#71

COMPLETE

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

Q1: Please provide the following details (*compulsory):	
Organisation*:	Clariant Produkte (Deutschland) GmbH
Town/City:	Sulzbach am Taunus
Country*:	Germany
Contact name:	Dr. Klaus Kund
E-mail address:	
Transparency Register ID number (if applicable)	221982814162-24
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

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):	20xy

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.

Nanomaterials	251 to 500
Mixtures	over 1,000
Articles	over 1,000

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.

Nanomaterials	251 to 500
Mixtures	over 1,000
Articles	over 1,000

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.

Nanomaterials	251 to 500
Mixtures	over 1,000
Articles	over 1,000

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).

Number of customers	more than 100

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	2
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	Nanomaterials (NMs) should be regarded as any other substance. In that context, as required by REACH for instance, data should be gathered by industry in order to perform risk assessments and ensure safe use of the products that are placed on the market. By this way, with relevant explanation on the process provided to the public, consumer trust could be increased. Specific legislation covering sensitive products containing nanomaterials, like cosmetics or biocides, already require information for consumers and health authorities. Also via the IUCLID database, consumers have access to nanomaterials registered under REACH and their potential application. An inventory is not the right tool for consumer communication. On the contrary, providing to consumers information on products containing NMs that are placed on the market could lead to a stigmatisation of NMs, with a negative effect on consumer trust, even if safe use is demonstrated by the implementation of the relevant regulations (REACH and/or sector-specific legislation).

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.	3
g) Protect confidential business information	3
Please provide additonal comments	It appears unclear what is meant in this case by the term relevant information (question b). Safety-related information is provided as necessary/mandatory (e.g. in the Safety Data Sheet). Products are usually provided with use instructions including the necessary information for the safe handling of the product. From our point of view this system is performing well. Different definitions for nanomaterials, diverging implementations in nanoproduct registers and a lack of suitable and commonly available measuring methods lead to additional complexity and uncertainty when dealing with nanomaterials (questions c and d). Additional requirements would constitute an administrative burden for companies with no guaranty of a potential positive impact on consumer trust. Negative consequences on the competitiveness and the innovation capacity of the chemical industry can nevertheless be expected.

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	The adequate response to health and environment risks is not linked to the information on the presence of nanomaterials in products but to an effective and reliable risk assessment of the substance. The experience gained with the French notification scheme for nanomaterials shows, that the establishment of national registers hampers the European market, particularly with regard to the pigments and fillers industry. (JRC, Considerations on information needs for nanomaterials in consumer products: “National regulations of traceability measures may lead to different information requirements and could create cross-border trade barriers by influencing free market interplay at various levels (manufacturers, distributors/importers and downstream users) between the EU Member States.”)

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): Nanomaterials are no more hazardous substances than other chemicals. (SCENIHR, Risk Assessment of Products of Nanotechnologies (2009): “The hypothesis that smaller means more reactive and thus more toxic cannot be substantiated by the published data. In this respect nanomaterials are similar to normal substances in that some may be toxic and some may not.”).
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: From our point of view the existing regulations (REACH etc.) are sufficient/suitable for controlling risks. An inventory of nanomaterials is not in relation to any kind of risk from products, since risk is not linked to the nanomaterial definition. An inventory would therefore not contribute to identify risks from products.

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: The implementation of the French notification scheme for nanomaterials showed that actors within the supply chain tried to avoid products containing nanomaterials either due to the additional administrative effort related to the notification system or due to the “black-list” effect led by the stigmatisation of nanomaterials with such a scheme. Nano-free products are already requested by OEMs.
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: Depending on consumer knowledge, nanomaterials can be interpreted as a threat or a benefit. Generally outside professional users, there is poor knowledge about nanomaterials in products and the benefit they bring. This could lead to a priori negative feeling in the general public.

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: The implementation of the French national registry system led to a mistrustful perception from economic partners and consequently, to a negative impact on competitiveness. Additionally different definitions for nanomaterials, diverging implementations in nanoproduct registers and a lack of suitable and commonly available measuring methods lead to additional complexity and uncertainty when dealing with nanomaterials.
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 Nanomaterials are not more or less hazardous than any other chemical. Consequently there is no reason for establishing a specific register only for nanomaterial. Asking for a register would only create a burden on that specific industry producing, importing or using nanomaterials.

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
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
Please explain:	Pigments and fillers, considered as nanomaterials according to the current EU-definition, are present in nearly every product and article of our daily life. Therefore an EU notification scheme would impact nearly every substance, product, mixture or article if there would be no exemption. Investigation on endproducts like coatings and plastics containing pigments and fillers show that there is no release of nanomaterials if they are embedded in a matrix. (see D. Göhler, A. Nogowski, P. Fiala, M. Stintz, J. Phys.: Conf. Ser. 2013, 429, 012045.). So there is no scientific justification for a notification of articles mentioned under question d).

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): Disclosure of information like e.g. distribution, quantities of substances/products, sectors of use, formulation and name of customers would be in strong conflict with the confidentiality of business.

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 differences in notification scheme and definition of nanomaterials cause a significant extra workload for the involved companies; keeping it up to date every year means an unnecessary but considerable burden es-pecially for SMEs.

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
However due to implemented and planned nano register, market differences can be forseen.

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"?

An alternative notification scheme may be seen in the Norwegian approach, which is an additional tool within the existing product register for hazardous chemicals. The Danish product register concerns only consumer products, which narrows to one of the main tasks often mentioned namely the consumer information and protection. REACH is already an established kind of register for chemical substances and therefore also already covers nanomaterials.

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.

For workers and downstream users, the best information source is the safety data sheet, which is related to the products manufactured and brought into the market.
Use notifications are already existing in the food area, for cosmetics and biocides. Therefore an additional notification per use would bring no extra benefit in comparison to already existing regulations.

Q29: Which actors along the supply chain should be subject to notification requirements? (tick all that apply):	Please explain: No separate nanomaterial notification scheme is required as already existing regulation (REACH for manufac-turers and importers; sector specific legislation for downstream users) is sufficient.
Q30: The following should be subject to notification requirements (tick all that apply):	Please explain: No separate nanomaterial notification scheme is required as already existing regulation (REACH for manufac-turers and importers; sector specific legislation for downstream users) is sufficient.
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.) By all means substances, mixtures and articles already notified under existing schemes (REACH, CLP, biocides, cosmetics) should be exempted.
Q32: Is there a need to exempt certain uses of nanomaterials?	Yes, certain uses of nanomaterials should be exempted from a notification system , If yes, which uses should be exempted and why? (in terms of specific exposure scenarios, available knowledge, absence of hazards, etc.) At least, uses covered by sectoral legislation (Biocides, Cosmetics,…) should be exempted. Uses leading to no exposure to human health and the environment should be exempted as well. This covers nanomaterials embedded in matrices and not available as such during the whole life cycle.

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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e) Information on the hazards and risks of nanomaterials

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

In a consumer friendly way. The German websites: www.nanopartikel.info/ or www. Nanoportal-bw.de/ could be used as example.

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

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):

The administrative burden, the risk of releasing confidential information and the negative expected impact on economy and competitiveness outweigh any potential positive impact of the scheme. Indeed, no benefit from the French scheme has been identified so far, at least from a consumer perspective.

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

Nanomaterials are no more hazardous substances than other chemicals. Therefore no added value based on an additional notification scheme for nanomaterials can be expected.

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

Due to the extremely broad definition of nanomaterial, as applied in the EU commission recommendation, nearly every particulate material in the market has a realistic chance to fall under the definition and to be considered as a “nanomaterial”. Thus the focus is lost and it cannot be differentiated between relevant, new or even hazardous nanomaterials and materials with small particles known and used for many decades.
The lack of suitable and commonly available measuring methods should be solved preliminary.