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COMPLETE

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

Q1: Please provide the following details (*compulsory):	
Organisation*:	Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers (ETAD)
Town/City:	Basel
Country*:	Switzerland
Contact name:	Bertil Hanke
E-mail address:	
Transparency Register ID number (if applicable)	348028811869-06
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?	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	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	(a) the objective is important, however it is questionable if the EU nano definition is able to fulfil this objective as particle properties are ignored apart from their size. (b) consumers need to get information about safe use of a product (information they can refer to) (d) EC nano definition says nothing about toxicity and it's by far not clear that 1 positive toxicity study for 1 nanomaterial does automatically all nanomaterials toxic. Therefore differentiation is needed and the trust in 'traditional nanomaterials' should never been compromised unless proven differently (e) for safety handling of downstream users yes. Other (b)

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	3
c) Maintain competitiveness and innovation of businesses bringing nanomaterials or products containing nanomaterials to the market (including SMEs)	2
d) Ensure consumer trust in products containing nanomaterials	2
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.	4
g) Protect confidential business information	4
Please provide additonal comments	As around 70% of organic pigments on the market are likely to be nanomaterials, REACh has plenty of relevant information on Phase 1 and 2 substances. Whether the organic pigments are nano or not is secondary as long as the toxicological information is adequate to have a proper risk assessement. According to OECD are risk assessment used for other materials is in large parts also adequate for nanomaterials.

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	2
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	As long as there is no standardized method to prove that a material is nano according to the EC definition, all materials with Gaussian type particle size distribution at the borderline of 100nm can't conform or deny being a nanomaterial. Additionally is there no harm proven for all materials, which could be nano. Therefore should the information given where the harm is proven.

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 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): Toxicologic effects have been shown on a very specific set of nanomaterials, which differ chemically quite vastly from materials like organic pigments. Also the crystallographic nature is different with organic pigment being molecular crystals in contrast to nanomaterials like gold, silver, TiO2, Zn, SiO2 etc. no toxicologic effect has been proven to be found in every materials that could be nano according the EC definition.
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: As the toxicologic information in comparable tools like REACh and most of the Pigment are or will get registered, there is no additional benefit.

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: Many regulatory drafts did or still do prohibit nanomaterials to be used, despite no toxicologic proven concern for all potential nanomaterials. In this uncertain regulatory situation many downstream users avoid using materials that are labelled nano.

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: Consumers need information they can refer to like safe handling of goods they bought. A label 'nano' would just appear to them as just another piece of unknown witchcraft. In regards to organic pigments, they almost exclusively are handed over to a consumer, which uses the pigment in a matrix. Therefore there is no contact of an organic pigment with a customer.

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)
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

PAGE 8: Section VII – Possible impact of a registry on your company/members of your association

Q23: Overall, how would a possible obligation to notify nanomaterials at the EU level affect your company/the members of your association, assuming that no exemptions were to be made from 1 (no impact) to 5 (significant impact):

a) with respect to nanomaterials on their own	5
b) with respect to nanomaterials in mixtures	5
c) with respect to articles with intended release of the nanomaterials	4
d) with respect to articles containing nanomaterials in general (i.e. in case also articles without an intended release of nanomaterials were to be covered)	5

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): Color Strength and other parameters are dependent on the particle size distribution. Therefore disclosure of the additional information in question would highly conflict with confidential business information.
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? Different definition, regulations and exemptions lead to different outcome whether organic pigments have to be registered or not, which creates a mess whether they should now be regarded as nanomaterial or not. There are big issues to keep the message consistent, which leads to all kinds of barriers.
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"?

The best way to handle nanomaterial information is to adapt existing ones especially REACh.

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.

The additional benefit would be that it could be directly done in REACh so no additional inventory would be needed, as REACh has already a system like that.

Q29: Which actors along the supply chain should be subject to notification requirements? (tick all that apply):	Please explain: None of them, as long as there is enough risk assessment information available through REACh or other existing registries.
Q30: The following should be subject to notification requirements (tick all that apply):	Please explain: None of them, as long as there is enough risk assessment information available through REACh or other existing registries.
Q31: Is there a need to exempt certain types of nanomaterials?	*Respondent skipped this question*

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.)
Organic pigments are used for optical purposes. Particle size changes the Color strength, because of higher distribution and consecutively higher chance to change the wavelength of impacting light. There is no chemical or charge change involved in going to smaller particles, as organic pigments are molecular crystals.

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,

b) Information from market studies on nanomaterials and products containing nanomaterials

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c) Information on the use of nanomaterials across Europe

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d) Information concerning products containing nanomaterials

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

Consumers need information they can refer to like safe handling of goods they bought.

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):

REACh has all data, that are needed.

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

None! Organic pigments are well evaluated under REACh. There is no added value for a separated registry with asks for the same information.

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

The current nanodefinition includes way more materials than the typical 13 'list of representative nanomaterials' (OECD). Any toxicologic effect observed with those materials has yet to be proven for all substances that are caught with the definition. There are huge differences chemically and crystallographically which has to be taken into account, when it comes to risk assessment.
Additionally a lot of materials are already registered under REACh and have a proper risk assessment.