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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*:	FIDE - European Dental Industry
Town/City:	Cologne
Country*:	Germany
Contact name:	Gregor Stock
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 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?	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 , 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

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):	3250

Q7: Please indicate the number of employees. ≥ 250 employees

Q8: Please indicate the approximate annual turnover of your organisation and the annual turnover which relates to nano-related products (where these include nanomaterials as well as mixtures and articles containing nanomaterials).

Annual turnover	≥ €50m
Nano-related annual turnover	≥ €50m

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

Nanomaterials	less than 6
Mixtures	over 1,000
Articles	over 1,000

Q10: Please indicate the number of nano-related products (where these include nanomaterials as well as mixtures and articles containing nanomaterials) that you place on the EU market.

Nanomaterials	less than 6
Mixtures	over 1,000
Articles	over 1,000

Q11: Please indicate the number of nano-related products (where these include nanomaterials as well as mixtures and articles containing nanomaterials) that you place on the global market.

Nanomaterials	less than 6
Mixtures	over 1,000
Articles	over 1,000

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

Number of customers	more than 100
Number of suppliers	51 to 100

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	4
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

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	3
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)	1
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	3
f) Ensure the proportionality of the information requirements and the associated costs and administrative burden.	1
g) Protect confidential business information	4

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	4
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	4
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	4
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 currently existing nanoregisters in different Member States require different information. This lead to an inconsistent level of information. Thus we apply for one European nanoregister database.

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 not aware of any classified nanomaterials,

I am not aware of any 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):
Nanotubes and nanowires have health hazards. Only workers are exposed in some cases to dust, that contain nanomaterials (e.g. asbestos, which has one dimension as nano).

Q17: With regard to the past and current use of nanomaterials (tick the relevant box):	I am aware of health and/or environmental incidents which have occurred , Please explain (if any, please report the events and any scientific publication): Asbestosis
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: Nevertheless we apply for an EU nanomaterial register in order to avoid a mixup caused by a lot of different Member States registers.

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)	c) Their purchasing decisions would not be affected , d) They would search for more information, Please explain: Not 100 % but the majority of our clients would not be affected. The minority, that would be affected would search for more information in order to decide.
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

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: Depends on the concrete content of the nanomaterial register.
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)	c) have no significant impact on intra-EU competitiveness , f) hamper the competitiveness of European companies against extra-EU companies , Please explain But we are not quite sure about the level/amount of hinderance.

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	2
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:	Dental manufacturers are downstream users of nanomaterial. Thus with regard to nanomaterials as such these manufacturers are not or less affected. However, with regard to the manufactured products (mixtures and articles), an obligation of notification would affect an estimated 90 % of all dental materials, since these materilas usually contain nano-scale fillers (aerosil) to tune the viscosity of any paste-like material, to give one example.
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): The amount of conflict depends on the details. The worst case would be the declaration of the name and/or description of the nanomaterial.
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? Different information to be supplied for different registries lead to unnecessary waste of time and money.
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"?	*Respondent skipped this question*

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.

A notification per use (based on articles and their application) may allow for better estimation of potential exposure routes (oral, inhalative, dermal).

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, Please explain: The answer requires that the downstream users communicate their uses to the manufacturers and importers.
Q30: The following should be subject to notification requirements (tick all that apply):	a) Substances, Please explain: Logical consequence of answer to question above.
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.) Naturally existing nanomaterials (e.g. iron oxides), nanomaterials with long history of use (inorganic fillers, pigments), to give just some examples.
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.) All uses that are not in connection with an intended release of nanomaterial.

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)	c) Information on the use of nanomaterials across Europe , e) Information on the hazards and risks of nanomaterials , f) Other (please explain): f) Information on favourable results with regard to nanomaterials.

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

Free available internet information and data base.

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):

For a balanced answer we need to know the concrete contents of the registry.

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

None, because
1. Nanoobjects are (or will be) subject to the biological evaluation of medical devices acccording to ISO 10993.
2. Release of nanomaterials should be considered in the REACH registration process.

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

Respondent skipped this question