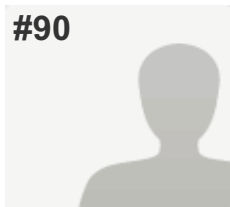


#90



COMPLETE

Answers Entered Manually

Collector: Web Link - Manual Entry 10 (Web Link)

Started:

Last Modified:

Time Spent:

IP Address:

PAGE 2: Section I - Identification

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

Organisation*:

Country*:

Belgium

Contact name:

E-mail address:

Transparency Register ID number (if applicable)

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):

e) is a formulator of mixtures containing nanomaterials

,

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):

C26.2

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

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 | 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 | 4 |
| 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

Nanomaterials (NMs) should be regarded as any other substance, in that some may be of concern, other will not. Given that the current attention given to NM is due to some health and environmental concern, setting up register(s) will inevitably result in stigmatizing NM as a very large group of substances/materials, including those used in ICT products. NMs are only defined by size, and not by a specific risk, as such. As

size, and not by a generic risk as such. As with REACH, data on NM should be gathered by industry in order to perform risk assessments and ensure safe use of the products that are placed on the market. Setting up a register for consumers on products containing NMs that are placed on the market could lead to a stigmatisation of those product, with a negative effect on consumer trust, even if safe use is demonstrated by the implementation of the relevant existing regulations (REACH and/or sector-specific legislation). Given the novelty of NM research, supply chain confidentiality is paramount to this enabling technology to become a commercial success. Any breach in confidentiality will prevent NM enabled technologies from being commercialized. Depending on the type of ICT technology, the degree of confidentiality will vary. For example, carbon black and commodity products have the advantage of being common among industry, whereas there are new NM developments which are highly proprietary. Any type of stigmatization of NM could lead the stifling the advances in the use of NM, which provide many benefits to society through many industrial sectors and technologies.

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 | 4 |
| 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) | 3 |
| 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. | 2 |
| g) Protect confidential business information | 4 |

Please provide additional comments

As OEM of ICT products, we believe that the current legislative framework, in particular REACH, is capable of assessing potential risks associated with engineered nanomaterials. Within REACH, additional attention should be given on

attention should be given on characterization of possible nanomaterials. In addition, the way of gathering (eco) toxicological data should be standardized and included in the REACH annexes. As for any other chemical, consumer trust can be increased by the sound implementation of the current European legislative framework provided that it is well explained to the public. The restriction and authorisation mechanisms in REACH provide appropriate tools for managing risks from nanomaterials. They involve assessment of risk and development of appropriate substance and product specific responses. Article 33 provides a mechanism for sharing information on the presence of SVHC and appropriate risk management measures but it creates significant burden for industry with little value. The ICT supply chain is a very complex and long and gathering information along it (from the 1st tier supplier, to 2nd tier supplier and their sub-suppliers) is highly burdensome. Therefore Article 33 should not be targeted as a mechanism to ensure broad communication on the presence of nanomaterials in products as such; instead the focus should be on the appropriate use of the authorisation and restriction mechanisms. However, Article 33, while burdensome, is better than setting up additional reporting requirements, as the REACH process is in place to assess the risk of specific NM before being added to the Candidate List.

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 | 3 |
| e) The establishment of national registries and notification schemes causes market fragmentation and hampers trade within the internal market | 5 |

Please provide additional comments

Ensuring an adequate response to health and environment risks is not achieved by providing information on the presence of NMs in products but by an effective and reliable risk assessment of the nanomaterial (as foreseen by REACH and product-specific regulations). Risk management is specific to the substance and its application, therefore the process to ensure good risk management of these individual substances is key, not the requirement to describe the presence of nanomaterials in a product. Single-walled carbon nanotubes are known for their hazardous properties. If this substance is used in specific applications, the necessary precautions need to be taken to ensure that they do not present any risk. As a response, many companies use safer alternatives such as multiple walled carbon nanotubes. A NM notification scheme does not add any value in terms of risk assessment, and only presents an administrative burden for industry and authorities. If there are different national schemes, with each their own specific scope, reporting requirements and exemptions, the administrative burden is only exacerbated.

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 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):
For example, DNELs and reference values are established for TiO₂ and carbon nanotubes (under REACH and NIOSH). For TiO₂, DNEL (TiO₂) worker: 10 mg/m³ (inhalation); consumer: 700 mg/kg bw/day (oral). This substance is used in a myriad of different applications, including printing inks and toners.

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:
We consider that risks can be controlled by the implementation of the current European regulatory framework (REACH, CLP and vertical legislation where needed), even if we acknowledge that amendments of REACH Annexes may be needed. Indeed, this framework foresees hazards identification requirements, risk assessment methodologies and ensures safe use of NMs that are placed on the market (as such, in mixtures and in articles) as well as the authorisation and restriction for risk control. Moreover, traceability can be ensured via SDS for industrial and professional users, including for specific hazardous (nano)materials.

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,
- c) Their purchasing decisions would not be affected
,
- d) They would search for more information,

Please explain:

All the answers could apply depending on the product in question and the information available, as well the profile of the user. Information can differ in quality and accuracy, which can lead to misinterpretation. Some companies avoid mentioning the presence of nanomaterials in their products, others promote it. However, it is should be noted that there are request for nano-free products. Also, in the development of market-access requirements (ecolabels for ICT product), nano-free requirements are being considered. The key issue for consumer trust is to ensure proper risk assessment and the implementation of the appropriate risk controls where there is a risk that needs to be controlled.

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:

Depending on consumer knowledge, nanomaterials can be interpreted as a threat or a benefit. Generally outside professional users, there is poor knowledge about nanomaterials in products and the benefits they bring. This could lead to a priori negative feeling of the general public. For example, in the cosmetics sectors, sunscreen have been screened by NGO to see which ones are 'nano-free'; while cosmetics is a different sector than ours, it sets a precedent for other sectors employing NM.

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:

The implementation of the French national registry system led to a mistrustful perception from economic partners and consequently, to a negative impact on competitiveness and innovation. This shows that a register can stigmatize a substance or material, including innovative NM which can be used as a replacement for ITO-touch screen solutions in ICT products, replacing rare earth materials in ICT products as well as increasing energy efficiency.

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

Some ICT companies, in particular those based in the EU doing research on NM, could experience additional costs/admin burden as a result of a EU NM registry. A register would create a burden on that specific industry producing, importing or using nanomaterials when competing with other non nano substances. In addition the cost of such register would most probably be borne by consumers, resulting in increased prices for value chains in EU vs non-EU markets.

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):

b) with respect to nanomaterials in mixtures 4

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:

As ICT OEM, or the entire ICT sector for that matter, has a very long and complex supply chain. In case we would have to report ALL NM present in our products, this would create a lot of additional supply chain engagement and burden, which eventually will be passed on the consumer. For the ICT sector, we do not expect to use any NM that is intended to be released. It should be noted that the current EU NM definition in the Commission's Recommendation would have to be adapted to address those NM specifically used in articles and that there currently is no standardised method to measure whether a material is a NM or not. This will result in different interpretations along the supply chain and will result in an incoherent NM inventory with arbitrary information.

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 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):
Indeed, several confidential information could be disclosed with a notification scheme: - The name of the substance/material itself as sometimes competitors don't know that a substance can exist at nano-scale (the actual use of NM as such can infringe on business confidentiality and will hamper competitiveness and innovation; eg use of a NM in particular application can give away the exact identity of the NM) - The information linked to the substance identity (characterisation of the NM) - The uses - The quantities put on the market - The name of the customers/suppliers As OEM, revealing supplier name can breach Non-Disclosure Agreements. In addition for OEMs at the end of the supply chain, revealing their supply base would reveal sensitive business strategies.

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?
As explained above, the need for a NM scheme needs to be proven, as the current legislative framework, in particular REACH, provides the tools to manage substance risk. If the need for a NM registry is proven, it should be done so at EU level and in a harmonized way in order to reduce barriers as much as possible and only address hazardous materials. The current NM registry developments at the Member State level, each with their own notification schemes and, each with their own scope and requirements, do present barriers for companies, as they only add administrative burden and cost, and do not provide any risk mitigation for users.

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

If yes, please describe these differences
ICT products are developed for global markets in general

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”?

One clear and agreed upon definition of NM should be used and consistency among Member States in terms of scope and reporting requirements.

Web-based declaration are the most effective

CBI should be diligently considered and managed in order not to hamper innovation and competition

An industry agreed upon methodology for identifying hazardous NM

There should be no requirements for notification down the supply chain where the NM are in finished products. Notifying that products contain the NM should be sufficient for the authorities, as these products are often ubiquitous. For example, there is no value in making all distributors of ink cartridges notify the presence of nanomaterials in pigments when these cartridges are used globally in office environments.

Include a “de minimis” level below which reporting is not required, determined at the product level

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.

The notification per use versus the notification per substance is ambiguous. We support the current REACH methodology. Data on mixtures/articles is best to be found in safety data sheets, which is already an existing tool to describe risks/hazards per mixture/article. There would be no added value in collecting information which is already being collected.

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

Please explain:

Notification systems already exist for chemical substances and mixtures, additional ones should not be needed specifically for nanomaterials. There is also no value in requiring distributors or professional users down the supply chain of finished products to notify the presence of NM.

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

Please explain:

Notification systems already exist for chemical substances and mixtures, additional ones should not be needed specifically for nanomaterials. There is also no value in requiring distributors or professional users down the supply chain of finished products to notify the presence of NM.

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.)
Notification systems already exist for chemical substances and mixtures, additional ones should not be needed specifically for nanomaterials. There is also no value in requiring distributors or professional users down the supply chain of finished products to notify the presence of NM. Should the need for a NM register be proven, non-hazardous NM should be exempt. NM should only be listed on the basis of risk, not on particle size alone.

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.)
Notification systems already exist for chemical substances and mixtures, additional ones should not be needed specifically for nanomaterials. Should the need for a NM register be proven, non-hazardous NM should be exempt. In addition, materials which are hazardous, but are used below the de-minimis level at the product level should not be registered.

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)

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
,

f) Other (please explain):
Information established in the Observatory should be taken from already existing sources and voluntary submissions, not from new and/or additional legislation. For example, the peer reviewed scientific literature will provide a very good overview of the NM developed and potential for use in consumer products. Information on the hazards and risks of nanomaterials should be considered in the sense that some NM may be hazardous, while others not, as any chemical substance.

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

For consumers, market studies would be of greater value. For workers and authorities, more detailed information from ECHA dissemination would be useful. The information should be structured with the appropriate level of detail.

Q35: In what ways could the information on nanomaterials from registries be potentially useful (tick all that apply):

f) General education of the public,
g) Other purposes (please specify)
As ICT OEM, we believe that a NM registry will not improve transparency nor provide benefits for consumers, given that the current legislative available framework and tools and the information and transparency provide this already. There might be some benefit if information on NM would be made comprehensible to the general public, in terms of general education, but we expect the benefits to be limited. On the contrary, a registry will have the stigmatizing effect on NM per se, as one of the drivers are health and environmental concerns. Secondly, competitive information could be used by companies not subject to registration or more importantly, by those who have not invested in the NM developments. Besides the education of the general public, current frameworks like REACH, CLP and other sector-specific legislation such as the food, cosmetics and biocides regulations do provide more than sufficient ground to assess risk and health issues in a proper way. Overall, we anticipate that the negative impacts of a registry will outweigh any positive impacts. Negative impacts include consumer confusion over which materials are hazardous and which are not, as well as confusion on which authoritative list is relevant, for example REACH article 33 information versus a NM register.

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 that the administrative burden, the risk of releasing/revealing confidential information and the negative impact on economy outweigh the potential positive impact of the scheme. For example, no benefit from the French scheme has been identified so far, at least from a consumer perspective.

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

We consider that no added value has been identified so far. However this can be said for any substances or products put on the market. Nanomaterials are not more dangerous per se as any other chemicals. The only advantage of an EU registry would be the replacement of the multiple national registries, reducing the increasing burden on member companies while providing a single platform for information.

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

We believe that the existing legislative framework, REACH in particular, is sufficient to manage NM. An all-encompassing register for NM will provide no benefit for consumer and stifle innovation.