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COMPLETE

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

Q1: Please provide the following details (*compulsory):	
Name of organisation* (if applicable):	Council of European Dentists
Town/City:	Brussels
Country*:	Belgium
E-mail address:	
Transparency Register ID number (if applicable):	4885579968-84
Q2: Please indicate if you are responding to this questionnaire on behalf of/as:	d) a consumer organisation/trade union/environmental organisation/non-governmental organisation
Q3: 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
Q4: We might need to contact you to clarify some of your answers. Please state your preference below:	I am available to be contacted

PAGE 3: Section III – Problem definition and objectives

Q5: 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)	3
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	5
f) Ensure the proportionality of the information requirements and the associated costs and administrative burden	4

administrative burden.

g) Protect confidential business information	3
Please provide additional comments	The CED is restricting its answer to materials relevant to dentistry. The CED believes that the composition of filling materials (substances and nanoscale substances) should be declared by the manufacturer or at least be made available to professional users (i.e. dentists). Dentists are obliged by regulation to achieve valid consent for the treatment they offer and provide and consequently require the information about the materials available to them in order for them to be confident in doing so. We note, however, that, according to the EU recommendation, potentially relevant dental materials will be classified predominantly as nanocomposites rather than nanomaterials, since the constituent nanoparticles do not occur “in an unbound state or as an aggregate or as an agglomerate”. Furthermore, many of the existing dental uses will fall into the exempted category of fillers (p. 11 of the draft impact assessment report). We therefore assume that the proposed measures should not apply to dental materials in the majority of cases. However, we note that these definitions could be subject to change, and that they are not consistently applied across Member States; we will therefore respond to the questionnaire on this basis. The use of nanocomposites in dental materials particularly those containing silica and aluminium oxides such as composite fillings is well established. There is, as yet, little sound scientific data in regard to adverse health or environmental issues related to nanoparticles in dental materials. Their intended purpose in this context is to be stable and inert while improving the physical properties of the filling material.

Q6: 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	Do not know
b) Provide consumers with relevant information on products containing nanomaterials on the market	Do not know
c) Maintain competitiveness and innovation of businesses bringing nanomaterials or products containing nanomaterials to the market (including SMEs)	Do not know
d) Ensure consumer trust in products containing nanomaterials	Do not know
e) Ensure the availability of relevant information on the presence of nanomaterials or products containing nanomaterials on the market	Do not know
f) Ensure the proportionality of the information requirements and the associated costs and administrative burden.	Do not know
g) Protect confidential business information	Do not know

Q7: 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	2

PAGE 4: Section IV – Health and environmental aspects

Q8: **With regard to health and environmental hazards and risks of specific nanomaterials/types of nanomaterials, please tick the relevant boxes:**	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): The CED is restricting its answer to materials relevant to dentistry. Sound scientific data in regard to health or environmental effects are not yet established.
Q9: **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): The CED is restricting its answer to materials relevant to dentistry with the acknowledgement that sound scientific data on health and environmental effects have not yet been established.
Q10: **The establishment of an EU nanomaterial registry (tick the relevant box):**	Would significantly contribute to reducing the health and/or environmental risks related to the use of nanomaterials , If appropriate, please explain further: We would consider the following categories i. i. materials in established use ii. ii. materials with known hazardous properties iii. iii. novel materials for which safety data are not yet available. We suggest that materials of all three types should be subject to notification. A registry of types ii. and iii. would significantly contribute to reducing associated risks, and by including type i. would provide downstream users including healthcare professionals with the information required to make the best choice of materials, use them in the safest possible way for human health and environmental protection and inform patients of any associated risks.

PAGE 5: Section V – Consumer trust

Q11: In case information on the presence of nanomaterials in specific products were made available, what impact do you think this would have on consumers? (Please tick all that would apply)

d) They would search for more information,

Please explain:
Consumer reaction would depend on the way the information is presented to them. Nowadays consumers are more conscious of what they buy and use. This reflects the efforts made through several EU policy initiatives to empower and enhance consumers' rights, namely the EU Consumer Policy strategy 2007-2013. An EU register publicised positively and with care may enhance professional users and consumer trust. Single agenda action groups have not helped public perception of the health benefit assessment presentation of the safety of some dental materials. We consider that any consideration of the risks and benefits of all dental materials should be presented in a balanced and evidence based manner. Information presented in a way that supports this aim is to be welcomed.

Q12: 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)

Comments:
CED would suggest that this is a difficult question for which to provide anything other than a subjective response based on personal general experience. It may be that experienced marketers could offer an evidence based answer using the data from previous similar situations.

PAGE 6: Section VI - Innovation and competitiveness

Q13: 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)

Respondent skipped this question

Q14: 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)

Respondent skipped this question

PAGE 7: Section VIII – Possible options and exemptions

Q15: What would be the added value of a notification per use (i.e. for each mixture/article) compared to a notification per substance? – Please consider the usefulness of the information for public authorities, downstream user companies, workers and consumers.

The CED believes that a clear scope that does not affect service providers is needed - downstream users should not include healthcare professionals who are not involved in manufacture or reformulation, i.e. the notification duty should not be applicable to users such as dentists placing dental restorations.

Q16: 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: Undue concern should not be generated among patients with regard to materials in long-established use. However, we support the requirement for some transparency measures such that healthcare professionals have access to information from manufacturers and can pass it on to patients if they require/choose.
Q17: 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 , d) Articles containing nanomaterials without intended release
Q18: 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.) It is tempting to suggest that dental materials that have been in established use for considerable time with no apparent current evidence of adverse effects should be exempted subject to continued monitoring and change of notification status if indicated by the results of monitoring evidence. This, however, does not take account of the absence of data in respect of the effects, particularly in the long term. It would, therefore, be prudent to include all dental materials where the relevant data are absent.
Q19: Is there a need to exempt certain uses of nanomaterials?	No, all uses of nanomaterials should be subject to notification obligations , If yes, which uses should be exempted and why? (in terms of specific exposure scenarios, available knowledge, absence of hazards, etc.) The CED's response, however, is in respect only of materials used in dentistry. We have no view on nanomaterials outside this scope.

PAGE 8: Section IX – Nanomaterials Observatory

Q20: 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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d) Information concerning products containing nanomaterials

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e) Information on the hazards and risks of nanomaterials

Q21: How should the information in a Nanomaterials Observatory be presented in order to reach the consumers, workers and authorities?

Respondent skipped this question

PAGE 9: Section X - Potential use and benefits of a nanomaterial registry

Q22: In what ways could the information on nanomaterials from registries be potentially useful (tick all that apply):

a) Risk assessment and/or risk management,

b) Enforcement of worker protection,

c) Promotion of safe use of nanomaterials in products

,

d) Development of strategies to ensure the safe use of nanomaterials

,

e) Informed purchasing decisions by consumers,

f) General education of the public

Q23: 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):

Professional users need full disclosure of the composition and risks of the constituents of materials in order to recommend and discuss appropriate treatment in their patients' best interests. Simultaneously, professional users and, particularly, employers of the dental team must be confident that they are aware of any risks in the storage, preparation and use of the materials to members of the dental team so that appropriate processes and protocols for safe use can be established where necessary. This information should be easily accessible. Dental patients need to have enough easily understood information to make valid choices about the oral health care they are offered by dentists. This must be evidence-based and enable a health cost benefit analysis to be made.

Q24: What would be the added value of a European nanomaterial registry beyond the current framework of chemicals legislation, including REACH registration?

The CED supports a route to dental professionals' access to comprehensive information about the materials available for supply and will support moves to improve full disclosure of composition.

Q25: Please provide any other comments that you would like to share regarding transparency measures for nanomaterials on the market.

The CED welcomes this initiative to increase transparency and ensure regulatory oversight on nanomaterials. In this context and restricting our answer to materials relevant to dentistry, the CED believes that disclosure of substances and nanoscale substances should be made available online for professional users and consumers/patients to access and included in the packaging material.