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COMPLETE

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

Q1: Please provide the following details (*compulsory):	*Respondent skipped this question*
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:	*Respondent skipped this question*
Q3: We might need to contact you to clarify some of your answers. Please state your preference below:	*Respondent skipped this question*
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):**	f) is a manufacturer of articles containing nanomaterials without intended release
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	*Respondent skipped this question*
Q7: Please indicate the number of employees.	*Respondent skipped this question*
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.	*Respondent skipped this question*
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	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	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.	5
g) Protect confidential business information	5
Please provide additional comments	These 7 objectives are major subjects for development of technologies based on the use of nanomaterials. The development of nanotechnologies and nanomaterials in products can become a key element of competitiveness and gives companies the opportunity to answer their customers' expectations in an innovative and efficient manner. To be able to do so, it is necessary to ensure workers, customers and consumers trust in such products. Companies will be able to build and maintain trust if they have the means to provide their stakeholders with appropriate response to health and environmental risks of nanomaterials. Being able to prove that we control the content of the products and the processes that are set up to produce these products is also very important. For industries, it is also essential to limit the costs and administrative burden that will be necessary to get information and provide it to their stakeholders.

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	2
b) Provide consumers with relevant information on products containing nanomaterials on the market	1
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	1
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.	3
g) Protect confidential business information	Do not know
Please provide additonal comments	The JRC web platform does not provide easy access to useful information on nanomaterials or products containing nanomaterials. The current applicable legislative framework does not specifically cover nanomaterials themselves. In the case of manufacturers / first tier suppliers, ilt should be possible to provide pragmatic and conservative guidelines on how to treat different types of nano-materials without the need for extensive analysis, to guide users on safe use. For example a nano-metallic powder can be expected to be more active than the bulk form with at least the same basic characteristics; and guidelines can be developed on this basis. Or when working with carbon nanotubes, risk could be managed as for asbestos fibres based on lack of solubility in the body. This kind of general best practice advice would be of great value to industry or in academic environments.

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	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	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	It is important that National registries don't share commercially confidential information prior to appropriate protection. Information on the potential consideration of a substance for a given class of application could be commercially detrimental to the developer. Focusing on use does not help manage risk. Focus should be on the attribute of the particle itself and its impact on the body and the environment which could spread beyond the intended use . For b and c: ASD companies are not dealing with consumers. ASD therefore has no legitimacy to answer these questions.

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 aware of health and/or environmental hazards of specific nanomaterials/types of nanomaterials , 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 not aware of any classified nanomaterials, I am aware of 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): •Our members are aware of health or environmental hazards based on literature surveys, there is currently no regulatory source to state on these issues. • Our members are aware that all hazardous substances, including nanomaterials that fulfill CLP criteria should be labelled and classified. However we are not aware of any harmonised classification of nanomaterials under CLP. • Some of our members are aware of possible DNEL and indicative thresholds related to nanomaterials, these limits come from literature or recommendation from institutes (e.g NIOSH) but as of today, no regulatory OEL have been agreed. • Our members are to some degree aware of uses of nano-materials in consumer products but not related to our sectors. These could have wide dispersive use and considerable skin contact such as cosmetics. These are of more concern than applications in our sector where exposure can be controlled more easily.
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
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 , If appropriate, please explain further: A EU nanomaterial registry will allow to track the use or the import of nanomaterials but it would not contribute significantly to reduce the health and safety risks related to the uses of nanomaterials. Harmonised standards and/or regulations on HSE risk management (definition, risk assessment methodology, engineering controls and monitoring strategy) would help to ensure a proper management of uses of nanomaterials and then, to reduce the health risks.

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)	a) They would be more inclined to purchase those products , b) They would try to avoid those products, d) They would search for more information, Please explain: a) They would be more inclined to purchase products containing nanomaterials / or nanotechnologies if it is demonstrated that nanomaterials can show operational advantages or that they can reduce costs in their daily activities (e.g. maintenance costs) b) They could try to avoid those products if for example the general communication about nanomaterials generates suspicion among public opinion c) - d) They would search for more information if doubts may exist on the use of nanomaterials
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)	Comments: a) For our sector, it can generate trust among our customers, consumers, especially if nanomaterials are used and introduced in our products to enhance safety b) - c) Generate insecurity or stigmatise the products : if bad image or suspicion in public opinion Overall, public perception of the whole of nano-materials could be very sensitive to adverse events. A single event of scare in a consumer product would have very damaging repercussions across the whole nano-technology industry.

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)	c) hamper innovation in the EU (e.g. through concerns about confidential business information or through additional costs related to providing information) , Comments: A and C. Information on nanomaterials and products containing nanomaterials could : - On one hand, stimulate innovation if such a type of registry allows better knowledge on nanomaterials and their properties, particularly around hazard and handling guidelines. - On the other hand, hamper innovation if the administrative burden and the costs to find information to be provided are too high. It would also be damaging if the confidentiality of information was compromised.

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)	f) hamper the competitiveness of European companies against extra-EU companies , Please explain Positive effects through availability of risk information would be available to all globally. Any compromise of confidentiality in product development would be to the detriment of EU businesses who had to register.

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	1
b) with respect to nanomaterials in mixtures	2
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)	4
Please explain:	Some of ASD's company members would mainly be impacted as downstream users.

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): • If the notification is required by substance and the use of the substance • To cope with confidentiality issues, products suppliers/manufacturers shall do the notification, and not the downstream users • Registration should not be disclosed until some IP protection is in place.

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? In the French scheme for example, if a member of our association is declared to the French authorities by one of their suppliers as a user of products / mixtures containing nanoparticles, they can expect to be required to provide authorities with specific information about the risks assessment on human health and/or the environmental impact assessment of the use these nano-substances. In such a case, the regulatory framework should also ensure that it is mandatory for the suppliers to inform their clients (i.e. downstream users) that their products/mixtures contain nanomaterials or nanoparticles, with their main specificities. Moreover, due to the possible lack of scientific knowledge about these nanomaterials, it could be very difficult and/or expensive to provide relevant information. As such, they could also face difficulties to prove that they set up the appropriate technical prevention/protection measures.
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
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"?	*Respondent skipped this question*

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.

A structured view per application would be more accessible.

A substance based notification system independent of use would be more helpful to the management of risk especially as substances do not present risk solely through their intended or initial use.

Q29: 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)

Q30: 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: Through the substance not the use
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.) • Non intentional / non engineered nanomaterials could be exempted. • Nanomaterials for which it is already known that there are not hazardous. • Also, to consider the treatment and implications for nano-emmissions eg diesel or welding fume.
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.) • Exempt laboratories activities, research & development

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, 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): • By scientific studies

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

Information sorted by substance, and for each substance the available information about:
- Specific properties
- Health/toxicological effects
- Main risks identified
- Impacts on the environment
- Best practices identified for the use of the substance
- Controls measures to remove or reduce the risks related to use of nanomaterials

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,

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

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):

Justification for 1a, b, c and d:
The HSE risk management should be adjusted to the nanomaterials. Indeed, depending on the characteristics of the nanomaterials, the hazards of the nanomaterial itself is different (size, shape, chemical composition…). Gathering more information on the nanomaterials will allow to adapt the HSE approach and anticipate the risks related to each task involving use of nanomaterials.
Data that would be necessary:
EHS information on substance itself (key characteristics of the nanomaterials: size, chemical, shape, persistence…) and substance in the product.

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

A European nanomaterial registry could have an added value if set up in a transversal approach: this means this registry should be linked with the other applicable chemicals legislation (reach, BPR, f-gases, ODS…) and related existing registries.

A registry should be a basis to establish best appropriate regulation framework/ prioritization of actions, identify most risky applications, most widely used substances

This registry should be:
- transparent for the registrants and users
- user friendly
- ease the agreement for a harmonised definition of nanomaterials

It should also help to establish regulation/standards on HSE risk management of nanomaterials (risk assessment methodology, occupational exposure limits, monitoring standard…)
And it should not add additional administrative burden for the stakeholders

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

Respondent skipped this question