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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*:	European Semiconductor Industry Association (part of EECA)
Town/City:	Brussels
Country*:	Belgium
E-mail address:	
Transparency Register ID number (if applicable)	22092908193-23 EECA
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):	f) is a manufacturer of articles containing nanomaterials without intended release
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):	C26.1.1 - Manufacture of electronic components
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

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.

Articles	less than 6

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.

Articles	less than 6

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.

Articles	less than 6

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	6 to 15

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	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.	5
g) Protect confidential business information	5
Please provide additional comments	The objective listed under part a) is important but is there evidence supporting the proposal that a register would acheive the objective? In terms of b), d) and e) again it is important that consumers have relevant information however a nano observatory rather than a nano registry would be a more efficient way of informing the public where the relative safety of a product can be put into context.

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	4
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	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	4
Please provide additonal comments	Response scores to this question are relating only to the semiconductor sector. We are not in a position to provide input on other sectors. For part (a) it has been recognized that there are some shortcoming with REACH in terms of addressing nanomaterial specific requirements but these are currently being addressed. With regard to part (b) very few obligations are in place requiring consumers to be informed about nanomaterials. However 'relevant information' would be if there was a risk of exposure which is not the case for this sector as nanomaterials are entirely embedded and fixed in a matrix.

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	2
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	3
c) The current level of available information on the presence of nanomaterials and products containing nanomaterials on the market is detrimental to consumer trust	3
d) The available information on the presence of nanomaterials and products containing nanomaterials on the market is presented in an incoherent or	3

on the market is presented in an incoherent or ineffective way	
e) The establishment of national registries and notification schemes causes market fragmentation and hampers trade within the internal market	4
Please provide additional comments	We can only speak for our own sector, not the market as a whole (a) ESIA supports openness and transparency with the consumer. However since ESIA products on the market pose no health or environmental risk as a result of the use of nanomaterials (nanomaterials are entirely enclosed and bound in a matrix, analogous to pebbles in concrete) there is no evidence to suggest that there is insufficient information available. In terms of information that pertains to components or materials in the supply chain the quality of the information relating to nanomaterial content has not been fully verified. If a nanomaterial was identified as hazardous and categorised as an SVHC under REACH however, such information would be available as per the REACH article 33 obligation. (b) Product Safety Directive and CLP regulations already in place should protect consumers' safety. We are not aware of evidence that consumers feel they are lacking information. If consumers would like more information about nanomaterial content of products a 'Nano Observatory' would achieve this while also putting the information in context thereby maintaining consumer confidence. (c) Since there is no health or environmental risk posed from products produced by the sector the lack of information on nanomaterials should not be detrimental to consumer trust. We are not aware of any research that suggests that the level of information available is detrimental to consumer trust. Any additional legal measures put in place such as a register or observatory should be focused on educating consumers and building consumer trust. (d) This comment is addressed towards the wider NM market. Publicly available information and public education regarding the presence of Nanomaterials or products containing Nanomaterials could be improved. We would question however whether a public register would be the most effective means to improve knowledge. A 'nanomaterials observatory' where information is interpreted and put into context would be a better solution. This would provide the opportunity to portray the full story of nanotechnology including societal benefits. (e) In general different schemes giving rise to additional administrative burden can hamper trade. No products from our sector are currently within the scope of the national registers and so there is no first hand knowledge in this case. Inconsistent notification or labeling schemes do have trade implications and

	schemes do have trade implications and any measures to bring into effect registration or labeling schemes should be across the EU market.

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 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 are aware that NIOSH and other regulatory bodies have proposed OELs for specific nanomaterials.
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
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: We support transparency and openness but are not aware of direct result of improved health and safety that would arise from a registry. Rather than leaving the control of health and environmental hazards to a register to allow consumer choice a more protective approach already exists under other more effective legal frameworks such as REACH. Where there are improvements to be made to REACH pertaining to nanomaterials, those improvements are already underway.

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)**	Please explain: We don't believe that there are any health or environmental risks associated with semiconductor sector products containing nanomaterials. We have not undertaken any research in the area of client perception but the concern is that consumer confidence might be damaged by a perception that products listed on a register are automatically hazardous. An alternate means of communicating to consumers such as the proposed 'Nano Observatory' would be a better option.
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: We have not undertaken any research in this area but the concern is that consumer confidence might be damaged by a perception that products listed on a register are automatically hazardous.

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: If confidential business information is not properly protected there could be an impact on innovation.
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 Regulatory compliance with a registry leads to additional administrative costs that would not be applicable outside the EU.

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):

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:	The Semiconductor industry produces some articles that contain, in small amounts, namomaterials that would not foreseeably be released under normal conditions of use as they are fixed and embedded in a matrix. There would be a certain impact associated with administrative compliance but the main concern would be that confidential business information could be compromised.

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):
The exact type and use of the nanomaterial(s) is confidential business information and intellectual property.

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?

No, we do not expect any barriers,

If yes, please describe these barriers?
We do not expect barriers because the sector's products are currently exempt based on the conditions for reporting. However if the sector were in scope and a registration scheme had to be in place we would be in favour of one overarching EU scheme rather than member state level reporting to reduce administrative burden.

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"?

- Include a 'de minimus' level below which reporting would not be required, measured at the product level
- Exclude products containing nanomaterials where there is no foreseeable exposure to consumers exists
- consistent interpretation and implementation within member states
- Web-based declaration are the most effective
- CBI should be diligently considered and managed in order the not to hamper innovation and competition

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.

Disclosing the use or the substance may compromise IP in some sectors.

Q29: Which actors along the supply chain should be subject to notification requirements? (tick all that apply):	Please explain: No response
Q30: The following should be subject to notification requirements (tick all that apply):	Please explain: No response
Q31: Is there a need to exempt certain types of nanomaterials?	If yes, which types should be exempted and why? (in terms of specific properties, available knowledge, absence of hazards, etc.) No response
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.) No response

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 , c) Information on the use of nanomaterials across Europe , 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?

Information in a Nanomaterials Observatory should be presented as a searchable webpage where information pertaining to nanomaterials and products containing nanomaterials would be accessible to consumers, workers and authorities.

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):

b) Enforcement of worker protection,

c) Promotion of safe use of nanomaterials in products

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

,

e) Informed purchasing decisions by consumers,

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):

Consumers are capable of making intelligent choices, however no unsafe nanomaterials or products containing nanomaterials should be put on the market and other existing legislation such as REACH and product safety directive is designed to achieve that. Where there are gaps they should be (and are being) addressed within the framework of that legislation Therefore the register would only contain information on products and materials where either risk was adequately controlled or there was no hazard in the first place. The consumer should be protected no matter which consumer choice they make and the register would not contribute to that end. A Nano Observatory would address an additional information consumers might be interested in learning.

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

The added value of a register is not clear. Additional information for consumers in general on nanomaterials, on specific types of nanomaterials and any related health concerns as well as technological advances and innovation using nanomaterials would be of interest to consumers but a system such as the proposed Nanomaterial Observatory would be a better way of conveying such information in context.

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

Respondent skipped this question