#89

COMPLETE

Answers Entered Manually

Collector: Web Link - Manual Entry 10 (Web Link)
Started:
Last Modified:
Time Spent:
IP Address:

PAGE 2: Section I - Identification

Q1: Please provide the following details (*compulsory):	
Organisation*:	Japan Business Council in Europe (JBCE)
Town/City:	Brussels
Country*:	Belgium
Contact name:	Akihito Nakai
E-mail address:	
Transparency Register ID number (if applicable)	6836857120-55
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 , b) has to notify to the Cosmetic Products Notification Portal , 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 , g) is a manufacturer of articles containing nanomaterials with 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):	Our memberships come from various sectors
Secondary business sector (NACE 4 digit code):	Our memberships come from various sectors

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.	*Respondent skipped this question*
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.	*Respondent skipped this question*

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.	*Respondent skipped this question*
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	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	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.	4
g) Protect confidential business information	5
Please provide additional comments	Principally, it's difficult to prioritize all of given items because they are in mutual relationship and it should not be judged separately. It is very important to make balance on trade-off between various stakeholders such as associated costs, appropriate choice of risk communication, confidential business information, transparent EU harmonized legislation, social trust to nanotechnology together with appropriate risk information to citizen etc.

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	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)	5
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	3
f) Ensure the proportionality of the information requirements and the associated costs and administrative burden.	4
g) Protect confidential business information	Do not know
Please provide additonal comments	There is short information in order to share and assess nano risk with standard or certain justification in current legislative framework. It is also important for SMEs and citizen to educate and disseminate how to use available database and how to understand legislative framework by simple and easy method.

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	3
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	2
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	2
e) The establishment of national registries and notification schemes causes market fragmentation and hampers trade within the internal market	5
Please provide additional comments	It is first to establish system to collect and share appropriate information with scientific evidence and EU harmonized standard / procedure. We are afraid that obligation of information disclose only containing nano give consumers unnecessary anxiety and block nano related competitiveness and innovation. We believe that national registries causes market fragmentation and hampers due to incoherent information requirement without identification methods and effects on the health and/or environment by 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 not aware of any classified nanomaterials, I am not aware of any DNELs/PNECs/OELs set for specific nanomaterials/types of 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 recognize it is common challenge to collect such scientific data including cost and definition of test method. The link below might be useful if you are not aware. http://www.environmental-expert.com//news/worker-illness-after-nanomaterial-exposure-examined-in-first-us-427275?utm_source=News_Health_Safety_15052014&utm_medium=email&utm_campaign=newsletter&utm_content=feattextlink
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): We have some information concerning health and environmental incident but almost of these cases are not clear whether they are in causal relationship with the nanomaterial specific properties.
Q18: The establishment of an EU nanomaterial registry (tick the relevant box):	I do not know, If appropriate, please explain further: We don’t think nano registry contribute to reduce the health and/or environmental risks directly and the objective of registry should be clarified at first. However the information from registry contribute as source to prioritize scientific risk assessment and it is important to take into account information requirement according to the objective.

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)	d) They would search for more information, Please explain: It depends on the contents of information. Even if there is information only containing nano, it is not affected for purchasing decision because the good feature of the nano is well useful for the clients. What it is important is to inform them appropriate information with scientific evidence and there is no good effect for them to communicate insufficient information they can't do anything. A membership of JBCE made a comment, "Many users are interested in nanomaterials, but some users avoid our products because they contain 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: It depends on the content of information. If the information is only for containing nano, it will lead to their insecurity because they can't do anything.

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)	b) have no significant impact on innovation, Comments: We don't have specific reason for a) and c). Therefore we ticked b). However it is under condition that confidential business information is secured. In particular, information security for uses in case manufacturer that doesn't intentionally take patent property should be clarified.
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 , d) have no significant impact on the competitiveness of European companies against extra-EU companies , Please explain We think this is too small thing to stimulate intra-EU competitiveness as well as hamper the competitiveness of European companies against extra-EU companies.

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	4
b) with respect to nanomaterials in mixtures	4
c) with respect to articles with intended release of the nanomaterials	4
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:	Your recital explanation is asked for national level, but question in No.1 is asked for EU level. It seems contradiction or mistake, but If national registry is separately required, it will arise administrative burden with increasing non-effective cost. In addition, there is generally some difficulty in answering this question regarding intended release. In case of articles, a nanonmaterial is "fixated" or bound in the product via e.g. binding materials and even if there is a peeling or abrasion effect and flakes might occur it is difficult to think that such flakes or peeled off parts or also powder have the size of nanomaterial. Rather such parts are most likely of a larger size than nanomaterial scale. However, this cannot be guaranteed fully and that is why for instance a R&D on incorporating nanomaterials in tires was stopped, because uncertainty for flying apart particles existed. It means definition of intended release and test method should be defined clearly. We think that articles containing nanomaterials without intended release should not be in scope for notification obligations because there is too hard to identify articles without an intended release and it seems it is too difficult to make the definition.

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): It depends on level of information requirement. In particular, information security for uses in case manufacturer that doesn't intentionally take patent property is at least needed to be clarified.

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? Generally speaking, if national registry is separately required, it will arise administrative burden with increasing non-effective cost. If we answer whether it is significant or not in specifically France/Belgium/Denmark, it must be significant if information requirement is different among the Member States.
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"?

It depends on objective EU would like to achieve. If EU would like to get information immediately anyway in order to make how EU should prioritize next action, we recommend the Danish system as best practice because the information to be submitted is minimum.

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.

Risk is different by each uses including exposure scenario and notification per substance sometimes doesn't reflect its risk and hazard in uses.

On the another hand, If based on use, it should be considered how to make the downstream companies understand this principle and how to avoid duplication of notification for same substance in long supply chains. It will maybe take long time to reach a 100% notification.

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) , Please explain: It should be considered how to avoid duplication of notification for same substance in long supply chains for in particular downstream users.
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 , Please explain: Refer to answer of section VII, 1.

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.) If there is available knowledge for absence of hazards, it may be exempted. However it leads to necessity of development for definition of available knowledge for absence of hazards. Considering current knowledge, it seems that it is not realistic option.
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.) Refer to answer above.

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 , d) Information concerning products containing nanomaterials , e) Information on the hazards and risks of nanomaterials

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

We don’t have detailed good idea, but a party consisting of Industry, university, NGO and government might be helpful to ask how to collect which kind of information.

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):	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 , f) General education of the public

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):

Risk is different by each uses including exposure scenario and notification per substance sometimes doesn't reflect its risk and hazard in uses. What it is the most important thing as final objective is to inform citizen appropriate information to be able to handle nanomaterials in safety way.

It is unrealistic to provide such information for all products by uses, but it may be possible to create some classification in practical and workable way.

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

There is no standardized analytical measurement methods/conditions and no obligation for nanomaterial less than 1 ton in current framework of chemicals legislation.
It depends on registry requirement at European level and it might be able to be covered by REACH amendment or implementation of guidance, but if a European nanomaterial registry clarify this points together with nanomaterial definition, more correct and useful information will be gathered.
Otherwise, insufficient or mis-understandable information will be mixed and it will lead to both unnecessary insecurity and non-beneficial cost for industries.
From different angle, it might be linked to leading position for EU regarding nanotechnology.

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

We hope that a global and good functioning Registry can be established and the market will develop positively.