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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*:	I&P Europe (Imaging and Printing association Europe)
Town/City:	Frankfurt am Main
Country*:	Germany
Contact name:	Bjoern-Markus Sude
E-mail address:	
Transparency Register ID number (if applicable)	03883572935-58
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 , c) is a manufacturer of nanomaterials, d) is an importer of nanomaterials, e) is a formulator of mixtures containing nanomaterials , f) is a manufacturer of articles containing nanomaterials without intended release , h) is a distributor of nanomaterials and/or mixtures containing nanomaterials , i) is a distributor of articles 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):	C20.3
Secondary business sector (NACE 4 digit code):	G46.6

Q7: Please indicate the number of employees.	≥ 250 employees

Q8: Please indicate the approximate annual turnover of your organisation and the annual turnover which relates to nano-related products (where these include nanomaterials as well as mixtures and articles containing nanomaterials).

Annual turnover	≥ €50m
Nano-related annual turnover	≥ €50m

Q9: Please indicate the number of nano-related products (where these include nanomaterials as well as mixtures and articles containing nanomaterials) that you place on the national market.	*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	3
c) Maintain competitiveness and innovation of businesses bringing nanomaterials or products containing nanomaterials to the market (including SMEs)	5
d) Ensure consumer trust in products containing nanomaterials	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	While information distribution to the general public is essential to earn consumer trust, too much information can have the opposite effect, leading to stigmatisation. Nanomaterials are a group of chemicals only defined by their physical size, not by their chemical properties, and so it is not possible to assign a generic set of risks to them, meaning requirements need to be substance specific and not across the “class” of nanomaterials in general. There is a difference between professional users and consumers in that professional users are better informed regarding understanding hazard and risk assessments, the use of risk management measures and the operation of a safe workplace. Consumers (the general public) do not have the same level of training and understanding and are more likely to be subjective in their response to new information, depending on how it is presented. I&P Europe believes that the current European framework (REACH) is more than capable of assessing the (possible) risks that are associated with (manufactured) nanomaterials, albeit with the necessary adaptations/extensions to the annexes.

Q14: To what degree (from 1 - not at all to 5 - fully) does the current legislative framework (including the REACH and CLP Regulations and product-specific legislation) and the currently available databases (including the JRC web platform, see http://ihcp.jrc.ec.europa.eu/our_databases/web-platform-on-nanomaterials) meet the following objectives?

a) Provide decision makers, regulatory authorities and professional users with information that allows for an appropriate response to health or environmental risks of nanomaterials	4
b) Provide consumers with relevant information on products containing nanomaterials on the market	2
c) Maintain competitiveness and innovation of businesses bringing nanomaterials or products containing nanomaterials to the market (including SMEs)	3
d) Ensure consumer trust in products containing nanomaterials	3
e) Ensure the availability of relevant information on the presence of nanomaterials or products containing nanomaterials on the market	4
f) Ensure the proportionality of the information requirements and the associated costs and administrative burden.	3
g) Protect confidential business information	4
Please provide additonal comments	As mentioned above, I&P Europe believes that implication of REACH on nanomaterials should be sufficient to earn and maintain consumer trust. However additional attention should be given on characterization of possible nanomaterials, to distinguish whether or not they answer to the EC definition. Also (the way of) gathering (eco)toxicological data should be standardized and included in the REACH Annexes.

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	3
c) The current level of available information on the presence of nanomaterials and products containing nanomaterials on the market is detrimental to consumer trust	2
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	Environmental and health issues should be properly addressed, but this will not be improved by information on the presence of nanomaterials in products. Risk management is specific to the substance and its use, therefore the process to ensure good risk management of these individual substances is key, not the requirement to describe the presence of nanomaterials in a product.

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 not aware of any 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): Titanium dioxide is for instance mentioned under REACH. DNEL (TiO_2) worker: 10 mg/m³ (inhalation); consumer: 700 mg/kg bw/day (oral). This substance is used in a myriad of different applications, including printing inks and toners.
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: I&P Europe wants to emphasize again that it believes that the majority of tools for hazards identification and risk assessment are already available. Only fine tuning needs to be implemented to get standardized protocols for identification of individual nanomaterial properties and assessment of their (eco)toxicological profile. However, a single EU-wide registry would be preferable to multiple national registries which multiply the burden on companies several times over and create additional difficulties within the EU.

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 , b) They would try to avoid those products, c) Their purchasing decisions would not be affected , d) They would search for more information, Please explain: All the answers could apply depending on the product in question and the profile of the user. Some companies avoid mentioning the presence of nanomaterials in their products, others promote it.
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 dual role of information was already mentioned before. In general, professional users will have a better understanding of the term nanomaterial, while the general public only has a marginal clue of the presence and/or specific benefits of nanomaterials. More information will not per se lead to a better understanding, nor will it improve consumer trust.

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: Based on the French model, it was found that competitiveness and innovation were hampered, due to uncertainties amongst economic actors and perception issues from economic partners.

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 While the benefits of a European register for nanomaterials would be rather marginal, the cost and administrative burden would be substantial. This could result in higher pricing of EU manufactured products and thus competition issues with non-EU companies. However, a single EU-wide registry, which still is seen as questionable, would be preferable to multiple national registries which multiply the burden on companies several times over and create additional difficulties within the EU.

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)	3
Please explain:	The highest impact of nanomaterial registration will be expected on the level of mixtures for most I&P Europe members. Silicas and titanium dioxide are used as additives in variety of inks and toners.

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): A nanomaterial register will disclose some vital data: • Customer names • Name, form and physical/chemical properties of certain additives, which can have a huge impact on the desired properties of the mixture • Quantities put on the market • Uses, in some cases

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 biggest concern from I&P Europe is that the divergence of the different notification schemes will result in a significantly increased workload creating additional costs which are negatively impacting the bottom line without additional benefit. Compliance will become more difficult due to differences in legislative texts of the different member states.
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 most important aspect is the use of only one definition on nanomaterials.
• To lower the administrative burden, notification numbers should be made available down the supply chain.
• Confidentiality of certain information (CBI) should receive considerable attention.
• Web-based notification system is effective.
• National notification schemes should require the same information, in the same format at the same due date for the same timeframe.

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.

• Data on mixtures/articles is best to be found in safety data sheets, which is already an existing tool to describe risks/hazards per mixture/article.

• Very similar mixtures with small formulation differences can result in multiple products all of which may need to be notified individually. The burden from this is significantly greater than the burden of notifying per use of a substance and does not change the value to those receiving the information.

Q29: Which actors along the supply chain should be subject to notification requirements? (tick all that apply):	Please explain: Notification systems already exist for chemical substances and mixtures, additional ones should not be needed specifically for nanomaterials.
Q30: The following should be subject to notification requirements (tick all that apply):	Please explain: Notification systems already exist for chemical substances and mixtures, additional ones should not be needed specifically for nanomaterials.
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.) Notification systems already exist for chemical substances and mixtures, additional ones should not be needed specifically for nanomaterials.

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.)
Notification systems already exist for chemical substances and mixtures, additional ones should not be needed specifically for nanomaterials.

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

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e) Information on the hazards and risks of nanomaterials

,

f) Other (please explain):
Information established in the Observatory should be taken from already existing sources and voluntary submissions, not from new and/or additional legislation.

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

For consumers, a publicly accessible website would be a good resource.

For professional workers and authorities, the information could be disseminated via the ECHA website or similar, together with safety data sheets.

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):

f) General education of the public,

g) Other purposes (please specify)
If the information from registries could be made more readily comprehensible, it poten-tially could be used to help the general education of the public, but the benefits would be limited. Besides the education of the general public, current frameworks like REACH, CLP and other sector-specific legislation such as the food, cosmetics and biocides regulations should provide more than sufficient ground to assess risk and health issues in a proper way.

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):

Although potentially there could be opportunities for education of the public, in practice based on the experience with the French scheme, no benefits could be determined for consumers.

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

For I&P Europe, the only advantage to an EU registry would be if it replaced the multiple national registries and thus reduced the increasing burden on member companies while providing a single platform for information which is already being gathered by individual member states.

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

Respondent skipped this question