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COMPLETE

Answers Entered Manually

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PAGE 2: Section I - Identification

Q1: Please provide the following details (*compulsory):	
Organisation*:	
Town/City:	
Country*:	United Kingdom
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):	c) is a manufacturer of nanomaterials, d) is an importer of nanomaterials, e) is a formulator of mixtures containing nanomaterials , f) is a manufacturer of articles containing nanomaterials without intended release , h) is a distributor of nanomaterials and/or mixtures containing nanomaterials , i) is a distributor of articles 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):	C20.1.2 - Manufcature of dyes and pigments
Secondary business sector (NACE 4 digit code):	C20.3.0 - Manufacture of paints, varnishes and similar coatings, printing ink and mastics

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.

Mixtures	51 to 100

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.

Mixtures	101 to 250

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.

Mixtures	101 to 250

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	16 to 30

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	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	4
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	The definition of nanomaterial provided in 2011/696/EU does not permit clear delineation to ena-ble us to classify our materials as nanomaterials or otherwise. It should be carefully considered which information is “relevant”. The information of nanomaterial being contained in a product in general is useless without knowing the specific impact of the pre-sent material. to b) Previous experience shows that the share of consumer products inducing direct contact to nanomaterial is rather low compared to the vast overall amount of products containing nanomaterial. So the information of nanomaterial being contained is not “relevant” in every case. to e) Relevant information for the supply chain is first of all the information whether a product is safe and how it can be handled safely. Only due to specific regulatory requirements for nanomaterials in different sectors (cosmetics, biocides) and regions (France) the information “nano” or not “nano” is relevant there.

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)	2
d) Ensure consumer trust in products containing nanomaterials	2
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.	1
g) Protect confidential business information	1
Please provide additonal comments	The definition of nanomaterial provided in 2011/696/EU does not permit clear delineation between intentionally manufactured, functional nanomaterials which derive specific properties from their size and general powdered products which do not gain any advantage though their primary particles being nano-form. to c) and d): Different definitions for nanomaterials, diverging implementations in nanoproduct registers and a lack of suitable and commonly available measuring methods provoke intricacies when dealing with nanomaterials. This hampers the competitiveness and innovation especially for smaller companies and detracts consumer trust. Furthermore the whole discussion about nanomaterials is rather based on assumptions than on facts. to g): Industry and authorities seem to have different perceptions on “confidential information”, a lot of information published on ECHA-webpage is pretty useful to non-European companies.

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	1

consumer choice	
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	This hinges on the broad definition provided in 2011/696/EU. Existing bulk materials which by chance contain nanoform materials are already well-characterized and covered by existing data and risk assessments whereas newer intentionally manufactured, functional nanomaterials which derive specific properties from their size may not be as well-characterized. The problem with what is provided in 2011/696/EU is that few will understand the difference. to c) The accentuation of nanomaterials compared to other substances in different sectors evokes the consumer's fear of potential hazards and thus is detrimental to consumers' trust. The current level of information is adequate in our view. to d) Manifold definitions in different registers do not lead to a coherent and effective way as the comparability between these registers is hampered. On the other hand other established regulations (REACH) provide the information sufficiently. Nevertheless for consumer communication inventories are not the right tools. Good examples for consumer communication are the "Verbraucherportal" of the State Government of Baden-Württemberg http://www.nanoportal-bw.de/pb/,Lde/55726.html or the portal of the German Government www.nanopartikel.info. to e) Previous experience with the French Register shows that there is a high burden (effort and cost) especially for smaller companies. The establishment of national registers hampers the European market, particularly with regard to our industry (pigments and fillers). (JRC, Considerations on information needs for nanomaterials in consumer products: "National regulations of traceability measures may lead to different information requirements and could create cross-border trade barriers by influencing free market interplay at various levels (manufacturers, distributors/importers and downstream users) between the EU Member States.")

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 aware of health and/or environmental hazards of specific nanomaterials/types of nanomaterials , I am aware of specific nanomaterials that are classified as hazardous under Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures , I am aware of DNELs/PNECs/OELs set for specific nanomaterials/types of nanomaterials , I am aware of significant exposure of workers/users/consumers to specific nanomaterials/types of nanomaterials , Please explain your responses (if any, please report the nanomaterials, the health and/or environmental hazards, any relevant classification, any DNELs/PNECs/OELs, any exposure and in which condition): Please explain your responses below (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): Again the answer to this is predicated upon the broad definition provided in 2011/696/EU. We know of no data specific to nanomaterials newer intentionally manufactured, functional nanomaterials which derive specific properties from their size but are aware that a different answer may result if one applies the broad definition provided in 2011/696/EU to those thousands of powdered materials fall into its scope. We are aware of consumer exposure (e.g. cosmetics); however in these cases the products are already subject to an official risk assessment and authorization. We are also well aware of the exposure of workers, thus worker safety protection measurements and exposure limit values are well established and complied in our industry.
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): Please explain (if any, please report the events and any scientific publication): None specific to nanomaterials which have been intentionally manufactured, functional nanomaterials which derive specific properties from their size but a different answer may result if one applies the broad definition provided in 2011/696/EU. In its loosest form thousands of materials fall into scope.

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: Only if it could be shown to be specific to nanomaterials which were intentionally manufactured, functional nanomaterials which derive specific properties from their size but not if applied to the thousands of powdered materials fall into the scope of the broad definition provided in 2011/696/EU. The existing regulations (REACH etc.) are sufficient/suitable for controlling risks.

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, Please explain: Recent attempts by ECHA, France and other legislatures to demand a register of nanomaterials has brought with it a similar stigma to that which is rightly and properly present for SVHCs, CMRs vPvB etc. substances. The connotation is that “nano” materials must be seen as undesirable and negatively impacts on substances so classified. The same is extended to non-intentionally manufactured, non-functional nanomaterials which fall into the scope of 2011/696/EU only by virtue of their size. Discussions with different industries (e.g. food, cosmetic, automotive supplier and automotive industry) show that a lot of industries in the end of the supply chain request for nano-free products. The reasons for this are the additional efforts and costs in these companies or the additional labelling requirements. This might evoke the consumers to wish to avoid nanomaterials.
Q20: Do you believe that the public availability of information on the presence of nanomaterials in products would be likely to…(choose one of the following answers)	c) generate insecurity or stigmatise such products, and thus have a negative effect on the market for the concerned products , Comments: Recent attempts by ECHA, France and other legislatures to demand a register of nanomaterials has brought with it a similar stigma to that which is rightly and properly present for SVHCs, CMRs vPvB etc. substances. The connotation is that “nano” materials must be seen as undesirable and negatively impacts on substances so classified. The same is extended to non-intentionally manufactured, non-functional nanomaterials which fall into the scope of 2011/696/EU only by virtue of their size. See Section V Q1.

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: Hampers innovation through technical people spending their time on the bureaucracy of registration and attempting to count SEM/TEM pictures for nanoparticulates. Adds to costs so reducing resources that can be put onto other innovative R&D. See Section III Q2. Increased effort and costs, administrative burden.
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 The Recommended Definition 2011/696/EU does not discriminate between intentionally manufactured, functional nanomaterials and those existing conventional and traditional materials which fall into the scope of 2011/696/EU only by virtue of their size. Those companies manufacturing the conventional products will need to spend time and effort on registration even for export markets whilst those outside the EU will pay no heed to this definition. Nanomaterials are no more or less dangerous than other chemicals; so there is no reason for establishing a specific register only for nanomaterial. A register for nanomaterials is only an extra burden for the industry affected by that. Therefore it is a disadvantage for producers and users of nanomaterials compared to producers and users of other chemicals and an disadvantage for European industry compared to non-European 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
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:	Confusion. Multiplicity of test requirements and associated costs. Stigmatization of products which have been in market for decades. Pigments and fillers, considered as nanomaterials according to the current EU-definition, are present in nearly every product and article of our daily life. Therefore nearly every product/article has to be registered if there was no exemption. Investigation on end products like coatings and plastics containing pigments and fillers show that there is no release of nanomaterials if they are bound in a matrix. (see D. Göhler, A. Nogowski, P. Fiala, M. Stintz, J. Phys.: Conf. Ser. 2013, 429, 012045.) So there is no scientific justification for a registration of articles mentioned under d).

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): We would need to provide detailed breakdown of non-hazardous products in nano-form which would not be required under current REACH/CLP rules. The compromises our IP/CBI to no benefit. Information on e.g. distribution, quantities of substances used in different sectors, formulation and name of customers would highly conflict with the confidentiality of business. (see also Section III Q2.)

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? Confusion. Multiplicity of test requirements and associated costs. Stigmatization of products which have been in market for decades. The differences in notification scheme and definition of nanomaterials mean a lot of extra workload for the companies; keeping it up to date every year means an unnecessary but considerable burden especially for SMEs.

Q26: Is the market for your nanomaterials/products containing nanomaterials significantly different from Member State to Member State?	Yes, the markets differ at national level

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"?

If this is strictly necessary then base it on the definition proposed in Australia. The NICNAS working definition is:
"…industrial materials intentionally produced, manufactured or engineered to have unique properties or specific composition at the nanoscale, that is a size range typically between 1 nm and 100 nm, and is either a nano-object (i.e. that is confined in one, two, or three dimensions at the nanoscale) or is nanostructured (i.e. having an internal or surface structure at the nanoscale)"
Notes to the working definition:
intentionally produced, manufactured or engineered materials are distinct from accidentally produced materials
'unique properties' refers to chemical and/or physical properties that are different because of a material's nanoscale features when compared with the same material without nanoscale features, and result in unique phenomena (e.g. increased strength, chemical reactivity or conductivity) that enable novel applications
aggregates and agglomerates are considered to be nanostructured substances
where a material includes 10% or more number of particles that meet the above definition (size, unique properties, intentionally produced) NICNAS will consider this to be a nanomaterial.
Another alternative implementation for notification schemes might be the Norwegian approach, which is an additional tool to the existing chemical legislation. The Danish product register concerns only consumer products, which is in our view the best of the mentioned registers regarding the information for consumers. REACH is already an established kind of register for chemical substances and therefore also already covers nanomaterial.

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.

Notifications should be restricted to those materials with 'unique properties' which refers to chemical and/or physical properties that are different because of a material's nanoscale features when compared with the same material without nanoscale features, and result in unique phenomena (e.g. increased strength, chemical reactivity or conductivity) that enable novel applications. It should not be necessary for non-engineered non-functional materials which are already adequately covered under existing REACH provisions.
The notification per use would bring no extra benefit in comparison to already existing regulations, as the information for downstream user companies and workers are already covered by the safety data sheets, which are also common for non-hazardous substances. Regarding consumer products sufficient regulation is already established (cosmetic regulation, food information/regulation, biocides).

Q29: Which actors along the supply chain should be subject to notification requirements? (tick all that apply):	Please explain: None of the above unless or until there is proof that there are specific issues with nano materials. No separate nanomaterial registry is required as sufficient regulation/notification systems already exist (see Section VIII Q1.)
Q30: The following should be subject to notification requirements (tick all that apply):	c) Articles with intended release of nanomaterials , Please explain: None of the above unless or until there is proof that there are specific issues with nano materials. No separate nanomaterial registry is required as sufficient regulation/notification systems already exist (see Section VIII Q1.)

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.) All should be exempted except perhaps those with 'unique properties' which refers to chemical and/or physical properties that are different because of a material's nanoscale features when compared with the same material without nanoscale features, and result in unique phenomena (e.g. increased strength, chemical reactivity or conductivity) that enable novel applications.) Even in these cases it is not clear why anything beyond ordinary REACH provisions and CLP classifications should apply. Sufficient regulation/notification systems already exist (see Section VIII Q1.)
Q32: Is there a need to exempt certain uses of nanomaterials?	If yes, which uses should be exempted and why? (in terms of specific exposure scenarios, available knowledge, absence of hazards, etc.) All uses should be exempted except in the case of those requiring 'unique properties' which refers to chemical and/or physical properties that are different because of a material's nanoscale features when compared with the same material without nanoscale features, and result in unique phenomena (e.g. increased strength, chemical reactivity or conductivity) that enable novel applications). Sufficient regulation/notification systems already exist (see Section VIII Q1.)

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)	e) Information on the hazards and risks of nanomaterials , f) Other (please explain): Sufficient regulation/notification systems already exist (see Section VIII Q1.)

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

See Q1.

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

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

Q36: Please give a justification for your views (presented in the previous question) and describe which data would be necessary to allow the desired use (e.g. would information on substances alone be enough for informed consumer purchase decisions, or would this require information for each concerned product):

Sufficient regulation/notification systems already exist (see Section VIII Q1.)

Presently there are thousands of existing and traditional materials which would be classified as nanomaterials according to the Commission's Recommendation: 2011/696/EU. This does not discriminate between intentionally manufactured, functional nanomaterials and those existing conventional and traditional materials which fall into the scope of 2011/696/EU only by virtue of their size. Those companies manufacturing the conventional products will need to spend time and effort on registration even for export markets whilst those outside the EU will pay no heed to this definition.
The registry should be limited to intentionally manufactured, functional nanomaterials and nothing more.

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

None. See Section VIII Q3.

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

Due to the extremely broad definition of nanomaterial applied very many materials are "nano". Thus the focus is lost and it cannot be differentiated in relevant, new or hazardous nanomaterial and material with small particles known and used for many decades.
The lack of suitable and commonly available measuring methods should be solved preliminary.
A proper definition such as that provided in Australia needs to be established as the basis for targeting the right group of materials.
This is an essential prerequisite to progress.