement. Conclusion of SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks) on nanos is: “It should be stressed that 'nanomaterial' is a categorization of a material by the size of its constituent parts. It neither implies a specific risk, nor does it necessarily mean that this material actually has new hazard properties compared to its constituent parts or larger sized counterparts” in presentation of Wim H. De Jong, Vice- chair SCENIHR of 13 January 2013. It is scientifically recognized that the nano issue is a case-by-case issue. Therefore what will be the added value of making a stronger legal framework ?

Q15: 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	3
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	3
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	So far no standardized and valid methods are clearly identified to assess a potential specific hazard effect of nanos versus “normal size” substances. This is stated by SCENIHR : “Currently, the risk assessment procedure for the evaluation of potential risks of nanomaterials is still under development. It can be expected that this will remain so until there is sufficient scientific information available to characterise the possible harmful effects on humans and the environment. Therefore the knowledge on the methodology for both exposure estimations and hazard identification needs to be further developed, validated and standardized” in the report “Risk Assessment of Products of Nanotechnologies” (2009) which is still valid. Why therefore today making a general information rules on something which is not general ?

PAGE 5: Section IV – Health and environmental aspects

Q16: **With regard to health and environmental hazards and risks of specific nanomaterials/types of nanomaterials, please tick the relevant boxes:**	I am not aware of any health and/or environmental hazards of specific nanomaterials/types of nanomaterials , I am not aware of any DNELs/PNECs/OELs set for 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): This is a cas-by-case issue. We cannot be aware of all potential case, in particular when there is no agreed methodology to differenciate the hazard due to the ssubstance itself or the hazard due to its size (here nanoscale).
Q17: **With regard to the past and current use of nanomaterials (tick the relevant box):**	I am not aware of any health and/or environmental incidents which have occurred , Please explain (if any, please report the events and any scientific publication): see above

Q18: 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

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If appropriate, please explain further:
It is understandable to make a harmonized registry in replacement of national registries with various rules, requirements, objectives, boundaries and definition. However, we do not see the added-value of such harmonized registry knowing that when the nano definition will become binding with the revision of REACH, it will become mandatory for the registrants to tick the “nanobox” in their IUCLID dossier. The registration dossier is already a very detailed inventory. Therefore, overregulation and duplication of requirements should be avoided. The political message of the Commission is to simplify the existing EU regulations …In addition, as REACH is a regulation, it has to be implement as is across all the Members States. According to the European Commission's Regulatory Fitness and Performance programme REFIT,” actions should be taken to make EU law simpler and to reduce regulatory costs, so contributing to a clear, stable and predictable regulatory framework supporting growth and jobs. In this respect, a package of initiatives covering regulatory fitness of the chemical sector will be launched in 2014, including a Cumulative Cost Assessment and a Fitness Check of the most relevant chemicals legislation other than REACH. The conclusions of the various strands of this work including the ongoing evaluation of the occupational health and safety legislation and the results of the earlier REACH Review will provide a complete picture and an outlook on any further possibilities to improve regulatory fitness in this area. The Commission invites stakeholders and Member States to enter into a joint reflection on these questions and feed in to a stock-taking report foreseen for 2016”. For REACH, the Commission “considers that a continued effort is needed at EU, Member State and stakeholder levels to further facilitate the implementation of legislation on chemicals, notably REACH, and to reflect on specific areas where rules can be simplified and burdens reduced” in Communication from the Commission 2014/368 of 18 June 2014 on the Regulatory Fitness and Performance Programme (REFIT): State of Play and Outlook (p. 11 & 12).

PAGE 6: Section V – Consumer trust

Q19: In case information on the presence of nanomaterials in your products were made available, what impact do you think this would have on your clients? (Please tick all that would apply)	c) Their purchasing decisions would not be affected , d) They would search for more information, Please explain: The specifications of the products are known by the supply chains. Users might ask additional information only because of the regulatory/administrative pressure.
Q20: 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)	c) generate insecurity or stigmatise such products, and thus have a negative effect on the market for the concerned products , Comments: Specific hazard properties of nanos is a case-by-case issue. Overregulating this will not improve health and safety in general but could affect the competitiveness of the industry and discourage investments in that field on the EU territory with as a consequence know-how and innovation leakage outside the EU.

PAGE 7: Section VI - Innovation and competitiveness

Q21: 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, Comments: Companies are making since always the necessary b-to-b communication and contacts in their supply chains in order to innovate and remain competitive. Regulatory interference will not bring any added-value. The wheel should not be re-invented. The role of regulatory bodies is needed to support competitiveness, support research activities, ensure level playing field between EU and non-EU manufacturers, ensure CBI, avoid unfair competition and dumping prices as well as circumventions and EU regulations, ensure proper controls, in particular at the borders and leave the business operates in its field of competence.
Q22: 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 , f) hamper the competitiveness of European companies against extra-EU companies , Please explain The fact that nano materials are often presented as dangerous materials by NGO and some regulatory representatives creates a burden to EU manufacturers and hence affect their competitiveness vis-à-vis non-European manufacturers.

PAGE 8: Section VII – Possible impact of a registry on your company/members of your association

Q23: Overall, how would a possible obligation to notify nanomaterials at the EU level affect your company/the members of your association, assuming that no exemptions were to be made from 1 (no impact) to 5 (significant impact):	
a) with respect to nanomaterials on their own	3
b) with respect to nanomaterials in mixtures	3
c) with respect to articles with intended release of the nanomaterials	3
d) with respect to articles containing nanomaterials in general (i.e. in case also articles without an intended release of nanomaterials were to be covered)	3
Please explain:	It is not possible to provide relevant answers without knowing what would be the requirements of the register versus new requirements under REACH for nanos. Companies can be affected in terms of administrative burden if 28 registries would become mandatory.
Q24: Would disclosure of the notified information conflict with the confidentiality of business information?	Yes, there would be a conflict with business information confidentiality , If yes, please elaborate; you may differentiate according to the different information that may be required in a notification scheme (e.g.: if a notification is only per substance and general use, or if the exact use needs to be disclosed): Again, it depends upon the type of disclosure. REACH dossiers are already published on the ECHA website and we start seeing problems of using unlegitimate access to data. Tonnage put in the EEA market is a CBI !
Q25: Do you experience or expect any significant barriers for your company/members of your association from diverging registration obligations in the schemes in France/Belgium/Denmark?	Yes, we foresee significant barriers, If yes, please describe these barriers? Unnecessary commercial pressure may arise from some downstream users sectors due to the regulatory or political pressure and hence creating an unbalanced competition between materials without scientific grounds.
Q26: Is the market for your nanomaterials/products containing nanomaterials significantly different from Member State to Member State?	No, there is not any significant difference in the national markets for our products , If yes, please describe these differences The market is related to clients 'needs.

Q27: In case the European Commission were to recommend a best practice model for national notification schemes based on the experiences in France, Belgium and Denmark, which elements of these systems can be considered as "best practice"?

For Industry, the best practices should be to exclude from registry, inventory or observatory safe nanomaterials. Some nanos are used for decades without any recorded problems. Any approach on nanos should be in addition risked-based, taking into consideration exposure evidence for decades. I

Best practices depend upon the purposes, the goals of the measures. It is not so clear what the Members states plan to do. Increasing knowledge is too vague. REACH already gives a lot of information. In France, the REACH registration number is asked. The Commission should developed an extracting tool in REACH IT enabling to make this harmonized inventory, once the nano definition will be binding, and once the dossier will be updated accordingly, instead of creating a new registry (what legal basis ?), which might conflict with REACH. The last registration deadline is only in 4 years' time.

PAGE 9: Section VIII – Possible options and exemptions

Q28: 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.

No added value. It would be too complex as the supply chains change all the time.

Q29: Which actors along the supply chain should be subject to notification requirements? (tick all that apply):	Please explain: See REACH. Regarding uses see above. In case of substances of high concern, the authorization process is already considered under REACH for the uses. See question n°3.
Q30: The following should be subject to notification requirements (tick all that apply):	Please explain: Too complex supply chains. A good description of the uses as foreseen in the registration dossiers and a % of market applications are manageable and enough relevant.

Q31: 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.) Yes, non-hazardous nanos which are used since decades without any recorded health/environmental hazards like TiO2, carbon black, SiO2. In the Danish Order many items are exempt, including those regulated under other legislation, such as food contact materials, cosmetics and medical devices. Other exemptions include: • mixtures and articles containing unintentionally-produced nanomaterials; • articles containing “fixed” nanomaterials, unless the substances might be released during use; • printed articles, such as newspapers or labels, containing nanomaterials used in the ink; • textiles containing nanomaterials in the colours or dyes; • other products, such as paints, wood preservatives, glues and fillers, that contain nanoscale pigments used solely as colourants; and • rubber articles that contain nano carbon black or silicon dioxide. Products containing substances that are exempt from REACH registration, do not need to be notified to the Danish register. Reporting is thus limited to consumer products with intended release of nanoparticles.
Q32: 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.) It depends upon the properties of the nano, the objectives and the related requirements.

PAGE 10: Section IX – Nanomaterials Observatory

Q33: 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, c) Information on the use of nanomaterials across Europe , e) Information on the hazards and risks of nanomaterials , f) Other (please explain): Innovative potential

Q34: How should the information in a Nanomaterials Observatory be presented in order to reach the consumers, workers and authorities?

Safe nanos should not be reported. The focus should be only on new intentionally manufactured nanos materials.
Innovative potential
No political or emotional info like nano = danger but a balanced and factual/scientific info.
It depends also upon the goals. Is it to make consumers more confident into nanos ?
Insisting too much on the needs to provide info on nano give the impressions that indeed nanos are dangerous which can have a counter-effect.

PAGE 11: Section X - Potential use and benefits of a nanomaterial registry

Q35: In what ways could the information on nanomaterials from registries be potentially useful (tick all that apply):	a) Risk assessment and/or risk management, c) Promotion of safe use of nanomaterials in products , f) General education of the public
Q36: 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):	*Respondent skipped this question*

Q37: What would be the added value of a European nanomaterial registry beyond the current framework of chemicals legislation, including REACH registration?

No added value. Need of a tool to extract from REACH dossiers the information (see supra).

Q38: Please provide any other comments that you would like to share regarding transparency measures for nanomaterials on the market.

The nano = danger rumor should be avoided as it is counterproductive with scientific reality and the huge innovative potential of those materials which is needed to maintain the competitiveness of the EU Industry. EU regulatory bodies to focus on promoting support frontier research on new nano materials intentionally manufactured, materials application research and closed-to-the market industrial scale trials.