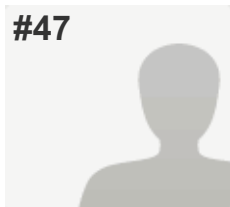


#47



COMPLETE

Collector: Nano Consult - Industry (Web Link)

Started:

Last Modified:

Time Spent:

IP Address:

PAGE 2: Section I - Identification

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

Organisation*:

Town/City:

Country*: UK

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?

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,

e) is a formulator of mixtures containing nanomaterials

,

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

Q6: Please indicate the four-digit NACE code of your primary and secondary business sector (if applicable). If you require information regarding NACE codes, please visit the European Commission Competition webpage at http://ec.europa.eu/competition/mergers/cases/index/nace_all.html

Respondent skipped this question

Q7: Please indicate the number of employees.

50-249 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 €10m to €50m

Nano-related annual turnover €10m to €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.

Nanomaterials less than 6

Mixtures less than 6

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.

Nanomaterials less than 6

Mixtures less than 6

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.

Nanomaterials less than 6

Mixtures less than 6

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

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

Nanomaterials (NMs) should be regarded as any other substance. In this context, as required by REACH for instance, data must be gathered by industry in order to perform risk assessments and ensure safe use of the products that are placed on the market. Consumer trust could be increased by providing the public with a relevant explanation on the process involved. Some specific sector legislation such as for cosmetics and biocides already requires information to be provided for consumers and health authorities. It is important to point out that by providing information to consumers on products containing NMs placed on the market; this could lead to a stigmatisation of NMs resulting in a negative effect on consumer trust. This may still be the case even if safe use is demonstrated by the implementation of the relevant regulations (REACH and/or sector-specific legislation). In terms of labelling requirements, we do not believe this to be necessary where the nanomaterial substance is not harmful.

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

Please provide additional comments

BYK Additives believes that, as for any other chemical, consumer trust can be gained through good implementation of current European legislation (even if some adaptations in the REACH annexes are needed); provided that this is explained well to the public. Additional requirements would constitute an administrative burden for companies with no guarantee of a potential positive impact on consumer trust. Negative consequences on the competitiveness and innovation capacity of the chemical industry can nevertheless be expected.

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 | 2 |
| 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 | 1 |
| e) The establishment of national registries and notification schemes causes market fragmentation and hampers trade within the internal market | 5 |

Please provide additional comments

The adequate response to health and environment risks is not linked to the information on the presence of NMs in products but to an effective and reliable risk assessment carried out for the whole life-cycle of the substance (as foreseen by REACH and product/worker/environment specific regulations). As regards question (e), on the basis of the experience gained by the chemical industry in France with the French notification scheme, this highlights the fact that a national system can create obstacles to trade within the EU internal market. The term nanomaterial used in the French, Belgian, and Danish schemes are not identical; the same applies for their respective exemptions from notification. In addition, no advice is given with regard to measurement methods. As a consequence, substances could be subject to (i) notification requirements in one Member State but not in others; and/or (ii) considered as a nanomaterial or not depending on the manufacturer's/importer's understanding of the definition and metrology skills used.

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):

BYK Additives are aware of the risks of substances we manufacture and comply accordingly.

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 aware incidents, initially attributed to nanomaterials but subsequently found to be unfounded. For example a recent publication stating that exposure to nano nickel entailed a sensitization effect in an unprotected worker in the US is attributable to the sensitising effect of the metal itself, not the particle size (Journey and Goldman, 2014. Am. J of Industrial Medicine). We have manufactured a nanomaterial for more than 40 years without issues in either our work force or customers.

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:
BYK Additives believes existing chemical-related regulations (REACH, CLP and sectoral legislation) are suitable to manage any potential risks from nanomaterials, as they are for other chemical substances. This framework ensures safe use of NMs that are placed on the market (as such, in mixtures and in articles). Furthermore for hazardous NMs, traceability can be ensured in the supply chain via Safety Data Sheets, which enable the forwarding of relevant information (hazard, exposure, risk management) to downstream users. Hence, the added value of an EU registry as regards to controlling potential risks is negligible.

PAGE 6: Section V – Consumer trust

Q19: In case information on the presence of nanomaterials in your products were made available, what impact do you think this would have on your clients? (Please tick all that would apply)

b) They would try to avoid those products,

c) Their purchasing decisions would not be affected

,

d) They would search for more information,

Please explain:
The French notification scheme for nanomaterials showed that situations b) and c) occurred within the supply chain. As regards to situation b), we have lost business as customers want to avoid products containing nanomaterials either due to the administrative burden of the notification system or stigmatisation of NMs with such a scheme.

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 and understanding, nanomaterials can be interpreted as a threat or a benefit. Generally outside professional users, there is poor knowledge about nanomaterials in products and the benefit they bring. This could lead to miss-informed negative perception in the general public.

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:

BYK would like to contribute on the basis of the experience gained by the chemical industry in France with the French notification scheme for nanomaterials. The implementation of this national registry system led to a mistrustful perception from economic partners and consequently, to a negative impact on competitiveness and innovation. More precisely, it brought many uncertainties amongst economic actors towards the French market, creating, in some cases, question marks regarding business developments and location of R&D activities in France.

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

We do not see a need for a register for nanomaterials, as they are similar to other chemical/substance forms in that some may be toxic and others are not. Asking for notification to a register for nanomaterials would create a burden on that specific industry producing, importing or using such substances when competing with other non-nanomaterial substances. In addition, the cost of such a register would most probably be borne by consumers thereby entailing increased prices for value chains in the EU vs. non-EU markets.

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 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:

Although we do not manufacture articles we supply customers who do.

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 have concerns that confidential information could be disclosed with such a notification scheme, these being: 1) Substance name (sometimes competitors don't know that a substance can exist at the nanoscale); 2) Information linked to the substance identity (i.e. characterisation of the nanomaterial); 3) Uses 4) Quantities placed on the market 5) Customers name(s).

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? Diverging notification obligations increase the workload for companies not only for filling the notification but also to ensure adequate compliance in schemes that diverge from each other. Definitions of the term nanomaterial used in the French, Belgian, and Danish schemes are not identical; the same applies for their respective exemptions from notification. In addition, no advice is given with regard to measurement methods. As a consequence, substances could be subject to (i) notification requirements in one Member State but not in others; and/or (ii) considered as a nanomaterial or not depending on the manufacturer's/importer's understanding of the definition and metrology skills used.

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"?

BYK does not see there are elements of best practice in the current national notification schemes.

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 by use for the purpose of registration, would be extremely difficult for industry to comply with due to the often large supply chains involved. More importantly, as a direct result of these supply chains, this would present a large bureaucratic burden to companies to track down each and every single use. BYK questions the benefit of any additional register of this nature since this in its simplicity is a list that does not guarantee the safety of these groups.

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

Please explain:

Notification of nanomaterials beyond existing legislative requirements is not needed. In BYK's view this is duplication and a better way to move forwards would be to opt for an Observatory approach as proposed by the CIA.

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

Please explain:

Apart from increasing the administration burden to companies making notifications due to going beyond substances, the purpose of a register must be defined first. BYK does not believe there is a need for this because an observatory approach would meet all stakeholder needs

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.)
Nanomaterials notified under existing regulatory notification schemes (such as REACH, CLP, biocides, cosmetics) should be exempted. There is no need to duplicate entries if an Observatory type approach were to be adopted as the best way forwards since this would enable the bringing together of all notifications into one database

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.)
Nanomaterials subject existing legislation (e.g. cosmetics, biocides etc.) should be exempt, as nanomaterials used in these sectors have already been notified. Uses leading to no exposure to human health and the environment would need to be exempted as well.

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
- ,
- e) Information on the hazards and risks of nanomaterials
- ,
- f) Other (please explain):
We believe the most logical and efficient way to provide the necessary information to satisfy all stakeholders, would be to expand the existing European Commission's Joint Research Centre web platform on nanomaterials to include notifications of nanomaterials to all current regulatory schemes. This ensures positive listing of nanomaterials where their safety assessment has been completely focused on risk assessment rather than hazard. Notifications would include information on nanomaterials used in food, cosmetics, medical devices, biocidal products as well as substances submitted under REACH (once Annexes are adapted for nanomaterials) and CLP (Classification, Labelling and Packaging). Efforts should also be made to coordinate this data at the substance specific level so that it is searchable. This can then be used for risk assessment by all stakeholders including regulators to identify on a case-by-case basis if there are any data gaps and if any specific risk management controls are needed. With this in place, we thereby see no reason for establishing a separate EU register on top of existing regulatory requirements

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

With reference to the above information on nanomaterials collected from all current regulatory schemes is already in the public domain and by bringing this together under an expanded European Commission's Joint Research Centre web platform makes this more accessible to consumers, workers and authorities. More importantly this would not only be a portal for bringing together all information, it should also be searchable by use and increase transparency of the risk assessment process for showing safe use of nanomaterials to the public. We believes this would bring reassurance to all stakeholders.

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

g) Other purposes (please specify)
 We do not believe any of the above deliverables can be effectively achieved from registries (EU and national) containing information on nanomaterials. Provisions are already made within existing sector European legislation that detail the requirements for appropriate risk assessment, so we therefore question the benefit of any additional register of this nature since this in its simplicity is a list that neither guarantees the safety of consumers nor workers and would very likely result in a further barrier to the commercial success of UK and European companies. We believe this could also have a scaremongering effect on the public when they enquire about the need for traceability.

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, together with the risk of releasing confidential information and the likely resulting negative impact on the economy outweighs any potential positive impact of such a scheme. Indeed, 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?

None.

A register whether it be national or European is an extra regulatory burden placed on companies, especially when notification is required annually and not as a one-time action. We also have concerns that the EU would be bound to make registration requirements a bureaucratic, complicated and therefore costly process. This would also be unique to the EU with little relevance to other global regions where companies do business thereby limiting international competitiveness for EU based businesses.

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

We would like to reiterate the fact that nanomaterials are similar to other chemical/substance forms in that some may be toxic and others are not. Their size does not indicate a step-change in hazard. And as such should be treated as any other chemical substance placed on the market.