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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*:	APEQ – Associação Portuguesa das Empresas Químicas
Town/City:	Lisboa
Country*:	Portugal
Contact name:	Luís Araújo
E-mail address:	
Transparency Register ID number (if applicable)	016963613959-23
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):	c) is a manufacturer of 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):	20xy
Secondary business sector (NACE 4 digit code):	21xy
Q7: Please indicate the number of employees.	*Respondent skipped this question*
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).	*Respondent skipped this question*

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	5
e) Ensure the availability of relevant information on the presence of nanomaterials or products containing nanomaterials on the market	2
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	Nanomaterials (NMs) should be regarded as any other substance. In that context, as required by REACH for instance, data should be gathered by industry in order to perform risk assessments and ensure safe use of the products that are placed on the market. By this way, with relevant explanation on the process provided to the public, consumer trust could be increased. Specific legislation covering sensitive products containing nanomaterials, like cosmetics or biocides, already require information for consumers and health authorities. Also via the IUCLID database, consumers have access to nanomaterials registered under REACH and their potential application. An inventory is not the right tool for consumer communication. On the contrary, providing to consumers information on products containing NMs that are placed on the market could lead to a stigmatisation of NMs, with a negative effect on consumer trust, even if safe use is demonstrated by the implementation of the relevant regulations (REACH and/or sector-specific legislation). However, it is important to communicate to downstream users, particularly when safety is a concern.

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)	2
d) Ensure consumer trust in products containing nanomaterials	2
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	4
Please provide additonal comments	We believe that, as for any other chemical, consumer trust can be increased by a good implementation of the current European legislative framework (even if some adaptations in the REACH annexes are needed), provided that it is well explained to the public. Additional requirements would constitute an administrative burden for companies with no guaranty of a potential positive impact on consumer trust. Negative consequences on the competitiveness and the innovation capacity of the chemical industry can nevertheless be expected, as shown by the current cosmetics legislation requirements. However, current regulatory requirements like REACH could be specified to cover nanomaterials in more details.

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	1
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	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	3
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 adequate response to health and environment risks is not linked to the information on the presence of NMs in products but to an effective and reliable risk assessment carried out for the whole life-cycle of the substance (as foreseen by REACH and product-specific regulations). As regards question e), on the basis of the experience gained by the chemical industry in France with the French notification scheme, such a national system creates obstacles to trade within the internal market. The additional burden of other national schemes in Belgium and Denmark is worsening the situation. Definition is not applied the same way in these countries and metrology skills do not guarantee harmonised interpretation.

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): DNELS and reference values are existing for TiO2 and carbon nanotubes (under REACH and NIOSH). Where consumer exposure occurs with sunscreens or biocides, the products are subject to an official risk assessment and authorization.
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 , Please explain (if any, please report the events and any scientific publication): No unexpected incidents are reported. Health and environmental incidents only happen with substances for which the hazardous potential is already known for the non-nano form (e.g. nickel).
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 believe that risks can be controlled by the implementation of the current European regulatory framework (REACH, CLP and sectoral legislation), even if we acknowledge that amendments of REACH Annexes may be needed. Indeed, this framework foresees hazards identification requirements, risk assessment methodologies and ensures safe use of NMs that are placed on the market (as such, in mixtures and in articles). Moreover, for hazardous NMs, traceability can be ensured via the Safety Data Sheet as regards industrial and professional users. Hence, we do not see the added value of an EU registry as regards risks control.

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)	b) They would try to avoid those products, d) They would search for more information, Please explain: The implementation of the French notification scheme for NMs showed that situations b) occurred within the supply chain. Clients wanted to avoid products containing NMs either due to the administrative burden of the notification system or due to the “black-list” effect led by the stigmatisation of NMs with such a scheme. Nano-free products are already requested. However depending on cultural basis or businesses (higher in the value chain), some would not be affected.
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: Depending on consumer knowledge, nanomaterials can be interpreted as a threat or a benefit. Generally outside professional users, there is poor knowledge about nanomaterials in products and the benefit they bring. This could lead to a priori negative feeling in the general public. However dialogue with end users have shown that there is no big interest in nanotechnology at this level. Appropriate and timely communication is needed to overcome a priori feelings in public eyes.

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)

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 There is no reason a priori to consider that a register is need for nanomaterials: they are not more or less hazardous than any other chemical. Asking for a register would create a burden on that specific industry producing, importing or using nanomaterials when competing with other non nano substances. In addition the cost of such register would most probably be borne by consumers so entailing increased prices for value chains in EU vs non-EU markets. The effect would be even stronger when industry would have to deal with several national registers. Intra-EU competitiveness would be hampered in this case.

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	5
b) with respect to nanomaterials in mixtures	5
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)	4
Please explain:	As chemical industry, an EU notification would mainly impact substances and mixtures. However nanomaterials are sometimes already embedded in a matrix at production level and so in this case could be considered as part of articles. This information will have to be provided to article producers and the burden would also be on the suppliers.

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): Indeed, several confidential information could be disclosed with such a notification scheme: - The name of the substance itself as sometimes competitors don't know that a substance can exist at nanoscale - The information linked to the substance identity (characterisation of the NM) - The uses - The quantities put on the market - The name of the customers For some data disclosure will not affect confidentiality.
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? Diverging notification obligations increase the workload for companies not only for filling the notification but also to ensure adequate compliance in schemes that diverge from each other.
Q26: Is the market for your nanomaterials/products containing nanomaterials significantly different from Member State to Member State?	*Respondent skipped this question*

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"?

- Use of the same nanomaterial definition.
- Transmission of the notification numbers along the supply chain in order to minimize the burden for companies and protect confidential information.
- Consider as much as possible information as Confidential Business Information in order not to hamper more competitiveness and innovation.

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.

For workers and downstream users, the best information should be found in safety data sheets and is then related to a substance/mixture notification.
However, we consider that substance notification (as practice under REACH and CLP) is a good start for a NM Observatory.
Use notifications are already existing in the food area, for cosmetics and biocides. This encompasses already enough consumer sectors.

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: Manufacturers and importers through REACH and downstream users through existing sector-specific requirements.
Q30: **The following should be subject to notification requirements (tick all that apply):**	Please explain: See above questions n° 1 and 2. The scope of the scheme can only be defined when its goals are clearly established. Anyway, asking for information on all articles (even articles with no intended release) can lead to an overarching vague of notifications that could hide any potential added value that could be brought by such a system.
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.) By all means substances, mixtures and articles already notified under existing schemes (REACH, CLP, biocides, cosmetics) should be exempted. However, exemptions could create confusion and mistrust among consumers.
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.) At least, uses covered by sectoral legislation (Biocides, Cosmetics,…) should be exempted. Uses leading to no exposure to human health and the environment should be exempted as well. This covers nanomaterials embedded in matrices and not available as such during the whole life cycle.

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?

The REACH database and the work engaged by ECHA on Brief Profiles could be a good start.
For consumers, market studies would be of greater values. For workers and authorities, more detailed information from ECHA dissemination would be useful.
In a consumer friendly way, the German website: www.nanopartikel.info/ could be used as example.

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):	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):

We consider that the administrative burden, the risk of releasing confidential information and the negative expected impact on economy outweigh the potential positive impact of the scheme. Indeed, no benefit from the French scheme has been identified so far, at least from a consumer perspective.

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

No added value identified so far. It seems nice to have in case of a potential problem would occur. However this can be said for any substances or products put on the market. Nanomaterials are not more dangerous per se as any other chemicals.

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