#60

COMPLETE

Collector: Nano Consult - Non-Industry (Web Link)
Started:
Last Modified:
Time Spent:
IP Address:

PAGE 2: Section I - Identification

Q1: Please provide the following details (*compulsory):	
Name of organisation* (if applicable):	British Dental Association
Town/City:	London
Country*:	UK
E-mail address:	
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

g) Protect confidential business information	3
Please provide additional comments	We restrict our answer to materials relevant to dentistry. The BDA believes that the composition of filling materials (substances and nanoscale substances) should be declared by the manufacturer, or at least made available to professional users (i.e. dentists). Dentists must obtain valid consent for the treatment they offer and therefore require information about the materials available to them. It should be noted 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 – particularly those containing silica and aluminium oxides – in dental materials such as composite fillings is well established. As yet, there is little sound scientific information on adverse health or environmental effects of 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?	*Respondent skipped this question*
Q7: To what extent do you agree with the following statements from 1 (strongly disagree) to 5 (strongly agree):	*Respondent skipped this question*

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): We restrict our answer to materials relevant to dentistry. Sound scientific data in regard to health or environmental effects are not yet available.
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): Again, we restrict our answer to materials relevant to dentistry and note that sound scientific data on health or environmental effects are not yet available
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. materials in established use ii. materials with known hazardous properties 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)**	Please explain: Consumer reaction is likely to depend on how the information is presented. Consideration of the risks and benefits of dental materials should be presented in a balanced and evidence-based manner.
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)**	*Respondent skipped this question*

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.**

A clear scope is required that does not affect service providers: a notification duty should not be placed on healthcare professionals who are not involved in manufacture or reformulation, 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?	No, all kinds of nanomaterials should be subject to notification obligations , 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 materials in established use with no evidence of adverse effects should be exempted, subject to continued monitoring and change of notification status as required by the evidence. However, this does not take account of the absence of data in respect of their 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.) We restrict our opinion to materials used in dentistry.

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 , c) Information on the use of nanomaterials across Europe , d) Information concerning products containing nanomaterials , 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 discuss and recommend appropriate treatments in the best interests of patients. Also, professional users – particularly employers of the dental team – must be confident that they are aware of any risks to staff in the storage, preparation and use of the materials, so that appropriate processes and protocols for safe use can be established where necessary. This information should be readily accessible.
Dental patients should have enough easily-understandable information available to make valid choices regarding oral health care 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?

We support a route to dental professionals' access to comprehensive information about the materials available, and will support moves to ensure full disclosure of composition.

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

Respondent skipped this question