#72

COMPLETE

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

PAGE 2: Section I - Identification

Q1: Please provide the following details (*compulsory):	
Organisation*:	Cosmetic, Toiletry and Perfumery Association
Town/City:	London
Country*:	UK
Contact name:	Amanda Isom
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 , b) has to notify to the Cosmetic Products Notification Portal , d) is an importer of nanomaterials, e) is a formulator of mixtures containing nanomaterials , h) is a distributor of nanomaterials and/or mixtures containing 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):	2042

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	1
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)	5
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	1
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	Please note: The answers provided here are

	in the context of the development of a new registry covering all sectors as an additional requirement to those contained within the European Cosmetics Regulation (EC) 1223/2009 which covers human safety. Whilst we support the objectives listed above, any measures should not create a heavy administrative burden with duplication of work and should maintain the protection of confidential information. In respect of cosmetic products, many of the objectives listed above are already provided for by the Cosmetics Regulation, namely: 1. Transparency of the presence of nanomaterials in products via on-pack labelling. Cosmetic products are labelled with a full list of ingredients and additionally must indicate the presence of nanomaterials with the inclusion on "nano" in brackets after the relevant ingredient name. 2. Additional transparency to Member States authorities through a two-tier notification system. All products placed on the market must be notified under Article 13. Any product containing a nanomaterial must be indicated as such as part of this notification. Additionally, Article 16 requires a specific notification, including the submission of an extensive data package relating to the characteristics of the nanomaterial and providing for its risk assessment. Based upon this package, the European Commission is able to request an evaluation by the EU Scientific Committee on Consumer Safety (SCCS) and/or exercise adequate control of the substances concerned. 3. Risk assessment of nanomaterials used in cosmetic products. Every cosmetic product must undergo an assessment for safety, taking into account the particle size. Additionally, any colour, preservative or UV filter must be included in the Cosmetics Regulation positive lists. Specific mention must be provided for nanomaterials, following a review by the SCCS. 4. Through regular publication of a catalogue by the European Commission, the general public will be able to view information about nanomaterial substances in use and in which categories of cosmetic product. These extensive provisions have been part of the Cosmetics Regulation since its application in July 2013 and already provide for consumer safety, consumer information, information to regulatory authorities and decision makers and general public information.

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	5

professional users with information that allows for an appropriate response to health or environmental risks of nanomaterials	
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	As mentioned in question 1, in respect of cosmetic products, many of the objectives listed above are already provided for by the Cosmetics Regulation, namely: 1. Transparency of the presence of nanomaterials in products via on-pack labelling. Cosmetic products are labelled with a full list of ingredients and additionally must indicate the presence of nanomaterials with the inclusion on "nano" in brackets after the relevant ingredient name. 2. Additional transparency to Member States authorities through a two-tier notification system. All products placed on the market must be notified under Article 13. Any product containing a nanomaterial must be indicated as such as part of this notification. Additionally, Article 16 requires a specific notification, including the submission of an extensive data package relating to the characteristics of the nanomaterial, including information on physical and chemical properties, toxicological profile and quantities used, and providing for its risk assessment. Based upon this package, the European Commission is able to request an evaluation by the EU Scientific Committee on Consumer Safety (SCCS) and/or exercise adequate control of the substances concerned. 3. Risk assessment of nanomaterials used in cosmetic products. Every cosmetic product must undergo an assessment for safety, taking into account the particle size. Additionally, any colour, preservative or UV filter must be included in the Cosmetics Regulation positive lists. Specific mention must be provided for nanomaterials, following a review by the SCCS. 4. Through regular publication of a catalogue by the European Commission, the general public will be able to view information about

	nanomaterial substances in use and in which categories of cosmetic product. These extensive provisions have been part of the Cosmetics Regulation since its application in July 2013 and already provide for consumer safety, consumer information, information to regulatory authorities and decision makers and general public information.

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	1
e) The establishment of national registries and notification schemes causes market fragmentation and hampers trade within the internal market	5
Please provide additional comments	Again, many of the objectives listed above are already provided for by the Cosmetics Regulation, namely: 1. Transparency of the presence of nanomaterials in products via on-pack labelling. Cosmetic products are labelled with a full list of ingredients and additionally must indicate the presence of nanomaterials with the inclusion on "nano" in brackets after the relevant ingredient name. 2. Additional transparency to Member States authorities through a two-tier notification system. All products placed on the market must be notified under Article 13. Any product containing a nanomaterial must be indicated as such as part of this notification. Additionally, Article 16 requires a specific notification, including the submission of an extensive data package relating to the characteristics of the nanomaterial and providing for its risk assessment. Based upon this package, the European Commission is able to request an evaluation by the EU Scientific Committee on Consumer Safety (SCCS) and/or exercise adequate control of the substances concerned. 3. Risk assessment of nanomaterials used in cosmetic products. Every cosmetic product must undergo an assessment for safety, taking into account the particle size

taking into account the particle size. Additionally, any colour, preservative or UV filter must be included in the Cosmetics Regulation positive lists. Specific mention must be provided for nanomaterials, following a review by the SCCS. 4. Through regular publication of a catalogue by the European Commission, the general public will be able to view information about nanomaterial substances in use and in which categories of cosmetic product. These extensive provisions have been part of the Cosmetics Regulation since its application in July 2013 and already provide for consumer safety, consumer information, information to regulatory authorities and decision makers and general public information.

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

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I am not aware of any classified nanomaterials,

I am aware of DNELs/PNECs/OELs set for specific nanomaterials/types of nanomaterials

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I am not aware of any significant exposure of workers/users/consumers to 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):
Only a small number of nanomaterials are used as ingredients in cosmetic products e.g. zinc oxide and titanium dioxide (non nano-size also used), carbon black. These ingredients have been used in cosmetic products for many decades and a long history of safe use is available alongside a large database of toxicological studies. There is currently no evidence that any health or environmental hazards are linked to nanomaterials in the broad sense but may be linked to the specific chemical composition of each substance so that each material should be considered on a case-by-case basis.

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): Some cosmetic ingredients on the nano scale have been used in cosmetic products for many decades and a long history of safe use is available alongside a large database of toxicological studies. There is currently no evidence that any health or environmental hazards are linked to nanomaterials in the broad sense but may be linked to the specific chemical composition of each substance. - The nano forms of titanium dioxide and zinc oxide have been used safely in cosmetic products for around 30 years - Carbon black has been used in decorative cosmetic products safely for over 1000 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:
In respect of cosmetic products, many of the objectives listed above are already provided for by the Cosmetics Regulation namely: 1. Transparency of the presence of nanomaterials in products via on-pack labelling. Cosmetic products are labelled with a full list of ingredients and additionally must indicate the presence of nanomaterials with the inclusion on "nano" in brackets after the relevant ingredient name. 2. Additional transparency to Member States authorities through a two-tier notification system. All products placed on the market must be notified under Article 13. Any product containing a nanomaterial must be indicated as such as part of this notification. Additionally, Article 16 requires a specific notification, including the submission of an extensive data package relating to the characteristics of the nanomaterial and providing for its risk assessment. Based upon this package, the European Commission is able to request an evaluation by the EU Scientific Committee on Consumer Safety (SCCS) and/or exercise adequate control of the substances concerned. 3. Risk assessment of nanomaterials used in cosmetic products. Every cosmetic product must undergo an assessment for safety, taking into account the particle size. Additionally, any colour, preservative or UV filter must be included in the Cosmetics Regulation positive lists. Specific mention must be provided for nanomaterials, following a review by the SCCS. 4. Through regular publication of a catalogue by the European Commission, the general public will be able to view information about nanomaterial substances in use and in which categories of cosmetic product. These extensive provisions have been part of the Cosmetics Regulation since its application in July 2013 and already provide for consumer safety, consumer information, information to regulatory authorities and decision makers and general public information.

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:
Cosmetic products are already labelled with a full list of ingredients and additionally must indicate the presence of nanomaterials with the inclusion on "nano" in brackets after the relevant ingredient name.

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)	b) have no significant impact, Comments: Cosmetic products are already labelled with a full list of ingredients and additionally must indicate the presence of nanomaterials with the inclusion on "nano" in brackets after the relevant ingredient name. Thus far we are not aware of any significant impact on consumer behaviour. However, it would be of concern if the general term 'nano' became unfairly association with negative connotations and safety concerns. All cosmetic products and their ingredients, irrespective of particle size, must by law be safe.

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 confidential business information and increased administrative burden (with associated costs, which for some SMEs may be prohibitive).
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 confidential business information and increased administrative burden (with associated costs, which for some SMEs may be prohibitive) for companies operating in specific Member States (where national registries exist).

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:	For a) & b), for the cosmetic industry, under Regulation 1223/2009 there is already a two-tier noti-fication system in place. All products placed on the market must be notified under Article 13. Any product containing a nanomaterial must be indicated as such as part of this notification. Additionally, Article 16 requires a specific notification, including the submission of an extensive data package relating to the characteristics of the nanomaterial and providing for its risk assessment. Based upon this package, the European Commission is able to request an evaluation by the EU Scientific Committee on Consumer Safety (SCCS) and/or exercise adequate control of the substances concerned. Inclusion of cosmetics and cosmetic ingredients in an additional reporting scheme would create an administrative burden without any added benefits. c) & d) are not applicable to the cosmetics industry

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): There would be a conflict with the confidentiality of business information if the exact usage is disclosed or the substance and use conditions.
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 cosmetics industry has already experienced problems with the introduction of the French nanomaterial registry with an increased administrative burden and confusion arising from the diverging requirements/nanodefinition compared with the EU CPNP system and Cosmetics Regulation definition.

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
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If yes, please describe these differences
The Cosmetics Regulation covers all Member States, however there are differences in administrative burdens due to existing national-specific registries

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"?

Our preference is not to implement national registers as they create the potential for market differences between EU countries and with this an unnecessary administrative burden.
If a best practice model for national notification should be recommended, the Danish notification scheme could be considered as a suitable model. This system exempts cosmetic ingredients and products due to their notification under sector-specific legislation.
If no exemption is possible for cosmetic products, then limiting this to the notification of substances, rather than uses, could minimise the overlap with the notification by product already required under Cosmetics Regulation 1223/2009. Registration only when new products enter the marketplace and not on a yearly basis should be recommended.

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.

Because of the already existing notification provisions under Cosmetics Regulation 1223/2009 there would be no added value for cosmetic products from a scheme that included notification per use.
For public authorities: All products placed on the market must be notified under Article 13. Any product containing a nanomaterial must be indicated as such as part of this notification. Additionally, Article 16 requires a specific notification, including the submission of an extensive data package relating to the characteristics of the nanomaterial and providing for its risk assessment. Based upon this package, the European Commission is able to request an evaluation by the EU Scientific Committee on Consumer Safety (SCCS) and/or exercise adequate control of the substances concerned.

For Downstream user companies and workers : no added value. Information is already supplied via MSDS or general information.
For Consumers: Cosmetic products are labelled with a full list of ingredients and additionally must indicate the presence of nanomaterials with the inclusion on "nano" in brackets after the relevant ingredient name.

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:
Downstream users are covered under sectorial legislation (e.g. notification under Cosmetics Regulation). Additionally, only manufacturers and importers are able to provide the appropriate information.

Q30: The following should be subject to notification requirements (tick all that apply):	Please explain: There is no need to include cosmetic products or their ingredients in a notification system. All products placed on the market must be notified under Article 13 of the Cosmetics Regulation. Any product containing a nanomaterial must be indicated as such as part of this notification. Additionally, Article 16 requires a specific notification, including the submission of an extensive data package relating to the characteristics of the nanomaterial and providing for its risk assessment. Based upon this package, the European Commission is able to request an evaluation by the EU Scientific Committee on Consumer Safety (SCCS) and/or exercise adequate control of the substances concerned.
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 nanomaterials should be exempted: - Cosmetic products and ingredients covered by Regulation 1223/2009 (already notified in the EU) - Nanomaterials not intentionally manufactured to be on the nano-scale - Naturally-occurring substances - 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.)
Cosmetic uses should be exempted because: 1. Transparency of the presence of nanomaterials in products via on-pack labelling. Cosmetic products are labelled with a full list of ingredients and additionally must indicate the presence of nanomaterials with the inclusion on "nano" in brackets after the relevant ingredient name. 2. Additional transparency to Member States authorities through a two-tier notification system. All products placed on the market must be notified under Article 13. Any product containing a nanomaterial must be indicated as such as part of this notification. Additionally, Article 16 requires a specific notification, including the submission of an extensive data package relating to the characteristics of the nanomaterial and providing for its risk assessment. Based upon this package, the European Commission is able to request an evaluation by the EU Scientific Committee on Consumer Safety (SCCS) and/or exercise adequate control of the substances concerned. 3. Risk assessment of nanomaterials used in cosmetic products. Every cosmetic product must undergo an assessment for safety, taking into account the particle size. Additionally, any colour, preservative or UV filter must be included in the Cosmetics Regulation positive lists. Specific mention must be provided for nanomaterials, following a review by the SCCS. 4. Through regular publication of a catalogue by the European Commission, the general public will be able to view information about nanomaterial substances in use and in which categories of cosmetic product. These extensive provisions have been part of the Cosmetics Regulation since its application in July 2013 and already provide for consumer information, information to regulatory authorities and decision makers and general public information.

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):
Under the Cosmetics Regulation, the Cosmetic Product Notification Portal is already used for the notification of cosmetic products and the publication of the European Commission catalogue on nanomaterials used in cosmetics provides information on nanomaterials used, categories of products and the reasonably foreseeable exposure conditions.

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

The needs of these groups are different in the nature and level of information required. Therefore, the content and presentation should directly relate to the purpose of the observatory e.g. safety information for authorities or general information for consumers. These provisions are already in place for cosmetic products and ingredients under Regulation 1223/2009.

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)
Because of the already existing notification provisions under Cosmetics Regulation 1223/2009 there would be no added value from a nanomaterial registry for cosmetic products or cosmetic ingredients: 1. Transparency of the presence of nanomaterials in products via on-pack labelling. Cosmetic products are labelled with a full list of ingredients and additionally must indicate the presence of nanomaterials with the inclusion on "nano" in brackets after the relevant ingredient name. 2. Additional transparency to Member States authorities through a two-tier notification system. All products placed on the market must be notified under Article 13. Any product containing a nanomaterial must be indicated as such as part of this notification. Additionally, Article 16 requires a specific notification, including the submission of an extensive data package relating to the characteristics of the nanomaterial and providing for its risk assessment. Based upon this package, the European Commission is able to request an evaluation by the EU Scientific Committee on Consumer Safety (SCCS) and/or exercise adequate control of the substances concerned. 3. Risk assessment of nanomaterials used in cosmetic products. Every cosmetic product must undergo an assessment for safety, taking into account the particle size. Additionally, any colour, preservative or UV filter must be included in the Cosmetics Regulation positive lists. Specific mention must be provided for nanomaterials, following a review by the SCCS. 4. Through regular publication of a catalogue by the European Commission, the general public will be able to view information about nanomaterial substances in use and in which categories of cosmetic product. These extensive provisions have been part of the Cosmetics Regulation since its application in July 2013 and already provide for consumer safety, consumer information, information to regulatory authorities and decision makers and general public information.

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):

Please see above

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

None. Please 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