#21

COMPLETE

Collector: Nano Consult - Industry (Web Link)
Started:
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Time Spent:
IP Address:

PAGE 2: Section I - Identification

Q1: Please provide the following details (*compulsory):	
Organisation*:	
Town/City:	
Country*:	Netherlands
Contact name:	
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 but should be kept anonymous
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?	Yes

PAGE 3: Section II - Organisation Information

Q5: Please indicate which of the following applies to you or your members (tick all that apply):	*Respondent skipped this question*
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	*Respondent skipped this question*
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	4
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	5
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.	5
g) Protect confidential business information	5
Please provide additional comments	We support that transparency and traceability are important factors in ensuring con-sumer's can trust the use of nanotechnology and nanomaterials in products. However, this must be done in a proportionate way that avoids duplication of work, a heavy ad-ministrative burden and ensures business confidential information is protected. The extensive and nano-specific provisions in the Cosmetics Regulation adequately cover for cosmetic substances and cosmetic products all of the objectives of a potential EU nanomaterial registry, including but not limited to consumer information, general public information, information to decision makers, regulatory authorities and professional users, as well as ensuring safe uses of nanomaterials. Furthermore, the Food Information to Consumers Regulation requires labeling of ingredients that are engirneered nanomaterials from December 29014 onwards ensuring transparency on nanomaterial use for Foods.

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	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.	1
g) Protect confidential business information	5
Please provide additonal comments	The extensive and nano-specific provisions adequately cover for cosmetic substances and cosmetic products all of the objectives of a potential EU nanomaterial registry, including but not limited to consumer information, general public information, information to decision makers, regulatory authorities and professional users, as well as ensuring safe uses of nanomaterials. In addition, the requirements for nanomaterials as laid down in legislation relating to the use of nanomaterials in foods and food contact materials (such as Novel Food, Food Contact material, Food information to Consumers and Food additives) ensure safe use, traceability and information to consumers. However, this aim is compromised by inconsistent and unclear technical definitions of nanomaterials and a lack of validated and EU-recommended analytical techniques to reliably characterise nanomaterial content, especially in complex product matrices. Experience has learned that the requirements as imposed by the French decree and the regulations relevant for foods and cosmetics has lead to a large administrative burden due to duplication of work and moreover non-alignment in definitions and approach. We have reported the resource required in the RPA Impact Assessment on this topic.

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	3
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 extensive and nano-specific provisions adequately cover for cosmetic substances and cosmetic products all of the objectives of a potential EU nanomaterial registry, including but not limited to consumer information, general public information, information to decision makers, regulatory authorities and professional users, as well as ensuring safe uses of nanomaterials. In addition, the requirements for nanomaterials as laid down in legislation relating to the use of nanomaterials in foods and food contact materials (such as Novel Food, Food Contact material, Food information to Consumers and Food additives) ensure safe use, traceability and information to consumers.

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 not aware of any classified nanomaterials, I am aware of DNELs/PNECs/OELs set for specific nanomaterials/types of nanomaterials , I am aware of 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): For the limited number of engineered nanomaterials that are currently used in our product portfolio, we have an adequate risk assessment framework in place that addresses human, environmental and occupational safety and is based on an extensive set of toxicological studies and a long history of safe use. This framework allows for a case-by-case approach and where required appropriate risk management is put in place.
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): Nanomaterial ingredients used in cosmetic products have a long history of safe use, with, as far as we know, no health &/or environmental incidents reported: - Carbon black: has been used safely for more than 1000 years in decorative products - nano TiO2, nano ZnO have been used safely in cosmetic products for about 30 years

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:
The extensive and nano-specific provisions adequately cover for cosmetic substances and cosmetic products all of the objectives of a potential EU nanomaterial registry, including but not limited to consumer information, general public information, information to decision makers, regulatory authorities and professional users, as well as ensuring safe uses of nanomaterials. In addition, the requirements for nanomaterials as laid down in legislation relating to the use of nanomaterials in foods and food contact materials (such as Novel Food, Food Contact material, Food information to Consumers and Food additives) ensure safe use, traceability and information to consumers.

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)

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 labelling of product containing nanomaterial is already in application for cosmetic products, with currently no reported impact on sales. However, it remains to be seen how this will work out for nano labelling of food products that will enter into force through the Food information to Consumer regulation. Depending on how the benefits and risks of nanomaterials cotninue to/will be communicated the public perception could go either way. At the same time it has to be acknowledged that even though there is limited consumer awareness on nanomaterials the perceptions on the materials can differ considerably per country.

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: The labelling of product containing nanomaterials is already in application for cosmetic products with no reported impact on sales. However, it remains to be seen how this will work out for nano labelling of food products that will enter into force through the Food information to Consumer regulation. Depending on how the benefits and risks of nanomaterials continue to/will be communicated the public perception could go either way.

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: Concerns about confidentiality of business information and about additional costs related to providing information: overall increased administrative burden, with no associated benefit to the industry/sector
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 Concerns about confidentiality of business information and about additional costs related to providing information: overall increased administrative burden, with no associated benefit to the industry/sector

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	3
b) with respect to nanomaterials in mixtures	5
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:	We expect an unnecessary, redundant administrative burden if ingredients that already fall within requirements for nanomaterials such Cosmetics Regulation and Food related regulations, are not exempted from an additional obligation to notify nanomaterials at the EU level

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): There would be a conflict with business information confidentiality: - If notification is not only per substance but also per general use, - If the exact use needs to be disclosed

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?
We already experienced this problem with French nanomaterial registry because of increased administrative burden, poor understanding/various interpretations by various companies, including supplier companies.

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"?

1. 1st recommendation is not to implement national-specific registers because of the absence of market differences between various EU countries (unnecessary redundancy of administrative burden)
2. In case best practice should be recommended, the Danish notification scheme could be considered as a model since because of exemption of cosmetic ingredients and products, food and food contact materials
3. If no exemption possible for these products, then only limited to substances in order to try to limit administrative burdens and registration should not be done on a yearly basis but only when new products enter the market place.

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.

NO ADDED VALUE for products in our products portfolio , because of specific regulatory provisions both for nanomaterials (substances) used in cosmetics, foods and food contact materials
For authorities: An extensive information/data package is provided on the product and the nanomaterial considered, consisting of but not limited to toxicity and physico-chemical pro-files of the nanomaterial considered, risk assessment and tonnage information. This infor-mation package as well as the timing of its delivery permits the EU Commission to decide whether the safety of the nanomaterial/cosmetic product considered should be evaluated by the SCCS, thus enabling adequate control of those nanomaterials that represent non-regulated cosmetic substances. New engineered nanomaterials to be used in Foods would be subject to pre-market evaluation by EFSA and authorisation for food use under the provi-sions of the current novel food regulation (Regulation (EC) 258/1997) or the provisions of a revised novel food regulation, such as described in European Commission proposal COM(2013) 894 final, if adopted.

For Downstream user companies and workers : no added value because of an already existing appropriate identification of nanomaterials (use of MSDS and supplier information in general)
For Consumers: “Labelling”: all ingredients present as nanomaterials shall be clearly indicated in the list of ingredients (on-pack Full Ingredient Labelling). For Cosmetics the International Nomenclature of Cosmetic Ingredients (INCI) name of (nano qualities of) such ingredients shall be followed by the word “nano”’ in brackets (e.g. Titanium Dioxide [Nano]”. A similar requirement exists for Foods. This ensures direct consumer information.

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,

Please explain:
Only Manufacturers and Importers have all of the appropriate information on nanomaterials; additionally, downstreams users are covered by sectorial regulations, with cosmetic and food - specific regulation already containing a nano-notification scheme.

Q30: The following should be subject to notification requirements (tick all that apply):	Please explain: No need to include cosmetic and food ingredients and cosmetic and food products in the scope of notification re-quirements because of the existing specific notification of cosmetic products containing nanomaterials under Cosmetic Regulation 1223/2009: In addition to the general notifica-tion of cosmetic products (Article 13) that indicates whether the product considered con-tains a nanomaterial, cosmetic products containing non-regulated nanomaterial ingredients must go through a specific notification (article 16) 6 months before placing on the market. An extensive information/data package is provided on the product and the nanomaterial considered, consisting of but not limited to toxicity and physico-chemical profiles of the nanomaterial considered, risk assessment and tonnage information. This information pack-age as well as the timing of its delivery permits the EU Commission to decide whether the safety of the nanomaterial/cosmetic product considered should be evaluated by the SCCS, thus enabling adequate control of those nanomaterials that represent non-regulated cosmetic substances. New engineered nanomaterials to be used in Foods would be subject to pre-market evalua-tion by EFSA and authorisation for food use under the provisions of the current novel food regulation (Regulation (EC) 258/1997) or the provisions of a revised novel food regulation, such as described in European Commission proposal COM(2013) 894 final, if adopted.
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.) The following type of nanomaterials should be exempted: - Those used as ingredients by the cosmetic and food industry (already covered by specific regulations - Naturally-occurring substances - Non-intentionally created nanomaterials - Substances with long history of safe use

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.)
The extensive and nano-specific provisions adequately cover for cosmetic substances and cosmetic products all of the objectives of a potential EU nanomaterial registry, including but not limited to consumer information, general public information, information to decision makers, regulatory authorities and professional users, as well as ensuring safe uses of nanomaterials. In addition, the requirements for nanomaterials as laid down in legislation relating to the use of nanomaterials in foods and food contact materials (such as Novel Food, Food Contact material, Food information to Consumers and Food additives) ensure safe use, traceability and information to consumers.

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,

f) Other (please explain):
a) For cosmetic products, information already available on the CPNP portal and regular publication of a catalogue of all nanomaterials used in cosmetic products placed on the market, indicating the categories of cosmetic products and the reasonably foreseeable exposure conditions. f) No national register because of administrative burdens, but rather a EU registry which already exists for cosmetic products

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

The nature and presentation of the information in the potential nanomaterials Observatory should be directly related to the purpose of this observatory i.e safety information for the authorities and/or consumer/general public information and/or information permitting to establish reports /catalogues of nanomaterial uses. For each of these purposes, the nature and level of information needs are totally different.
Of note is that for cosmetic products and ingredients these various purposes are met by the aforementioned specific provisions laid down in regulation EC 1223/2009.
Similarly for food products, these various purposes are met by the requirements of the Novel food regulation, Regulation (EC) 258/1997.

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):

g) Other purposes (please specify)
The information from a potential additional nanomaterial registry would be of no added value for both cosmetic products and cosmetic ingredients because of the specific regulatory provisions both for nanomaterials (substances) used as cosmetic ingredients and for cosmetic products that contain these nanomaterials contained in Cosmetics regulation EC 1223/2009.

These specific provisions consist of: 1. “Labelling”: all ingredients present as nanomaterials shall be clearly indicated in the list of ingredients (on-pack Full Ingredient Labelling): the International Nomenclature of Cosmetic Ingredients (INCI) name of (nano qualities of) such ingredients shall be followed by the word “nano”’ in brackets (e.g. Titanium Dioxide [Nano]”. This ensures direct consumer information. 2. Specific risk assessment of nanomaterials used in cosmetic products a. Regulated substances listed in positive lists do not cover nanomaterials (except where specifically mentioned), which ensures review by the EU Scientific Committee on Consumer Safety (SCCS) of nanomaterial-specific safety dossiers b. For non-regulated substances, the risk assessment must take account of particle size, including nanomaterials 3. Specific notification of cosmetic products containing nanomaterials. In addition to the general notification of cosmetic products (Article 13) that indicates whether the product considered contains a nanomaterial, cosmetic products containing non-regulated nanomaterial ingredients must go through a specific notification (article 16) 6 months before placing on the market. An extensive information/data package is provided on the product and the nanomaterial considered, consisting of but not limited to toxicity and physico-chemical profiles of the nanomaterial considered, risk assessment and tonnage information. This information package as well as the timing of its delivery permits the EU Commission to decide whether the safety of the nanomateri-al/cosmetic product considered should be evaluated by the SCCS, thus enabling adequate control of those nanomaterials that represent non-regulated cosmetic substances. 4. Regular publication of a catalogue of all nanomaterials used in cosmetic products placed on the market, indicating the categories of cosmetic products and the reasonably foreseeable exposure conditions. The extensive and nano-specific provisions adequately cover for cosmetic substances and cosmetic products all of the objectives of a potential EU nanomaterial registry, including but not limited to consumer information, general public information, information to decision makers, regulatory authorities and professional users, as well as ensuring safe uses of nanomaterials. In addition, the requirements for nanomaterials as laid down in legislation relating to the use of nanomaterials in foods and food contact materials (such as Novel Food, Food Contact material, Food information to Consumers and Food additives) ensure safe use, traceability and information to consumers.

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):

See above

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

See above

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

Respondent skipped this question