

Impact Assessment on Possible Measures to Increase Transparency on Nanomaterials on the Market

Public Consultation – Industry Stakeholders

Background

As part of the Communication on the Second Regulatory Review on Nanomaterials¹, the Commission has announced to launch “an impact assessment to identify and develop the most adequate means to increase transparency and ensure regulatory oversight [on nanomaterials], including an in-depth analysis of the data gathering needs for such purpose. This analysis will include those nanomaterials currently falling outside existing notification, registration or authorisation schemes.”

More information on the background, methodology and planned timing of this impact assessment can be found in the working document (CASG(Nano)/02/14²). This document also contains a draft problem definition, policy objectives and a more detailed description of the following policy options that are under consideration:

0. Baseline scenario
1. Recommendation on how to implement a "best practice model" for Member States wishing to establish a national system (*soft law approach*)
2. Structured approach to collect information ("*Nanomaterials Observatory*")
3. Regulation creating an EU nanomaterial registry with one annual registration per substance for each manufacturer/importer/downstream user/distributor
4. Regulation creating an EU nanomaterial registry with one annual registration per use (including substances, mixtures and articles with intended release)

The European Commission (DG Enterprise and Industry) has commissioned Risk & Policy Analysts Ltd. (RPA) and BiPRO GmbH to undertake a study to support the Commission on the preparation of this impact assessment. The terms of reference and the first two draft reports are available online³. Further reports (including revised versions of the two reports) will be published on this website as they become available.

This public consultation is an integral part of this study. The objective of the public consultation is to obtain stakeholder views on the currently available information on nanomaterials on the market, the problem definition that forms the basis of the impact assessment, as well as the potential positive and/or negative impacts of the aforementioned policy options.

Please be aware that within the European Union, France has already established a mandatory

¹ Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, 'Second Regulatory Review on Nanomaterials', COM(2012) 572 final. <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1397055294226&uri=CELEX:52012DC0572>

² This document has been made available online (<http://www.rpald.co.uk/news-nano-consult.shtml>) and an updated version including a final version of the problem definition, objectives and policy options will be published in the second half of May.

³ See <http://www.rpald.co.uk/news-nano-consult.shtml>

reporting scheme for manufactured nanomaterials produced, imported or distributed in its territory. The Interministerial decree No. 2012-232 entered into force in January 2013⁴. Belgium and Denmark have notified draft legislation for national registries to the European Commission. The impact assessments made for the Belgian and Danish registries, as well as an impact assessment for a European registry prepared on the initiative of the German Environment Protection Agency, are available online⁵. Moreover, at European level, when cosmetic products containing nanomaterials are put on the EU market, Article 16 of Regulation (EC) No 1223/2009 requires the responsible persons to submit information on the nanomaterial(s) contained through the Cosmetic Product Notification Portal⁶.

Practical questions on the consultation can be sent to the Project Manager, Marco Camboni, by e-mail (marco.camboni@rpaltd.co.uk) or, alternatively, Craig Hawthorne, BiPRO project manager, by email (craig.hawthorne@bipro.de). Substantive questions may be directed to the Commission (Maurits-Jan.Prinz@ec.europa.eu).

**** Responses to the public consultation must be submitted by 5 August 2014 ****

Note: the term “nanomaterials” refers to nanomaterials as defined in Commission Recommendation 2011/696/EU on the Definition of Nanomaterial⁷. For the purpose of this consultation, only manufactured nanomaterials should be taken into consideration.

If you responding to this questionnaire on behalf of/as a private company or industry association, please continue.

If you responding to this questionnaire on behalf of/as

- a public authority / public administration / health and safety institute / academic organisation / research organisation;
- a consumer organisation / trade union / environmental organisation / non-governmental organisation; or
- an individual or other stakeholder.

Please return to the Public Consultation home page⁸ and complete the questionnaire for ‘other stakeholders’.

⁴ www.r-nano.fr

⁵ <http://www.rpaltd.co.uk/news-nano-consult.shtml>

⁶ <http://ec.europa.eu/consumers/sectors/cosmetics/cnpn/>

⁷ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:275:0038:0040:EN:PDF>

⁸ <http://www.rpaltd.co.uk/news-nano-consult.shtml>

Section I - Identification

1. Please provide the following details (*compulsory):

Organisation*:	Japan Business Council in Europe (JBCE)
Town/city:	Brussels
Country*:	Belgium
Contact name:	Akihito Nakai
e-mail Address:	nakai@jbce.org
Transparency Register ID number ⁹	6836857120-55

2. 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	X
My contribution may be published but should be kept anonymous	
I do not agree that my contribution will be published at all	

3. We might need to contact you to clarify some of your answers. Please state your preference below:

I am available to be contacted	X
I do not want to be contacted	

4. 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	<i>Please skip Section II and go directly to Section III</i>	
No / Do not know	<i>Please continue to next question</i>	X

⁹ If your organisation is not registered, you have the opportunity to register now:
<http://ec.europa.eu/transparencyregister/public/ri/registering.do?locale=en#en>

Section II – Supply chain characterisation

1. 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	X
b) has to notify to the Cosmetic Products Notification Portal	X
c) is a manufacturer of nanomaterials	X
d) is an importer of nanomaterials	X
e) is a formulator of mixtures containing nanomaterials	X
f) is a manufacturer of articles containing nanomaterials without intended release	X
g) is a manufacturer of articles containing nanomaterials with intended release	X
h) is a distributor of nanomaterials and/or mixtures containing nanomaterials	X
i) is a distributor of articles containing nanomaterials	X
j) None of the above	
k) Not sure whether we deal with nanomaterials	

If you ticked a) and/or b), please take the time to fill in the questionnaire on the administrative burden of the notification schemes¹⁰.

2. Please indicate the four-digit NACE code of your primary and secondary business sector (if applicable).

Primary business sector (NACE 4 digit code):	Our memberships come from various sectors
Secondary business sector (NACE 4 digit code):	Our memberships come from various sectors

3. Please indicate the number of employees.¹¹

1-9 employees	
10-49 employees	
50-249 employees	
≥ 250 employees	X

¹⁰ <http://www.rpaltd.co.uk/news-nanoregistry.shtml>

¹¹ Please note that if you are a partner enterprise, you must add a proportion (directly correlated with the stakes you have in another enterprise) of the other enterprise's staff head-count and financial details to your own data. If there are several partner enterprises, this must be done for each partner enterprise situated immediately upstream or downstream from yours. If you are a linked enterprise, all 100% of the linked enterprise's data must be added to those of your enterprise. For more details on calculation and exemptions, see:

http://ec.europa.eu/enterprise/policies/sme/files/sme_definition/sme_user_guide_en.pdf

4. Please indicate the approximate annual turnover¹² 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		Nano-related annual turnover
Less than €250k		Less than €250k	
Between €250k and €2m		Between €250k and €2m	
Between €2m and €10m		Between €2m and €10m	
Between €10m and €50m		Between €10m and €50m	
Over €50m	X	Over €50m	X

5. Please indicate the number of nano-related products (where these include nanomaterials (NMs) as well as mixtures (Mixt) and articles containing nanomaterials (Art)) that you place on the national, EU and global markets.

	9. National market			10. EU market			11. Global market		
	NMs	Mixt	Art	NMs	Mixt	Art	NMs	Mixt	Art
Less than 6									
Between 6 and 10									
Between 11 and 50									
Between 51 and 100									
Between 101 and 250									
Between 251 and 500									
Between 501 and 1,000									
Over 1,000									

Note: Total products from our memberships are at least over 11, but we could not see exact number of products.

6. 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).

	No. of customers	No. of suppliers
Less than 6		
Between 6 and 15		
Between 16 and 30		
Between 31 and 50		

¹² For small partner/linked enterprises, please see previous footnote.

Between 51 and 100		
Over 100		

Note: We don't know.

Section III – Problem definition and objectives

- Please rate the importance of the following objectives on a scale between 1 and 5 (1-not important at all / 5-very important).

	1	2	3	4	5
a) Provide decision makers, regulatory authorities and professional users with information that allows for an appropriate response to health or environmental risks of nanomaterials					X
b) Provide consumers with relevant information on products containing nanomaterials on the market			X		
c) Maintain competitiveness and innovation of businesses bringing nanomaterials or products containing nanomaterials to the market (including SMEs)					X
d) Ensure consumer trust in products containing nanomaterials				X	
e) Ensure the availability of relevant information on the presence of nanomaterials or products containing nanomaterials on the market				X	
f) Ensure the proportionality of the information requirements and the associated costs and administrative burden.				X	
g) Protect confidential business information					X
<i>Please provide additional comments:</i> Principally, it's difficult to prioritize all of given items because they are in mutual relationship and it should not be judged separately. It is very important to make balance on trade-off between various stakeholders such as associated costs, appropriate choice of risk communication, confidential business information, transparent EU harmonized legislation, social trust to nanotechnology together with appropriate risk information to citizen etc.					

- To what degree (from 1 - not at all to 5 - fully) do the current legislative framework (including the REACH and CLP Regulations and product-specific legislation) and the currently available databases (including the JRC web platform¹³) meet the following objectives?

	1	2	3	4	5	Don't know
a) Provide decision makers, regulatory authorities and professional users with information that allows for an appropriate response to health or environmental risks of nanomaterials						X
b) Provide consumers with relevant information on products containing nanomaterials on the market						X
c) Maintain competitiveness and innovation of businesses bringing nanomaterials					X	

¹³ http://ihcp.jrc.ec.europa.eu/our_databases/web-platform-on-nanomaterials

or products containing nanomaterials to the market (including SMEs)						
d) Ensure consumer trust in products containing nanomaterials						X
e) Ensure the availability of relevant information on the presence of nanomaterials or products containing nanomaterials on the market			X			
f) Ensure the proportionality of the information requirements and the associated costs and administrative burden.				X		
g) Protect confidential business information						X
<p><i>Please provide additional comments:</i></p> <p>There is short information in order to share and assess nano risk with standard or certain justification in current legislative framework.</p> <p>It is also important for SMEs and citizen to educate and disseminate how to use available database and how to understand legislative framework by simple and easy method.</p>						

3. To what extent do you agree with the following statements from 1 (strongly disagree) to 5 (strongly agree):

	1	2	3	4	5
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			X		
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		X			
c) The current level of available information on the presence of nanomaterials and products containing nanomaterials on the market is detrimental to consumer trust		X			
d) The available information on the presence of nanomaterials and products containing nanomaterials on the market is presented in an incoherent or ineffective way		X			
e) The establishment of national registries and notification schemes causes market fragmentation and hampers trade within the internal market					X
<p><i>Please provide additional comments:</i></p> <p>It is first to establish system to collect and share appropriate information with scientific evidence and EU harmonized standard / procedure. We are afraid that obligation of information disclose only containing nano give consumers unnecessary anxiety and block nano related competitiveness and innovation.</p> <p>We believe that national registries causes market fragmentation and hampers due to incoherent information requirement without identification methods and effects on the health and/or environment by Member States.</p>					

Section IV – Health and environmental aspects

1. 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	X
I am not aware of any 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 not aware of any classified nanomaterials	X
I am aware of DNELs/PNECs/OELs ¹⁴ set for specific nanomaterials/types of nanomaterials	
I am not aware of any DNELs/PNECs/OELs set for specific nanomaterials/types of nanomaterials	X
I am aware of significant exposure of workers/users/consumers to specific nanomaterials/types of nanomaterials	
I am not aware of any significant exposure of workers/users/consumers to specific nanomaterials/types of nanomaterials	X
<p>Please explain your responses below (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):</p> <p>We recognize it is common challenge to collect such scientific data including cost and definition of test method. The link below might be useful if you are not aware.</p> <p>http://www.environmental-expert.com//news/worker-illness-after-nanomaterial-exposure-examined-in-first-US-427275?utm_source=News_Health_Safety_15052014&utm_medium=email&utm_campaign=newsletter&utm_content=feattextlink</p>	

2. With regard to the past and current use of nanomaterials (tick the relevant box):

I am aware of health and/or environmental incidents which have occurred	X
I am not aware of any health and/or environmental incidents which have occurred	
<p>Please explain (if any, please report the events and any scientific publication):</p> <p>We have some information concerning health and environmental incident but almost of these cases are not clear whether they are in causal relationship with the nanomaterial specific properties.</p>	

3. The establishment of an EU nanomaterial registry (tick the relevant box):

Would significantly contribute to reducing the health and/or environmental risks related to the use of nanomaterials	
Would not significantly contribute to reducing the health and/or environmental risks related to the use of nanomaterials	
I do not know	X
<p>If appropriate, please explain further:</p> <p>We don't think nano registry contribute to reduce the health and/or environmental risks directly</p>	

¹⁴ **DNELs:** Derived No Effect Levels, exposure levels below which hazardous substances are expected to have no effect on human health; **PNECs:** Predicted No Effect Concentrations, exposure levels below which hazardous substances are expected to have no effect on the environment; and **OELs:** Occupational exposure limits

and the objective of registry should be clarified at first.

However the information from registry contribute as source to prioritize scientific risk assessment and it is important to take into account information requirement according to the objective.

Section V – Consumer trust

1. 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	X
<p>Please explain:</p> <p>It depends on the contents of information. Even if there is information only containing nano, it is not affected for purchasing decision because the good feature of the nano is well useful for the clients. What it is important is to inform them appropriate information with scientific evidence and there is no good effect for them to communicate insufficient information they can't do anything.</p> <p>A membership of JBCE made a comment, " Many users are interested in nanomaterials, but some users avoid our products because they contain nanomaterials. "</p>	

2. 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)

a) generate trust among consumers and the broad public, and thus have a positive effect on the market for the concerned products	
b) have no significant impact	
c) generate insecurity or stigmatise such products, and thus have a negative effect on the market for the concerned products	X
<p>Comments:</p> <p>It depends on the content of information. If the information is only for containing nano, it will lead to their insecurity because they can't do anything.</p>	

Section VI - Innovation and competitiveness

1. With regard to innovation, do you believe that information on nanomaterials and products containing nanomaterials that could be gathered in a nanomaterial registry would:

a) stimulate innovation (e.g. through increased consumer trust, increased awareness on nanomaterials)	
b) have no significant impact on innovation	X
c) hamper innovation in the EU (e.g. through concerns about confidential business information or through additional costs related to providing information)	
Comments: We don't have specific reason for a) and c). Therefore we ticked b). However it is under condition that confidential business information is secured. In particular, information security for uses in case manufacturer that doesn't intentionally take patent property should be clarified.	

2. 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):

a) stimulate intra-EU competitiveness	
b) enhance the competitiveness of European companies against extra-EU companies	
c) have no significant impact on intra-EU competitiveness	X
d) have no significant impact on the competitiveness of European companies against extra-EU companies	X
e) hamper intra-EU competitiveness	
f) hamper the competitiveness of European companies against extra-EU companies	
Please explain: We think this is too small thing to stimulate intra-EU competitiveness as well as hamper the competitiveness of European companies against extra-EU companies.	

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

It is noted that companies that so far have not been involved in a notification scheme may not have comprehensive information to answer all the questions below in full detail. Moreover, answers will also depend on the scope of a possible registry, which will be further delineated over the course of the impact assessment. Nevertheless, any insight companies/associations can provide on their expectations would be useful in assessing the implications and defining the scope of a possible registry. For the purpose of these questions, respondents may base their answers on the assumption that their nanomaterials would all be subject to notification requirements. If companies/associations feel that they cannot answer certain questions, they may be left empty.

Three of the five aforementioned policy options involve the establishment of a mandatory registry/registries for nanomaterials (option 3 and 4 at EU level, option 1 at national level), requiring

either an annual notification per substance (for manufacturers and importers, as well as for downstream users) or an annual notification per use (e.g. for each mixture or article). The following questions concern the impact of such a registry.

- 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):

	1	2	3	4	5
a) with respect to nanomaterials on their own				X	
b) with respect to nanomaterials in mixtures				X	
c) with respect to articles with intended release of the nanomaterials				X	
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)					X

Please explain:

Your recital explanation is asked for national level, but question in No.1 is asked for EU level. It seems contradiction or mistake, but If national registry is separately required, it will arise administrative burden with increasing non-effective cost.

In addition, there is generally some difficulty in answering this question regarding intended release. In case of articles, a nanomaterial is "fixated" or bound in the product via e.g. binding materials and even if there is a peeling or abrasion effect and flakes might occur it is difficult to think that such flakes or peeled off parts or also powder have the size of nanomaterial. Rather such parts are most likely of a larger size than nanomaterial scale. However, this cannot be guaranteed fully and that is why for instance a R&D on incorporating nanomaterials in tires was stopped, because uncertainty for flying apart particles existed. It means definition of intended release and test method should be defined clearly.

We think that articles containing nanomaterials without intended release should not be in scope for notification obligations because there is too hard to identify articles without an intended release and it seems it is too difficult to make the definition.

- Would disclosure of the notified information conflict with the confidentiality of business information?

Yes, there would be a conflict with business information confidentiality	X
No, I don't see any conflict	

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):

It depends on level of information requirement. In particular, information security for uses in case manufacturer that doesn't intentionally take patent property is at least needed to be clarified.

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3. Do you experience or expect any significant barriers for your company/members of your association from diverging notification obligations in the schemes in France/Belgium/Denmark?

Yes, we foresee significant barriers	X
No, we do not expect any barriers	
<p>If yes, please describe these barriers:</p> <p>Generally speaking, if national registry is separately required, it will arise administrative burden with increasing non-effective cost. If we answer whether it is significant or not in specifically France/Belgium/Denmark, it must be significant if information requirement is different among the Member States.</p>	

4. Is the market for your nanomaterials/products containing nanomaterials significantly different from Member State to Member State?

Yes, the markets differ at national level	
No, there is not any significant difference in the national markets for our products	X
If yes, please describe these differences:	

5. 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”?

It depends on objective EU would like to achieve. If EU would like to get information immediately anyway in order to make how EU should prioritize next action, we recommend the Danish system as best practice because the information to be submitted is minimum.

Section VIII – Possible options and exemptions

Different nanomaterial registries are under consideration. Firstly, an annual notification requirement per substance for each manufacturer/importer/downstream user/distributor (this would imply that a downstream user using one substance in multiple mixtures or articles would only submit one notification) or an annual notification requirement per use of a nanomaterial across the supply chain (e.g. for each mixture or article).

1. 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.

Risk is different by each uses including exposure scenario and notification per substance sometimes doesn't reflect its risk and hazard in uses.

On the another hand, If based on use, it should be considered how to make the downstream companies understand this principle and how to avoid duplication of notification for same substance in long supply chains. It will maybe take long time to reach a 100% notification.

2. Which actors along the supply chain should be subject to notification requirements (tick all that apply):

a) Manufacturers of nanomaterials	X
b) Importers of nanomaterials	X
c) Downstream users (e.g. re-formulators, manufacturers of products containing nanomaterials)	X
d) Distributors to professional users (e.g. wholesalers)	
e) Distributors to consumers (e.g. retailers)	
Please explain:	

It should be considered how to avoid duplication of notification for same substance in long supply chains for in particular downstream users.

3. The following should be subject to notification requirements (tick all that apply):

a) Substances	X
b) Mixtures containing nanomaterials	X
c) Articles with intended release of nanomaterials	X
d) Articles containing nanomaterials without intended release	
Please explain: Refer to answer of section VII, 1.	

4. Is there a need to exempt certain **types** of nanomaterials?

Yes, certain types of nanomaterials should be exempted from a notification system	X
No, all kinds of nanomaterials should be subject to notification obligations	
If yes, which types should be exempted and why? (in terms of specific properties, available knowledge, absence of hazards, etc.)	
If there is available knowledge for absence of hazards, it may be exempted. However it leads to necessity of development for definition of available knowledge for absence of hazards. Considering current knowledge, it seems that it is not realistic option.	

5. Is there a need to exempt certain **uses** of nanomaterials?

Yes, certain uses of nanomaterials should be exempted from a notification system	X
No, all uses of nanomaterials should be subject to notification obligations	
If yes, which uses should be exempted and why? (in terms of specific exposure scenarios, available knowledge, absence of hazards, etc.)	
Refer to answer above.	

Section IX – Structured approach to collect information ("*Nanomaterials Observatory*")

A Nanomaterials Observatory is intended to be a structured approach to collect information on nanomaterials on the market and to present it in a clear and user-friendly way.

1. 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	X
b) Information from market studies on nanomaterials and products containing nanomaterials	X
c) Information on the use of nanomaterials across Europe	
d) Information concerning products containing nanomaterials	X

e) Information on the hazards and risks of nanomaterials	X
f) Other	
If other, please explain or add any comment:	

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

We don't have detailed good idea, but a party consisting of Industry, university, NGO and government might be helpful to ask how to collect which kind of information.

Section X - Potential use and benefits of a nanomaterial registry

1. In what way could the information on nanomaterials from registries be potentially useful (tick all that apply):

a) Risk assessment and/or risk management	X
b) Enforcement of worker protection	X
c) Promotion of safe use of nanomaterials in products	X
d) Development of strategies to ensure the safe use of nanomaterials	X
e) Informed purchasing decisions by consumers	
f) General education of the public	X
g) Other purposes (please specify below)	

2. 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):

Risk is different by each uses including exposure scenario and notification per substance sometimes doesn't reflect its risk and hazard in uses. What it is the most important thing as final objective is to inform citizen appropriate information to be able to handle nanomaterials in safety way.

It is unrealistic to provide such information for all products by uses, but it may be possible to create some classification in practical and workable way.

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

There is no standardized analytical measurement methods/conditions and no obligation for nanomaterial less than 1 ton in current framework of chemicals legislation.

It depends on registry requirement at European level and it might be able to be covered by REACH

amendment or implementation of guidance, but if a European nanomaterial registry clarify this points together with nanomaterial definition, more correct and useful information will be gathered.

Otherwise, insufficient or mis-understandable information will be mixed and it will lead to both unnecessary insecurity and non-beneficial cost for industries.

From different angle, it might be linked to leading position for EU regarding nanotechnology.

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

We hope that a global and good functioning Registry can be established and the market will develop positively.

Thank you very much for answering our questions.