

#87



COMPLETE

Answers Entered Manually

Collector: Web Link - Manual Entry 9 (Web Link)

Started:

Last Modified:

Time Spent:

IP Address:

PAGE 2: Section I - Identification

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

Organisation*:	BASF
Town/City:	67056 Ludwigshafen
Country*:	Germany
Contact name:	Carolin Kranz
E-mail address:	
Transparency Register ID number (if applicable)	7410939793-88

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?	Yes
---	-----

PAGE 3: Section II - Organisation Information

Q5: Please indicate which of the following applies to you or your members (tick all that apply):	<i>Respondent skipped this question</i>
---	---

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	<i>Respondent skipped this question</i>
---	---

Q7: Please indicate the number of employees.	<i>Respondent skipped this question</i>
---	---

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).	<i>Respondent skipped this question</i>
---	---

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 | 3 |
| 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 | 3 |
| 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

Ad b) Based on our experience with consumer communication the interest of consumers on nanomaterials is still very little. For the time being it is rather an issue for consumer groups, environmental groups and trade unions. Consumers want the products they buy to be safe. According to the NanoView Study of the German Federal Institute for Risk Assessment none of the respondents asked for a nanoinventory and only 0.6% supported a labelling (Source: Nanoview <http://www.bfr.bund.de/cm/350/nanoview-einflussfaktoren-auf-die-wahrnehmung-der-nanotechnologien-und-zielgruppenspezifische-risikokommunikationsstrategien.pdf>) Ad e) Relevant information for the supply chain is first of all the information whether a product is safe and how it can be handled safely and not whether it is nano. This information is generally provided via safety data sheets. The information "nano" or not "nano" is not relevant for safety purposes. It is however relevant in order to comply with nano-specific requirements in certain sectors such as cosmetics, biocides and in regions with nano-specific regulatory requirements (France, Belgium, Denmark).

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 3
- 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 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. 4
- g) Protect confidential business information 4

Please provide additional comments

In principle the current legislative framework meets also the general objectives of an inventory. The problem is not a lack of regulation / tools, the problem is a lack of clarity. Since nanomaterials can be regarded as any other substance the existing tools such as REACH, CLP are also suitable for nanomaterials. However due to the ambiguity of the definition and the lack of its implementability any tool will not lead to satisfactory results. Also nanoinventories – if implemented - would not meet the general expectations. Generally inventories and databases are not the right tools for consumer communication. Therefore other tools need to be developed.

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 | 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 | 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

Ad a) Necessary adaptations are currently made for REACH. Ad b)-c) Generally consumer communication can be improved. However, inventories are not the right tools. Good examples for consumer communication are the "Verbraucherportal" of the State Government of Baden-Württemberg <http://www.nanoportal-bw.de/pb/,Lde/55726.html> or the portal of the German Government www.nanopartikel.info. For SMEs the website of the State of Hessen in Germany <http://www.hessen-nanotech.de> is a good and highly frequented source on nanotechnology. Another comprehensive portal is the DaNa website funded by the German Federal Ministry of Education and Research at www.nanopartikel.info. Also an example for good consumer communication are the fact sheets of the German Competent Authority UBA (Umweltbundesamt): <http://www.umweltbundesamt.de/publikationen/einsatz-von-nanomaterialien-in-beschichtungen> Ad e) National inventories like the one in France can create obstacles to trade within the internal market. Moreover inventories can cause international issues if they are not risk-based, which would be the case of a nanoinventory, because the nano-size itself is not per se a risk.

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 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
,

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):
If exposure occurs we apply the necessary risk assessment procedures and if needed we take the necessary risk management measurements. Company internal we have developed specific guidelines for the safe handling of nanomaterials at work places.

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):
We are not aware of nanomaterial specific health or environmental incidents. Magic nano or the Song publication on fatalities of Chinese workers, which are often quoted as nano-specific incidents, cannot be attributed to nano-specific effects.

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:
Nanoinventories do not deliver an additional benefit for the health and safety compared to existing tools such as REACH or the Cosmetics regulation. They could instead scare and confuse consumers and customers unless only hazardous materials are listed. However these materials should already be classified as hazardous under current legislation.

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:

We are already experiencing the request for nano-free products from our downstream users due to the unclear regulatory situation regarding the definition and the fear that consumers one day could reject products with 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)

c) generate insecurity or stigmatise such products, and thus have a negative effect on the market for the concerned products

,

Comments:

The big majority of consumers trust in the many mechanisms already in place, which assure that only products are marketed which are safe. Generally to date the knowledge of consumers about nanomaterials is very little as well as their interest to learn more about nanomaterials. We therefore fear that consumers will misinterpret the information "nano" as a warning.

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:

Innovation in the nano realm is already hampered in the EU due to existing nano-specific regulation. We are already experiencing today the request for nano-free due to the unclear regulatory situation, additional costs and possible stigmatisation.

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

A nano-inventory always comes along with costs and bureaucracy. New downstream communication measures to comply with the regulatory requirements would have to be implemented. We are already experiencing this in France. It would also make a difference whether the article would be imported or manufactured in Europe: If articles containing nanomaterials were imported, only the article would have to be notified and not the intermediates in the value chain. The consequence could be that articles would be assembled outside the EU borders and would only be imported to Europe. Finally a nanoinventory will send the signal that Europe again puts a high burden on an innovative technology discouraging possible investors outside of Europe from investments in Europe.

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 | 4 |

Please explain:

This is due to our product portfolio as a chemical company. The number of substances and mixtures is high while the number of articles is rather little.

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): Generally anything that requires us to disclose specification details is a competitive disadvantage. It should therefore be strictly limited to information necessary for the safe use of products and to information absolutely needed for consumer communication.

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? This is due to the fact that the scope of the inventories for the time being differ as do the information requirements. Therefore it has to be decided country by country whether a material has to be registered or not.

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”?

Comment: Best practice is communication of risk to downstream users through a REACH compliant SDS. If other requirements come into play they will only add confusion to downstream users that receive one type of information and a second communication with a different type of information.

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.

An inventory based on uses would be too comprehensive and therefore not manageable - neither for companies nor for authorities. The German UBA estimated in its impact assessment for a European nanoinventory 23 million hours needed for industry in the first 5 years. Assuming a 100€/hrs it would result in 2.3 billion € for European industry. Generally the results of this study (http://www.umweltbundesamt.de/sites/default/files/medien/378/publikationen/texte_23_2014_assessment_of_impacts_of_a_european_register_of_products_containing_nanomaterials-schwirn.pdf) should be included in the impact assessment of the EU.

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

Please explain:
None of them. Manufacturers and importers of substances are required to register under REACH and produce a REACH compliant SDS including all registered uses and risk mitigation measures for substances and mixtures.

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

Please explain: See comment to Q 1 and 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.)
Comment: Substances must be registered under REACH independently of whether they are new or existing. This guarantees the safe handling of all materials.

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.)
Uses of substances must be registered under REACH independently of whether the substances are new or existing. This guarantees the safe handling of all materials.

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
- ,
- e) Information on the hazards and risks of nanomaterials

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

The information should be worked up and presented in a consumer-friendly format. Examples are the DaNa Website of the German Federal Ministry of Education and Research at <http://www.nanopartikel.info/en/>, the "Verbraucherportal" of the State Government of Baden-Württemberg <http://www.nanoportal-bw.de/pb/,Lde/55726.html> or the portal of the State of Hessen <http://www.hessen-nanotech.de/dynasite.cfm?dsmid=13906>. Another example is the fact sheets of the German Competent Authority UBA (Umweltbundesamt): <http://www.umweltbundesamt.de/publikationen/einsatz-von-nanomaterialien-in-beschichtungen> Moreover further audience specific communication measures are necessary for consumers. The NanoDiode project of the EU-COM is currently developing approaches for stakeholder communication.

Finally safety data of substances can be accessed by the public via the ECHA database <http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances>. ECHA should remain the one single/only? source of information within the EU. There should not be multiple sources of information and opinions on the safe use of chemicals within the EU.

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):

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?

An inventory is not appropriate regarding the knowledge we have gained on the safety of nanomaterials. It would increase costs and bureaucracy for companies which is more urgently needed to increase innovation and improve competitiveness of European industry. It would not add much more benefit and increase the safety compared to the tools already available in Europe. And finally it is not a suitable tool for consumer communication.

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

Respondent skipped this question