#1

COMPLETE

Collector: Nano Consult - Industry (Web Link)
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PAGE 2: Section I - Identification

Q1: Please provide the following details (*compulsory):	
Organisation*:	Elkem AS
Town/City:	Kristiansand
Country*:	Norway
Contact name:	Dr. Bernd Friede
E-mail address:	
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 , c) is a manufacturer of nanomaterials, e) is a formulator of mixtures containing nanomaterials , 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):	C2410
Secondary business sector (NACE 4 digit code):	C2361
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.

Nanomaterials	less than 6
Mixtures	less than 6
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.

Nanomaterials	less than 6
Mixtures	6 to 10
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.

Nanomaterials	6 to 10
Mixtures	6 to 10
Articles	6 to 10

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	less than 6

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	4
f) Ensure the proportionality of the information requirements and the associated costs and administrative burden.	5
g) Protect confidential business information	5

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	3
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.	Do not know
g) Protect confidential business information	4

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	4
c) The current level of available information on the presence of nanomaterials and products containing nanomaterials on the market is detrimental to consumer trust	4
d) The available information on the presence of nanomaterials and products containing nanomaterials on the market is presented in an incoherent or ineffective way	4
e) The establishment of national registries and notification schemes causes market fragmentation and hampers trade within the internal market	4
Please provide additional comments	Each national nano inventory has specific requirements that are not harmonised and cause administrative burden to globally active companies that need to comply with more and more unharmonised pieces of chemicals legislation. France: limited to intentionally manufactured NM, Denmark: limited to consumer products, Norway: limited to hazard-classified NM

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 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
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: A register as such does not reduce any risks. The specific chemical safety assessment of NM however would. I would prefer a European nano inventory instead of 27 national EU member inventories that all would have different requirements.

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: Due to the uncertainty related to HSE effects of engineered NM, the public is confused, and NM containing products have a rather negative perception. There are however a number of high volume NM that are well characterised and assessed and that have been used for decades without negative impact: amorphous silica, titania, carbon black. Unless it is shown that a NM containing product has specific nano-related HSE issues, any labeling would be an unfair stigmatisation. It is important to convey the message that nano does not mean hazardous!
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: see above

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: NM research and product development is science based and carried out based on scientifc literature not a nano register.
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)	f) hamper the competitiveness of European companies against extra-EU companies , Please explain a nano register is like an open book for companies that want to copy NM technology from European manufacturers

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	1
b) with respect to nanomaterials in mixtures	1
c) with respect to articles with intended release of the nanomaterials	1
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)	1
Please explain:	luckily, Elkem is dealing with safe nano materials, and we have the proper documentation in place showing that the material is not hazardous. The product has been globally used for over 30 years, and the customer's trust in the material is correspondingly high.

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):
This will depend on the information to be disclosed in the nano register. It could be an open book for competitors that is easy to copy information and circumvent years of R&D.

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?
So far, the obligation to register NM in national inventories does not have any legal implication. It is simply annoying to annually report information to a variety of registers with diverging information requirements.

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"?

A European nano inventory should actually replace any national NM register and not come in addition! In any case, I do not support a NM register in the first place because it is stigmatising, adds administrative burden for both suppliers and customers, and does not add any value. I don't see the point to disclose the tonnage of a non-hazardous, safe-to-use product that now is suddently identified as a NM after the EC recommendation for NM has been launched.

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.

This implies that a NM has hazardous properties. The essential question is whether a NM or a NM containing product is safe for the consumer and the environment or not. Why not classifying into "safe NM" and "NM of concern"?

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) , d) Distributors to professional users (e.g. wholesalers) , e) Distributors to consumers (e.g. retailers), Please explain: for reasons of transparency and fairness, the notification obligations should not only be placed on the importer/manufacturer but also on all downstream actors.
Q30: The following should be subject to notification requirements (tick all that apply):	a) Substances, Please explain: I would expext that the tonnage will be part of the information requirements for a NM notification. If substances, mixtures, and articles will be required to be notified, then they tonnage would be counted 2x or 3x giving a completely wrong picture.
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.) as long as the NM is not hazardous, I don't see a point in notifying it to any register. No added value.
Q32: Is there a need to exempt certain uses of nanomaterials?	No, all uses of nanomaterials should be subject to notification obligations

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,

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?

it seems that only hazard and risk are of interest. Phys-chem properties are CBI anyway.

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

,

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):

Since NM generally seem to represent a potential hazard, the hazard profile of the NM should be included in the register. If applicable, the safe use of NM.
But what happens if different manufacturers of the same NM provide different hazard profiles of their NM? Even the C&L inventory is far away from a harmonisation, and anybody can submit whatever he wants without any proof. This should not be possible and should be avoided for a potential nano register.

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

I only see an added value if a European nano inventory replaces all upcoming national nano inventories. The hazard profile should be communicated in a harmonised way to avoid overall confusion.

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

I agree that the hazard properties of nano forms must be assessed in the same way as REACH has foreseen for bulk substances. But since nano does not necessarily mean hazardous, it is stigmatising to put all NM in one big bag instead of assessing them on a case-by-case basis.