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COMPLETE

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PAGE 2: Section I - Identification

Q1: Please provide the following details (*compulsory):

Organisation*:	IKEM – Innovation and Chemical Industries in Sweden
Town/City:	Stockholm
Country*:	Sweden
Contact name:	Michael Reineskog
E-mail address:	

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?

Do not know

PAGE 3: Section II - Organisation Information

Q5: Please indicate which of the following applies to you or your members (tick all that apply):

a) has to notify to the French Notification System

,

c) is a manufacturer of nanomaterials,

e) is a formulator of mixtures containing nanomaterials

,

h) is a distributor of nanomaterials and/or mixtures containing nanomaterials

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

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

Information on the presence of nanomaterials in a product is of limit value since products placed on the market should be safe to handle irrespective of their content of nanomaterials or in fact any other material or component. Should the presence of a nanomaterial or any other component have adverse effects on human health or the environment instructions for safe use and handling should be provided to ensure that that the risk is controlled in an adequate way. Such information is, in contrast to information on just the content of nanomaterials, relevant and necessary to supply to professional users as well as to consumers.

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 | 3 |
| f) Ensure the proportionality of the information requirements and the associated costs and administrative burden. | 3 |
| g) Protect confidential business information | 3 |

Please provide additional comments

The meaning of “relevant” in b) and e) is not entirely clear. If “relevant” is supposed to mean the presence of a nanomaterial at a certain level this has relevance neither for the function nor the safety of the product. If “relevant” on the other hand means information on how to use the product in a safe way as it has some hazardous properties as a result of the presence of hazardous components, nano or not, this would of course be relevant. To fully provide the desired objectives the current legislation (Reach) has to be somewhat amended, something that is currently under way.

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 5

e) The establishment of national registries and notification schemes causes market fragmentation and hampers trade within the internal market 5

Please provide additional comments

As stated previously the presence of nanomaterials per se is irrelevant if it does not give a product properties that warrant information on safe handling to avoid potential damage to humans and/or the environment.

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 DNELs/PNECs/OELs set for specific nanomaterials/types of nanomaterials

,

I am not aware of any 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):

The classification of nanomaterials as hazardous might not primarily be a result of the nano-size but the intrinsic properties of the substance meaning that the material is hazardous also when present in larger particle sizes. Health hazards have been reported in a number of in vitro-systems but the relevance of the results in intact organisms is still to be determined.

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

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)

b) They would try to avoid those products,

Please explain:

Some clients will take the presence of nano-specific information as a confirmation that nano is hazardous and therefore avoid such products.

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

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)

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

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 | 4 |
| b) with respect to nanomaterials in mixtures | 4 |
| 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 |

Q24: Would disclosure of the notified information conflict with the confidentiality of business information?

Yes, there would be a conflict with business information confidentiality

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

Q26: Is the market for your nanomaterials/products containing nanomaterials significantly different from Member State to Member State?

Respondent skipped this question

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.

Since there is no need for a registry there is as a consequence no need to consider different designs of it.

Nano Registry Public Consultation for the European Commission - Industry Questionnaire

Q29: Which actors along the supply chain should be subject to notification requirements? (tick all that apply):

Please explain:

No notification is necessary as existing legislation (with planned revisions) already covers nanomaterials.

Q30: The following should be subject to notification requirements (tick all that apply):

Please explain:

Again, no notification is necessary.

Q31: Is there a need to exempt certain types of nanomaterials?

If yes, which types should be exempted and why? (in terms of specific properties, available knowledge, absence of hazards, etc.)
Irrelevant as a registry is unnecessary.

Q32: Is there a need to exempt certain uses of nanomaterials?

If yes, which uses should be exempted and why? (in terms of specific exposure scenarios, available knowledge, absence of hazards, etc.)
Irrelevant as a registry is unnecessary.

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)

Respondent skipped this question

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

Respondent skipped this question

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):

Respondent skipped this question

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):

As nanomaterials already are covered by existing legislation and as the knowledge that something is nano really doesn't add anything concerning the safety of a product a registry is of very limited use.

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

Respondent skipped this question

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

Respondent skipped this question