

#54



COMPLETE

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

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

Organisation*:	UEAPME
Town/City:	Brussels
Country*:	Belgium
Contact name:	Rosa Solanes
E-mail address:	
Transparency Register ID number (if applicable)	55820581197-35

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
- ,
- b) has to notify to the Cosmetic Products Notification Portal
- ,
- c) is a manufacturer of nanomaterials,
- d) is an importer of nanomaterials,
- e) is a formulator of mixtures containing nanomaterials
- ,
- f) is a manufacturer of articles containing nanomaterials without intended release
- ,
- h) is a distributor of nanomaterials and/or mixtures containing nanomaterials
- ,
- i) is a distributor of articles 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

Primary business sector (NACE 4 digit code): NA
 Secondary business sector (NACE 4 digit code): NA

Q7: Please indicate the number of employees. ≥ 250 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.

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	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	3
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.	5
g) Protect confidential business information	5
Please provide additional comments	<p>Informing consumers on any aspects relevant for a safe use of products is highly important. This principle for us is applicable on all chemicals and not only NM. However, we highly question an added value related to safety for consumers and professional users of the information that a NM is in a product or that it was used to produce it. Communication of safety aspects (risk and hazard) can be easily covered by REACH and CLP communication instruments.</p>

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 | 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) | 2 |
| 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 | 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 additional comments

We consider that existing legislation covers NM well. Instruments of REACH are capable to investigate and cover NM in an efficient way if applied more flexible than now. In particular the substance evaluation is a mighty tool to close potential data gaps in individual dossiers. However, we have the impression that there is some need to fine-tune the presentation of existing information in dossiers, what would make evaluation more efficient.

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 | 1 |
| 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 | 1 |
| c) The current level of available information on the presence of nanomaterials and products containing nanomaterials on the market is detrimental to consumer trust | 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 | 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

See 1 and 2. We consider national registers problematic in relation to European law and it's intend to harmonise the internal market. Furthermore, we question that they are adequate tools where consumers or users can learn more about NM. We consider national and European registers on NM as a pure administrative burden with the purpose to react on irrational political pressure, which is at the same time burdening the smallest companies the most. In particular option 3 and 4 are critical, since we expect that additional testing for e.g. substance identity will become necessary. This is problematic for SMEs, where mostly no adequate testing equipment is available in house. That further contributes to higher costs and a disadvantage against competing large industry.

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

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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

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)

c) Their purchasing decisions would not be affected

,

Please explain:
Answering this is difficult, since the answer depends on the type of registry-option. We ticked the box for options 1, 3 and 4. For all 3 options also b) could be relevant due to a potential stigmatisation of NM. On the other hand a) could be achieved by option 2, but that depends what kind of information is presented and in what way.

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)

b) have no significant impact,

Comments:
Again, this question cannot be simply answered without keeping in mind a specific option. Again we ticked for options 1, 3 and 4. But also her option 2 could have a positive impact, depending which information is presented and how.

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:

Again, this question cannot be simply answered without keeping in mind a specific option. Again we ticked for options 1, 3 and 4. But also here option 2 could have a positive impact, depending which information is presented and how.

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

,

d) have no significant impact on the competitiveness of European companies against extra-EU companies

,

e) hamper intra-EU competitiveness,

f) hamper the competitiveness of European companies against extra-EU companies

,

Please explain

And again, this question cannot be simply answered without keeping in mind a specific option. Certainly option 2 could have a positive impact on innovation, depending what kind of information is presented. Options 1, 3 and 4 could hamper competitiveness, due to market fragmentation, disclosing of CBI, stigmatisation of NM and administrative burden. In order to prevent trade barriers and fragmentation of the internal market it is of great importance that any debate on risk management of nanomaterials and the provision of information on products containing nanomaterials, takes place at European – and not at national – level. At the moment, however, we observe that member states are drafting or debating national solutions for registration-schemes for nanomaterials. Option 1 would give an even greater incentive to do so. UEAPME considers these initiatives to be a serious threat to the functioning of the regulatory framework of the internal market, and in particular of the REACH regulation. These national initiatives may contravene the free movement of goods in EU's internal market and will hamper innovation in the field of nano-technology. Ultimately, this will have a negative effect on the growth of the European economy.

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 | 5 |
| b) with respect to nanomaterials in mixtures | 5 |
| c) with respect to articles with intended release of the nanomaterials | 5 |
| 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) | 5 |

Please explain:

It clearly would be an additional administrative burden and another potential leak for CBI.

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): This depends on concrete information requirements, but certainly the potential threat of losing CBI is real since many NM-registrants are active in R&D.

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? We see that between the national registries the information requirements differ. Furthermore the language and IT-format of submission tools is an obstacle. We are also not sure about the CBI-rules. Also the fact that CBI is saved on many national systems increases the risk for data-leakage. From our French members we can clearly state that the regulation is an additional burden to the work of companies, especially SMEs. In particular it is difficult for them to know if they have or not to declare and also what to declare. Furthermore it is often very difficult to identify suppliers and to collect data in the supply chain.

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"?

We did not observe any best practice. The national approaches are reverting the harmonisation of the internal chemical market. This harmonisation performed under REACH so far has cost immense investments, while it is more and more clear that the enforcement simply is not capable to ensure a level playing field for those companies who are respecting the legislation and who have made huge efforts to implement what was necessary so far.

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.

We do not see an added value. Information related to a safe use of NM, actually chemicals in general, for consumers and workers can be obtained by REACH and CLP. Added value we see only restricted to statistical processing of submitted information. That could be also and better obtained by option 2.

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

Please explain:
No need, since we consider option 2 to be the most efficient solution. Such information could be collected by market surveys, research institutes or similar to elaborate a holistic and qualitative overview on what is going on with NMs in relation to benefits and safety.

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

Please explain: None. See 2.

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.)
See 2.

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.)
If yes, which uses should be exempted and why? (in terms of specific exposure scenarios, available knowledge, absence of hazards, etc.) See 2.

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): ongoing work at OECD

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

An online information platform would be useful. It should offer:

- general and detailed information about NM,
- ongoing issues related to NM and
- the possibility for consumers to ask concrete questions including FAQs.

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):

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):

We consider option 2 as the best way forward and these aspects are related to it:

- 1a) overview of NM that are used on the market for consumer goods
- 1b) information about the benefits of those NM
- 1c) information about risks or data-gaps related to those NM if any
- 1d) information about grants that could be used for R&D and EHS-research
- 2a) an overview of NM that could become relevant for the market in the near future
- 2b) possible applications with the aim to push innovation
- 2c) discussions about risks/data gaps
- 2d) information about grants that could be used for R&D and EHS-research

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

For option 1, 3 and 4 we do not see any relevant benefits. We consider it as reaction to irrational political pressure.

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

Respondent skipped this question