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

Q1: Please provide the following details (*compulsory):	
Organisation*:	Federation of European Specialty Food Ingredients Indus-tries (ELC)
Town/City:	Brussels
Country*:	Belgium
Contact name:	Maryse HERVE
E-mail address:	
Transparency Register ID number (if applicable)	6160532422-38
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
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):	Non applicable
Secondary business sector (NACE 4 digit code):	Non applicable
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.	*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	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	The objectives per se are commendable of course and it is hardly possible not to rate them at the top of the scale. It would have been probably more meaningful if the objectives and questions would have been related to the relevance of such information where absence of safety issues is guaranteed by the existing regulatory framework.

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	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)	1
d) Ensure consumer trust in products containing nanomaterials	1
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.	1

g) Protect confidential business information	5
Please provide additonal comments	The responses provided here relate to the current legislative framework applying to specialty food ingredients: as all food ingredients, their safety is generally assessed according to Regulation (EC) 178/2002 (General Food Law), and most of them are submitted to a specific pre-market authorisation, e.g. food additives (Regulation (EC) 1333/2008). In addition, they are subject to nano-labelling obligations in the list of food ingredients of pre-packed foods as from 13 December 2014 (Regulation (EU) 1169/2011). Hence decision makers, regulatory authorities and professional users as well as consumers are already duly informed on the presence of nanomaterials or foods containing nanomaterials on the market, and their safey is assessed prior to their entry into the market. However as a consequence of the upcoming nano-labelling rules in food , a first reformulation of foodstuffs by our customers of the food industry is now observed with the aim to replace certain long and well-established food ingredients before the new labelling rules apply. Hence our concerns that the nano-labelling would be perceived as a warning labelling regrettably turn out to be true, and this occurs at the expenses of safe, technologically performant and non-novel ingredients, and of the European ingredients industries. This is of course seriously compromising the future of nanotechnologies in the food ingredients sector in Europe.

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	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	5
d) The available information on the presence of nanomaterials and products containing nanomaterials on the market is presented in an incoherent or ineffective way	5
e) The establishment of national registries and notification schemes causes market fragmentation and hampers trade within the internal market	5
Please provide additional comments	a & b) Here again the responses relate to specialty food ingredients only, for which adequate information is available through the food safety regulatory framework and the new food labelling obligations. c & d) However as mentioned in our response to Q2, the level of information on the presence of nanomaterials and products containing nanomaterials on the food market is detrimental to consumer trust, who perceives it as a warning labelling, despite of the proven absence of any food safety risk.in addition, the labelling rules apply indifferently to ingredients present on the market since decades and not only to novel nano-ingredients that exhibit specific novel properties, the new benefits of which would have been explained to the consumers. e) The establishment of national registries that do not exclude food and food ingredients from their scope (as is the case in France, unlike in Belgium & Denmark) creates significant and unnecessary administrative burden on manufacturers, distributors and importers of food/food ingredients, whilst specific nano-labelling rules (which are based on a different and more thorough definition for nanomaterial) are set in the European foodlegislation. The multiplication of definitions and related legal requirements result in confusion and market uncertainty for the operators.

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:**	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): The safety of food nanomaterials is assessed by EFSA according to the EFSA Scientific Opinion on Guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain. EFSA Journal 2011; 9(5):2140 [36 pp.]
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): This response relates to specialty food ingredients.
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: The safety of food nanomaterials is assessed by EFSA according to the EFSA Scientific Opinion on Guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain. EFSA Journal 2011; 9(5):2140 [36 pp.] The establishment of an EU nanomaterial registry that does not exclude food and food ingredients from its scope would create a significant and unnecessary administrative burden on EU manufacturers, distributors and importers of food/food ingredients.

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, Please explain: See response to Q2 in Section III As a consequence of the upcoming nano-labelling rules in food , a first reformulation of foodstuffs by our customers of the food industry is now observed with the aim to replace certain long and well-established food ingredients before the new labelling rules apply. Hence our concerns that the nano-labelling would be perceived as a warning labelling regrettably turn out to be true, and this occurs at the expenses of safe, technologically performant and non-novel ingredients, and of the European ingredients industries.

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 response to Q2 in Section III As a consequence of the upcoming nano-labelling rules in food , a first reformulation of foodstuffs by our customers of the food industry is now observed with the aim to replace certain long and well-established food ingredients before the new labelling rules apply. Hence our concerns that the nano-labelling would be perceived as a warning labelling regrettably turn out to be true, and this occurs at the expenses of safe, technologically performant and non-novel ingredients, and of the European ingredients industries.

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: See response to Q2 in Section III Because the nano-labelling in foods is perceived as a warning labelling despite their safety is assessed, this is of course seriously compromising the future of nanotechnologies in the food ingredients sector in Europe. Hence one could question the benefits of such “technology labelling” in addition to the regular labelling of the ingredient in pre-packed foods, when this ”technology labelling” is not related to a new novel property due to the nano-status of the ingredient, e.g. a new technological or nutritional property.
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 The establishment of an EU nanomaterial registry that does not exclude food and food ingredients from its scope would create an extra- significant and unnecessary administrative burden on EU manufacturers, dis-tributors and importers of food/food ingredients compared to non-EU competitors.

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
Please explain:	The establishment of an EU nanomaterial registry that does not exclude food and food ingredients from its scope would create a significant and unnecessary administrative burden on EU manufacturers, distributors and importers of food/food ingredients.
Q24: Would disclosure of the notified information conflict with the confidentiality of business information?	Yes, there would be a conflict with business information 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? The establishment of a national nanomaterial registry that does not exclude food and food ingredients from its scope, as is the case in France, creates a significant and unnecessary administrative burden on EU manufacturers, distributors and importers of food/food ingredients.
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"?

Those who exclude food and food ingredients from their scope, for the afore-mentioned reasons.

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.

None in the case of food and food ingredients.

Q29: Which actors along the supply chain should be subject to notification requirements? (tick all that apply):	Please explain: None in the case of food and food ingredients.
Q30: The following should be subject to notification requirements (tick all that apply):	Please explain: None in the case of food and food ingredients.

Q31: Is there a need to exempt certain types of nanomaterials?

Yes, certain types of nanomaterials should be exempted from a notification system

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If yes, which types should be exempted and why? (in terms of specific properties, available knowledge, absence of hazards, etc.)
Nanoparticles that are soluble and non-biopersistent under physiological conditions should be excluded: when solubilised, those nanomaterials lose their nano-characteristic properties and any potential hazard is no-longer size-dependent but only depends on the amount of the substance entering the body and the toxicity resulting from its chemical structure, as is clearly established by the EFSA (EFSA Scientific Opinion on Guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain. EFSA Journal 2011; 9(5):2140 [36 pp.])

Q32: Is there a need to exempt certain uses of nanomaterials?

Yes, certain uses of nanomaterials should be exempted from a notification system

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If yes, which uses should be exempted and why? (in terms of specific exposure scenarios, available knowledge, absence of hazards, etc.)
As previously explained, the safety of specialty food ingredients is generally assessed according to Regulation (EC) 178/2002 (General Food Law), and most of them are submitted to a specific pre-market authorisation, e.g. food additives (Regulation (EC) 1333/2008) during which their safety is assessed according to the EFSA Scientific Opinion on Guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain. In addition, they are subject to nano-labelling obligations in the list of food ingredients of pre-packed foods as from 13 December 2014 (Regulation (EU) 1169/2011). Hence decision makers, regulatory authorities and professional users as well as consumers are already duly informed on the presence of nanomaterials or foods containing nanomaterials on the market, and their safety is assessed prior to their entry into the market.

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?

For the aforementioned reasons a Nanomaterials Observatory would bring no added value in terms of safety or information for specialty food ingredients and foods. No such section should be consequently included in such an Observatory.

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):	*Respondent skipped this question*

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 in terms of safety or information for specialty food ingredients and foods.

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