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COMPLETE

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

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

Organisation*:	IMA-Europe, European Industrial Minerals Association
Town/City:	Brussels
Country*:	Belgium
Contact name:	Claire Lanne
E-mail address:	
Transparency Register ID number (if applicable)	14190001484-01

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?	No

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 , c) is a manufacturer of nanomaterials, d) is an importer of nanomaterials, e) is a formulator of mixtures containing nanomaterials , k) Not sure whether we deal with nanomaterials

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

Primary business sector (NACE 4 digit code):	0811 - 0812 - 0891 - 0899 - 2399 - 2352

Q7: Please indicate the number of employees.	≥ 250 employees
Q8: Please indicate the approximate annual turnover of your organisation and the annual turnover which relates to nano-related products (where these include nanomaterials as well as mixtures and articles containing nanomaterials).	*Respondent skipped this question*

Q9: Please indicate the number of nano-related products (where these include nanomaterials as well as mixtures and articles containing nanomaterials) that you place on the national market.

Nanomaterials	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

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

Q12: Please indicate the number of customers and, if applicable, number of suppliers for all your nano-related products combined (where these include nanomaterials as well as mixtures and articles containing nanomaterials).	*Respondent skipped this question*

PAGE 4: Section III – Problem definition and objectives

Q13: Please rate the importance of the following objectives on a scale between 1 (not important at all) and 5 (very important).

a) Provide decision makers, regulatory authorities and professional users with information that allows for an appropriate response to health or environmental risks of nanomaterials	5
b) Provide consumers with relevant information on products containing nanomaterials on the market	2
c) Maintain competitiveness and innovation of businesses bringing nanomaterials or products containing nanomaterials to the market (including SMEs)	5
d) Ensure consumer trust in products containing nanomaterials	5
e) Ensure the availability of relevant information on the presence of nanomaterials or products containing nanomaterials on the market	2
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	Like any other substances, some nanomaterials may be hazardous and some are not. It is important to have adequate and reliable information on nanomaterials available, which will allow decision makers, regulatory authorities and professional users to ensure that nanomaterials are properly handled according to their intrinsic hazards and exposure risks, if any. We consider that once the hazards and risks associated to nanomaterials have been properly assessed, resulting in a possible classification of the substance or mixture containing nanomaterials or risk management measures, information on hazardous nanomaterials should indeed be provided, like for any other chemicals, to professional and consumer users. However, providing information on the presence of nanomaterials, indistinctively, whether they are hazardous or not, just because they are nanomaterials provide little relevant information to consumers and the general public. There is a risk of misinterpretation or of associating the “presence of nanomaterials” to “risks”, which could be scientifically incorrect and detrimental to business competitiveness and innovation. In that sense, the objective of only providing information on the presence of nanomaterials or products containing them is not relevant in itself, as it does not bring any information in terms of toxicity or safety and is potentially misleading.

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)	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.	5
g) Protect confidential business information	4
Please provide additonal comments	As of now, the current legislative framework (including the REACH and CLP Regulations and product-specific legislation) offers a sufficient legal framework to provide relevant information in terms of health or environmental risks of nanomaterials. Their implementation as regards the way to ensure they properly address nanomaterials may be improved, but the tools are there. Thanks to specific legislations taking nanomaterials into account (e.g. cosmetics, food, feed, etc.), and following several Reports made by the European Commission and the JRC, there is available information on the identity and uses of nanomaterials on the EU market. We believe that the existing legal framework is sufficient to assess and inform about the toxicity and risks of these nanomaterials or the products containing them. However, it is worth noting that even existing provisions are having some impact on the competitiveness and innovation of nanomaterials: e.g. the current recommended definition, as it stands, leaves some uncertainties as to what falls under the definition or not, the revision of the REACH annexes might lead to more requirements for nanomaterials than for other substances. As regards the latter aspect, the fact that coated nanomaterials should not be regarded as a mixture but as a substance or form of a substance in itself may harm confidential business information, slow down innovation or lead to unreasonable costs linked to registration and the protection of sensitive information.

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
e) The establishment of national registries and notification schemes causes market fragmentation and hampers trade within the internal market	5
Please provide additional comments	We agree with the statement that the setting-up of national registries and notification schemes of nanomaterials, based only on the presence of nanomaterials regardless of any other relevant criteria such as any assessment of their toxicity, is useless and does not meet the objective of providing consumers with relevant information to make informed choices. It merely raises a de facto suspicion around nanomaterials, for which it is forgotten that they can also bring benefits to the society in that they can be a useful and innovative technology.

PAGE 5: Section IV – Health and environmental aspects

Q16: With regard to health and environmental hazards and risks of specific nanomaterials/types of nanomaterials, please tick the relevant boxes:

I am not aware of any 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 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):
We are aware of nanomaterials which have been assessed and which are not classified as hazardous according to Regulation (EC) No 1272/2008: e.g. nano calcium carbonate, nano silica fumes.

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 of nanomaterials which have been used for several years and for which no health and/or environmental incidents have been noted or reported.
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 believe that an EU registry risks hardly providing any additional useful information while it would constitute an administrative burden. As acknowledged by the European Commission in its Second Regulatory Review, carbon black and amorphous silica represent by far the largest volume of nanomaterials currently on the market, which, together with a few other nanomaterials, have been on the market for decades and are used in a wide variety of applications. The benefit versus the administrative efforts of registering such nanomaterials, for instance, needs to be assessed. Moreover, the current 2011 European Commission recommendation for a definition of nanomaterial needs to be considered. It is indeed very wide and technically difficult to implement, and if used as such for the purpose of a registry of nanomaterials without being revised or restricted, it might trigger uncertainties and many more products to be included in any declaration procedure than it is expected or useful when wanting to address "nanomaterials". With the current definition, products that are not really nanomaterials but may fall under the definition of having 50% of the number of particles between 1-100 nm may have to be declared, creating declaration burdens for industry and authorities without bringing any benefit in terms of human health or environmental risk information on nanomaterials under focus.

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, d) They would search for more information, Please explain: Amongst our member companies, some have already received requests from their customers to inform them whether the products contain nanomaterials. When it is the case and the products do contain nanomaterials, clients usually request explanations and an assessment of the safety of the products. Containing nanomaterials or using nanotechnology cannot be used as a marketing argument anymore because of the suspicion it arises in terms of safety and image for b2b products as well as for consumer products. For business-to-business products, clients moreover prefer to avoid any obligations linked to national notification schemes.
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: As mentioned above, we do not think that having publicly available information on the presence of nanomaterials in products, whether they are hazardous or not indistinctively, is bringing any useful information as such. Such information is indeed meaningless and can be misinterpreted without informed explanations about the meaning and health or environmental risk impact of this presence. As such, the mere availability of the information is not sufficient to ensure a greater trust amongst the large public. Moreover, since it is likely more difficult to obtain information about the presence of nanomaterials in products coming from outside the EU, an EU registry could not guarantee a full transparency on such a presence of nanomaterials in products.

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: The impact of a nanomaterial registry on innovation would obviously heavily depend on the type of information that would have to be notified. Due attention needs to be paid to giving access to sensitive information, such as confidential know-how, some coatings of nanomaterial, some innovative applications, etc. In a similar way, companies could be dis-couraged from innovating in nanomaterials if the legal notification provisions are too de-manding in terms of generating data, non-manageable and costly.
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 In sometimes complex supply chains, it is difficult to have data on the presence of nanomateri-als in products coming from outside the EU. In that perspective, EU companies are likely to be at a competitive disadvantage in terms of costs related to providing the information to a regis-try and in terms of innovation information (niche markets, new applications, etc.) which could then be easily accessible for competitors. Moreover, should the large public and consumer distrust products which may contain nano-material, following a precautionary approach, EU companies may be at a disadvantage due to a non-level playing field with non-EU competitors.

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	3
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:	For some of our member companies which are manufacturing nanomaterials, an obligation to notify substances, mixtures or articles containing nanomaterials would have a significant impact: they would have to notify or provide information to their clients so they can notify. Again the problem of the definition of "nanomaterial" being used arises. As it stands, the current EC recommended definition is very wide and technically difficult to implement: if the scope is not restricted, it leaves uncertainties as to applicable notification duties for some substances/mixtures/articles and may lead to different interpretations and unharmonised notification practices.

Q24: Would disclosure of the notified information conflict with the confidentiality of business information?

Yes, there would be a conflict with business information confidentiality

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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):
Any harm to the confidential business information will depend on the information to be notified. We see a conflict with confidentiality if such information as coatings of the nanomaterials, or some exact uses, need to be disclosed.

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?

No, we do not expect any barriers,

If yes, please describe these barriers?
The difference in scope and requirements is an administrative burden and time consuming for companies, however, we do not expect that they constitute any market “barrier”.

Q26: Is the market for your nanomaterials/products containing nanomaterials significantly different from Member State to Member State?

Respondent skipped this question

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"?

Should a best practice model for national notification schemes be recommended, we support the approach of the Danish nano-register. It has a reporting requirement for manufacturers/ importers of mixtures and products containing nanomaterials and intended for sale to the general public, where the nanomaterial itself is released under normal or reasonably foreseeable use, etc. The scope of the registry seems to be going in the right direction: firstly, it seems adequate to provide useful information to the general public since it is easier for the public to relate the notified information on articles or mixtures to their day-to-day products; and secondly, the scope focuses on situations where there is a possible risk exposure (release) instead of simply taking into account the mere presence of nanomaterials.

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.

In the industrial mineral sector, the products are used in a wide range of applications and uses, in different and sometimes complex supply chains.This would duplicate the notification requirements and efforts for a same substance, while we doubt the duplicated notifications would bring additional information in terms of human health or environmental hazard or risk compared to a notification per substance which would comprehensively consider all the uses.

Q29: Which actors along the supply chain should be subject to notification requirements? (tick all that apply):	a) Manufacturers of nanomaterials, b) Importers of nanomaterials, c) Downstream users (e.g. re-formulators, manufacturers of products containing nanomaterials) , d) Distributors to professional users (e.g. wholesalers)
Q30: The following should be subject to notification requirements (tick all that apply):	a) Substances, b) Mixtures containing nanomaterials, c) Articles with intended release of nanomaterials
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 which are: - not intentionally manufactured, or - which have been assessed as not hazardous, or - which are included in matrixes and are not released, or - which are included in articles without intended release should be exempted. The reason for this is that there is no health or environmental safety added-value in imposing notification obligations on these materials; it is only justified by the wish to make an academic exercise and have a comprehensive and "nice-to-have" information.

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.)
Uses of nanomaterials types mentioned in question 4 above could be exempted for the same reasons as explained above. Additionally, uses of nanomaterials which are already covered by other specific legislation should be exempted to avoid duplication of notifications.

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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e) Information on the hazards and risks of nanomaterials

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f) Other (please explain):
We can see the benefit of having a focal point which would structure for the large public already available information on nanomaterials, associating the information on their identity, applications, and hazards and risks.

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

There could be several layers of information for each nanomaterial substance or products containing it, which would adapt to the level of information of the audience. Authorities or specialists do not have the same level of knowledge nor the same need for details as an average consumer.

PAGE 11: Section X - Potential use and benefits of a nanomaterial registry

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

c) Promotion of safe use of nanomaterials in products

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g) Other purposes (please specify)
Risk assessment/management and worker protection are already ensured via other ex-isting legislations, and would not tremendously benefit from a registry indicating the presence of nanomaterials in products. We also believe that such a registry can hardly help consumers to make informed deci-sions or educate the public if it is not linked to providing more information and explain-ing the toxicity and risks related to the specific nanomaterial in the specific product. Moreover the registry may contained too much information for the average non-specialist public. One benefit we see in such a registry is to certainly raise the awareness on the topic of nanomaterials, and their safe use in products, provided a general suspicion on nano-materials contained in the registry is avoided.

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):

As mentioned above, a registry meant to help consumers to make informed decisions or educate the public should not merely provide a list of nanomaterials on the market. It should provide adequate information on the hazard and risk of specific nanomaterials in specific applications.

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

The current framework of chemicals legislation, including REACH registration, makes available and will probably make more available after the revision of the REACH Annexes a large amount of information on nanomaterials. This existing information on nanomaterials could be extracted and used. It is true that this information can be very detailed and difficult to understand for the general public, therefore some communication/explanation might be needed.
A EU nanomaterial registry can only have added value if it is intended to provide useful information to consumers that they can directly use and relate to their everyday life, such as a registry of products containing e.g. hazardous nanomaterials.

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

Respondent skipped this question