

#44



COMPLETE

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

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

Organisation*:

Town/City:

Country*: Germany

Contact name:

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 but should be kept anonymous

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):

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

Primary business sector (NACE 4 digit code): C22.2.1

Secondary business sector (NACE 4 digit code): C25.1.1

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).

Annual turnover ≥ €50m

Nano-related annual turnover ≥ €50m

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.

Articles 501 to 1,000

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.

Articles 501 to 1,000

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.

Articles 501 to 1,000

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).

Number of customers more than 100

Number of suppliers 6 to 15

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 | 1 |
| 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 | 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

Unfortunately there has been great hype about nanomaterials recently, leading to the misconception that they are dangerous per se. Nanomaterials have been in use for many now decades and the most common ones, like amorphous silica, carbon black and common colour pigments are not particularly dangerous. Consumers need to know if a product is safe, not just if they contain nanomaterials. A registry of all articles that contain embedded immobilized nanomaterials will only confuse consumers. It would need to contain practically every single consumer product on the market because nearly every product has labels employing printing ink. Manufacturers outside the EU in places like China and India would like a public registry: the information they would find would make it easier to copy products made by EU manufacturers.

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) 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 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

Unfortunately, there is a misconception that all nanomaterials are dangerous. Nanomaterials have been in use for many decades, in the older uses (tyres, newspapers, toothpaste etc.) without any fanfare. In order to protect confidential business information from competitors, industry does not normally publish its product formulations and purchasing specifications. As a result, nanomaterials have only been publicized since "nanotechnology" became a buzzword, useful for advertising. However, the (few) products advertised this way are not representative of the vast amount of products that contain "traditional" nanomaterials. There is a grave misconception that only a few products contain nanomaterials and that these products are particularly dangerous. Publishing a list of the millions and millions products that contain nanomaterials is not the solution because nobody can read it. A solution might be to publish a short list of consumer products that often or always contain nanomaterials, e.g. tyres, toothpaste, newspapers, magazines, magnetic tapes.

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 | 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 | 3 |
| e) The establishment of national registries and notification schemes causes market fragmentation and hampers trade within the internal market | 3 |

Please provide additional comments

Consumers do not need "special" information on whether products contain nanomaterials. What consumers need is information on product safety as a whole, not just one minor aspect that is usually not relevant to safety of consumer products. For a product to be unsafe, it must expose the consumer to a hazardous substance in a harmful amount. NGOs have been trying to undermine consumer trust by presenting nanomaterials as "especially dangerous". THAT is the problem. (Of course manufacturers handling nanomaterials in powder form need to take appropriate precautions to protect employees and the environment, but that is already covered in SDSs etc.)

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 not aware of any classified nanomaterials,

I am not aware of any DNELs/PNECs/OELs set for specific nanomaterials/types of nanomaterials

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I am not aware of any significant exposure of workers/users/consumers to specific nanomaterials/types of nanomaterials

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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):

Workers in industry should be protected from inhaling insoluble nanomaterials when they work with them in dry powder form. Otherwise, I am not aware of any particular problems.

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

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If appropriate, please explain further:

Because of the misconception that nanomaterials are always dangerous, a nanomaterial registry would simply mean that perfectly safe products made by compliant suppliers would drop in sales. As there are certainly not sufficient resources (personnel, analysis) to enforce the registry, particularly with respect to imported articles, many importers will not register products containing nanomaterials, either intentionally or out of ignorance. The result would be that the honest and knowledgeable European manufacturers would lose sales, while the dishonest and/or negligent importers and manufacturers gain market share. This would not improve overall product safety. In fact, overall product safety (relating to other hazards) might get worse because dishonest and negligent business operators would gain market share.

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:

Our less sophisticated customers believe the misrepresentations of NGOs that nanomaterials are "always dangerous". Our more sophisticated customers also want to sell to less sophisticated ones, so they too would tend to drop out.

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

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Comments:

This is because NGOs have been misrepresenting nanomaterials as "dangerous per se". Some scientists support this misrepresentation because the hypothesis is good for grant money these days. The best way to get the next grant is to have an inconclusive study that cannot rule out a hazard and hints at a "need for further study".

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)

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Comments:

Competitors would learn why our products work as well as they do. Every new product we develop would entail additional cost, due to the necessity to register it and to explain to customers that it isn't dangerous even though it is listed in the registry. And each of our customers and their customers as well (up to four levels after us!) would have to register their products as well...enormous costs for the the entire value chain!

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)

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

Please explain
 A nanomaterial registry would hurt EU industry as a whole. Companies outside the EU would make articles containing nanomaterials, using information gleaned from the registry and not bothering to mention the nanomaterials to importers. Because the resources do not exist to enforce compliance with such a registry on imports, importers would sell articles containing nanomaterials as if they were nanomaterial-free, while manufacturers with-in the EU would have to develop a huge bureaucracy, tracing and registering nanomaterials at each step of the product chain. As a result, costs for honest and compliant manufacturers would increase, while their sales would drop. Manufacturers of articles outside the EU would gain further advantage because enforcement on them would be impossible.

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 1
- c) with respect to articles with intended release of the nanomaterials 1
- 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:

Our products are articles that contain "traditional" nanomaterials embedded in a solid matrix. The nanomaterials are important to the performance of most of our products and have been present in our products for over 50 years. We would have to make many hundreds of entries for products that are very, very safe. Our customers' customers would erroneously believe that our products are somehow dangerous.

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): We do not want to disclose our formulations and purchasing specifications to our competition.

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?

If yes, please describe these barriers?
No barriers exist for us with these schemes because for our safe products no registrations are required due to the various exemptions in these schemes.

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”?

None of the registries make a great deal of sense because nanomaterials are not innately bad. However none of the schemes problematic for us, because they exclude our products in various ways.

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.

Notification per use would lead to at least 10000 times more entries, probably even more. That would just overload an already unwieldy system.

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

Please explain:
There should be no notification requirements. The relevant information is in safety data sheets for industrial products. If there is a consumer product that could expose consumers or the environment to a hazardous material (nanomaterial or other), then the safety instructions for that product must cover the hazard. As currently defined, nanomaterials are not special or new.

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

Please explain:
There should be no notification requirements. The relevant information is in safety data sheets for industrial products. If there is a consumer product that could expose consumers or the environment to a hazardous material (nanomaterial or other), then the safety instructions for that product must cover the hazard. As currently defined, nanomaterials are not special or new.

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

Yes, certain types of nanomaterials should be exempted from a notification system

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If yes, which types should be exempted and why? (in terms of specific properties, available knowledge, absence of hazards, etc.)
While we sincerely doubt the wisdom of making a registry, if a registry is set up, the following exemptions should be made. Nanomaterials that do not present special hazards should be exempt. So carbon black, amorphous silica and pigments should be exempted. If the nanomaterial is embedded in a solid matrix, there should be an exemption. If these exemptions are not made, the registry will be impossible to handle because there would be too many entries.

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

Yes, certain uses of nanomaterials should be exempted from a notification system

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If yes, which uses should be exempted and why? (in terms of specific exposure scenarios, available knowledge, absence of hazards, etc.)
While we sincerely doubt the wisdom of making a registry, if a registry is set up, the following exemptions should be made. If the nanomaterial is embedded in a solid matrix, there should be an exemption. If the nanomaterial is not sold as a consumer product, there should be an exemption. For industrial and professional uses, a safety data sheet must be sufficient. It would be confusing to have another separate document.

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

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c) Information on the use of nanomaterials across Europe

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d) Information concerning products containing nanomaterials

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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?

A solution might be to publish a short list of consumer products that often or always contain nanomaterials, e.g. tyres, toothpaste, newspapers, magazines, magnetic tapes, with a statement that these uses are neither new nor dangerous.

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):

We don't see any potential benefits. Such a registry only picks one particular aspect and places undue weight on it. It will harm European manufacturers and not improve product safety at all. Product safety must be approached as a whole.

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, just a waste of time and money.

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

What is missing in this whole discussion is the understanding that nanomaterials—as currently defined—are commonly used in the manufacture of many everyday articles and have been so for decades. The “traditional” nanomaterials amorphous silica (pyrogenic type), carbon black and colored pigments are used in a host of applications, including tyres, direct food additives and newspapers. These “traditional” nanomaterials differ from “new nanotechnology” in that the nanoparticles in the traditional nanomaterials always form agglomerates. What is new about “new nanotechnology” are measures to prevent the formation of agglomerates. If it is thought that “new nanotechnology” (non-aggregated nanoparticles) might pose some entirely new, special risk as a class of materials, then a new definition is needed for “nanomaterials”, excluding the aggregates/agglomerates.