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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*:	Committee of PET Manufacturers in Europe (CPME)
Town/City:	Brussels
Country*:	Belgium
Contact name:	Mike Neal
E-mail address:	
Transparency Register ID number (if applicable)	73204818098-04

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
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Q3: We might need to contact you to clarify some of your answers. Please state your preference below:	I am available to be contacted
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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
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PAGE 3: Section II - Organisation Information

Q5: Please indicate which of the following applies to you or your members (tick all that apply):	j) None of the above
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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):	2106
Secondary business sector (NACE 4 digit code):	4062

Q7: Please indicate the number of employees.	≥ 250 employees
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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	≤ €250k
Nano-related annual turnover	≤ €250k

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.

Mixtures 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.

Mixtures 11 to 50

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.

Mixtures 11 to 50

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 5

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 5

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
 There is no statement on proportionality of risk vs other risks, or on consideration of socioeconomic benefit or the fact that we are exposed to naturally generated (potentially hazardous or not) nano particles in every breath we take.

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	1
c) Maintain competitiveness and innovation of businesses bringing nanomaterials or products containing nanomaterials to the market (including SMEs)	4
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	2
f) Ensure the proportionality of the information requirements and the associated costs and administrative burden.	2
g) Protect confidential business information	4
Please provide additional comments	<p>On the question of consumer information. It would be expected that nanos would be properly controlled and therefore consumer information (vs industrial use) would need to be slight. It is important not to scaremonger. If there is a genuine risk then OK but if no risk then be careful about what is said. Note the damage that poor science and NGOs with an agenda can cause to society as a whole. These questions completely ignore the sharing of information on nano materials between raw material producers and their customers. This is the most important communication of all. Material Safety Data Sheets could be used to provide information on OELs and toxicity of any nanos in the product.</p>

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 | 1 |
| 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

c) in some respects there is a lot of NGO-driven scare mongering which in the true sense of the word is “in-formation” however the “information” is questionable and this should be addressed and refuted by regulators if untrue. e) In a diverse world then yes, multiple schemes are acceptable but in the EU we work on consensus and therefore it is not appropriate that individual countries take unilateral action – this is usually driven by internal, self interest groups and politics rather than scientific debate

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

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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):

This question is very woolly!! What is significant? Industrial hygiene practices prevent exposure beyond OELs – see Workshop report: Strategies for setting occupational exposure limits for engineered nanomaterials Steven C. Gordon a, † , John H. Butala b, Janet M. Carter c, Alison Elder d, Terry Gordon e, George Gray f, Philip G. Sayre g, Paul A. Schulte h, Candace S. Tsai i, Jay West Regulatory Toxicology and Pharmacology 68 (2014) 305–311. Consumer exposure to nanos? Are they significant? Remember that there are naturally occurring nanos eg dust, pollen etc

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

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If appropriate, please explain further:
If nanos are to be regulated then this should be by a specific regulation not a register. A register is open to abuse by political motivation and ignorance

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)

a) They would be more inclined to purchase those products

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b) They would try to avoid those products,

c) Their purchasing decisions would not be affected

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d) They would search for more information,

Please explain:

The question is wrong. It all depends on the consumer information supplied, ie for our products PET bottles. To tell a consumer they contain nanomaterials in an environment where nanomaterials are scary is very dangerous. To tell a consumer that our product contains nanomaterials when nanos are not scary would have no effect on purchasing decisions. In fact in PET bottles there are small amounts of nano materials and they are fully encapsulated and not available for human contact. PET is fully recyclable so very little if any will escape to the environment. Should it ever escape the nano will chemically bond to another material in the environment, and no harm would be expected.

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

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Comments:

As with most science, consumers do not understand the detail. Consider the confusion in food labelling of contents. Consider the confusion on package weight/volume price per unit (€/g, €/dm, €/cc). Would a consumer even know what a nano is? It is better to find a simple way of saying their product has been rigorously tested and is safe rather than to go into detail

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:

Consider the mess the current CLP register is in. It is too complex and is open to almost any form of interpretation. Why waste money on a register at all? If we have some form of legislation, nanos will be included in that legislation - not in a register which has too many opportunities for errors and omissions. Consider Intellectual Property (IP), a patent owner will either wish to sell his invention or may wish to retain exclusivity for commercial reasons, advertising the product in a register will have no effect on the intended use by the IP owner. Consumers do not need to know if a nano is present or not, they only need to know their product is safe.

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)

Please explain

None of the above Stop pre-supposing we will have a register!!!!!! The market will determine intra EU competitiveness; a register will have no effect on extra EU trade or competitiveness.

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
- 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:

A register is not necessary for any part of the EU. Or for EU manufactured products

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): Again this presupposes a registration scheme. This is not necessary. We have sufficient chemicals legislation in the EU to cope with nanos.

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?
Please see comments re individual country registers. They are not appropriate for the EU and should be stopped forthwith. Neither do the current notification processes cover all nanos

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”?

There are NO best practices for any individual country. There should be no register at any level either national or EU wide

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.

There is no added value for those forced to use a register as described in this proposal. Legislation already in force in the EU can cover all nano materials current today.

The principle of a register and forcing part of the community to complete the register is simply a derogation of duty on the part of the regulators. All forms of regulation are difficult, both for those who regulate, and those who are regulated. There should be an equal share of effort supplied by both sides

Q29: Which actors along the supply chain should be subject to notification requirements? (tick all that apply):

Please explain: None of the above

Q30: The following should be subject to notification requirements (tick all that apply):

Please explain: None of the above

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.)
There should be no need for exemption if there is no requirement to register

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.)
There should be no notification system

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)

Respondent skipped this question

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

There is no use for an "observatory" which is only a register by another name

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):

Respondent skipped this question

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):

Current industrial practices, reinforced by current legislation and current scientific understanding of nanos provide sufficient information to allow informed purchasing.
As scientific information on Health, Safety and Environmental issues is developed, this is made available to raw material purchasers to ensure the products they produce provide the reassurances required for the market.

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

There will be no added value for any enforced contributing party

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

Section II of this Questionnaire - Some manufacturing processes create nanos "in situ". These nanos are bound within the matrix of the final product. Also on occasion nanos are added in some raw material manufacturing processes. In every case the nanos are fully encapsulated and not available for release. This will be the case for many raw materials and articles and this concept does not appear to be covered in this survey - ie "raw materials (containing encapsulated nanos) producers" – which is CPME's sector of the industry.

THIS ALSO APPLIES TO OUR RESPONSE TO THE REMAINDER OF SECTION II

There is a huge amount of hype driving proposals for registers.
It would be better to evaluate current legislation and if needed revise the legislation to include nanos but only if this were really necessary and fully supported by scientific evidence (not political decisions). CPME would propose that the costs associated with setting up a register would be better spent on EU/government funded research on the short and long term effect of nanos of different sizes and different chemicals. For example does toxicity change with particle size, other chemistries certainly do? We know that the rules of physics don't apply at very, very small (quantum size) so do the rules of chemistry change at very small (nano size)? This questionnaire completely ignores the sharing of information on nano materials between raw material producers and their customers. This is the most important communication of all. Existing legislation/regulations could be revised and Material Safety Data Sheets (MSDS) used to provide information on OELs and toxicity of any nanos in the product.
Industry has many unnecessary burdens placed on it by poor legislation. This is a really good opportunity to demonstrate that better regulation rather than any legislation is the driver. Registers will not provide better regulation