Council of European Employers of the Metal, Engineering and Technology-based industries

Impact Assessment on Possible Measures to Increase Transparency on Nanomaterials on the Market Public Consultation – Non-industry Stakeholders

General Remarks:

The European MET (Metal, Engineering and Technology-based Industries) industry is increasingly harnessing the benefits of nanomaterials and nanotechnology to provide much needed 'economic growth' within the EU. Industry needs to be able to utilise the societal benefits of nanotechnology without being disadvantaged by regulation based on unjustified precautionary principles. If it is hindered, European industry is likely to become non-competitive in a global marketplace. The challenge will be to ensure and to demonstrate the safe use of nanomaterials whilst ensuring a competitive marketplace within a global economy.

Nanotechnology has been identified as a key enabling technology (KET) that can found in applications in virtually every sector of industry. In addition, the EU has a strong capability to engineer and develop nanotechnologies in a safe and responsible manner. As well as having societal benefits, there is a large employment potential to be gained from increased use by manufactures of this technology.

The approach proposed by the Commission in its second regulatory review is welcomed. It is logical to consider first how existing legislation is suited to address the potential concern related with the use of nanomaterials and adapt it if necessary. We consider that this applies not only to the REACH regulation, in which nanomaterials are covered, but also to worker protection legislation.

As stated in the second regulatory review, nanomaterials should be considered in the same way as other chemicals. Some may be hazardous for human health and some may not. Thus, when hazardous properties of a specific nano-substance are established on the basis of scientific evidence, it is possible to use existing legislative tools dealing with risks related to chemicals (Directives 98/34 and 2004/37) and to include this substance in the scope of the relevant Directive. No changes to European H&S directives seem necessary.

What matters most to MET companies is the real risk associated with the use of nanomaterials and the selection of appropriate controls to deal with it. This implies that:

- Knowledge on hazardous properties of specific nanomaterials has to be further improved and will be taken up within the existing legal framework (e.g. registration under REACH, self-classification under CLP and use of SDS for substances).
- Knowledge of risks associated with nanomaterials within final products, linked to potential release and exposure in the nanoparticle form should be further developed
- Registration for a broad scope of products and substances based on a hazard based approach should be avoided, on the basis that some risks from nanomaterials will be insignificant.

<u>It is imperative to make the following distinction between natural nanomaterials and manufactured nanomaterials,</u> which is currently absent.

Nanomaterials have always existed and are found in everyday items e.g. a cup of coffee, smoke etc. Meanwhile, manufactured nanomaterials concern completely newly designed substances which have no natural counterpart e.g. TiO2 in nano paint. In this example, the concentration of TiO2 in nano size

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in the nano paint is deliberately increased to give the nano paint a certain quality or property.

However, it should be noted that the current EU definition *(Commission Recommendation 2011/696/EU)* does not have this distinction and provides no specific definition for manufactured nanomaterials. This distinction should be taken on board when the definition outlined in *Commission Recommendation 2011/696/EU* is reviewed by the end of 2014.

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

Public Consultation – Non-industry Stakeholders

Background

As part of the Communication on the Second Regulatory Review on Nanomaterials[1], 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)/02/14[2]). 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 online[3]. Further reports (including revised versions of the two reports) will be published on this website as they become available.

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[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.rpaltd.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.rpaltd.co.uk/news-nano-consult.shtml

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 reporting scheme for manufactured nanomaterials produced, imported or distributed in its territory. The Interministerial decree No. 2012-232 entered into force in January 2013[4]. 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 online[5]. 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 Portal[6].

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 Nanomaterial[7]. For the purpose of this consultation, only manufactured nanomaterials should be taken into consideration.

Please see General Remarks on pages 1 & 2. In short, the above Commission recommendation did not provide a definition for manufactured nanomaterials. It is imperative that a distinction is made between natural nanomaterials and manufactured nanomaterials.

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.

If you responding to this questionnaire on behalf of/as a private company or industry association, please return to the Public Consultation home page[8] and complete the questionnaire for 'industry stakeholders'.

4 www.r-nano.fr

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

6 http://ec.europa.eu/consumers/sectors/cosmetics/cpnp/

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):

Your name:	**CEEMET**
Name of organisation* (if applicable):	**CEEMET (Council of European Employers of the Metal, Engineering and Technology-based Industries)**
Town/city:	**Brussels**
Country*:	**Belgium**
e-mail Address:	**diarmuid.lynch@ceemet.org**
Transparency Register ID number[9]:	**CEEMET is registered under the European Union 'Transparency Register' - ID Number:61370904700-45**

2. Please indicate if you are responding to this questionnaire on behalf of/as:

a)	an individual	
b)	a public authority/public administration	
c)	a health and safety institute/academic organisation/research organisation	
d)	a consumer organisation/trade union/environmental organisation/non-governmental organisation	
e)	other (please specify below)	X
	CEEMET is the Council of European Employers of the Metal, Engineering and Technology-based Industries. CEEMET is a non-for profit organisation representing European MET (Metal, Engineering and Technology-based Industries) employers. We speak on behalf of more than 200,000 companies (mostly SMEs), that provide employment for 35 million people.	

3. 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	

4. 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	

[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: ***Not applicable***

Section III – Problem definition and objectives

1. 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

Please provide additional comments:

For statements (b) and (d), consumers are not usually in a positon to be able to assess the risks from nanomaterials - especially manufactured nanomaterials (MNM). A distinction needs to be drawn between any risks at a consumer level between nanomaterials and MNM. Consumers are not directly exposed to MNM. The risk lies in the production phase of MNM. Therefore, risks are highest at the level of chemical producers, paint manufactures, etc.

2. 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 platform[10]) 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						
b) Provide consumers with relevant information on products containing nanomaterials on the market						
c) Maintain competitiveness and innovation of businesses bringing nanomaterials or products containing nanomaterials to the market (including SMEs)						
d) Ensure consumer trust in products containing nanomaterials						
e) Ensure the availability of relevant information on the presence of nanomaterials or products containing nanomaterials on the market						
f) Ensure the proportionality of the information requirements and the associated costs and administrative burden.						

[10] http://ihcp.jrc.ec.europa.eu/our_databases/web-platform-on-nanomaterials

g) Protect confidential business information						

Please provide additional comments:

It is not possible to answer above question as there are three different elements mixed together, in the questions which does not provide clarity when choosing how to answer. Do the above questions refer specifically to (1) REACH, (2) CLP (3) consumer legislation or (3) the currently available database? As the responder is asked to score from 1 – 5 on this, it is impossible to evaluate these three separate elements into a single score. As stated already, these questions which cover at least three different elements and therefore require at least three different answers for each element.

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

Please provide additional comments:

Registration (into a nanoregister) is a not a solution for the safe use of MNM. We do not believe that registration is the answer to managing and controlling any possible health risks from nanomaterials. Any registers and notification schemes should be linked to the supplier of MNM.

Additionally, due to the current REACH methodology, nanoregisters would only add a supplementary administrative burden on the complete value chain. Information regarding MNM should start at the top level at the production phase of MNM i.e. supplier. REACH is the existing instrument to achieve this.

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	X
I am not aware of any classified nanomaterials	

I am aware of DNELs/PNECs/OELs[11] 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
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): **This question is subjective given that there are risks associated with nanomaterials, while much work is ongoing within the OECD on risk assessment as well as work on the safe use of nanomaterials. However, significant challenges within this framework given the complexity of nanomaterials which influence strongly the behaviour, thinking about particle distribution, shape, etc., all factors potentially influencing the behaviour of the same nanomaterials. There is exposure potential mostly linked for MNM in the framework of the production and application of nanomaterials. This exposure risk can be well controlled using the OECD's guidelines at the level, such as the correct protective measures (e.g. double gloves, extraction etc.)**	

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	
I am not aware of any health and/or environmental incidents which have occurred	X
Please explain (if any, please report the events and any scientific publication):	

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	X
I do not know	
If appropriate, please explain further: **Any potential risk from manufactured nanomaterials is at the upstream stage of manufacturing (supplier level). Consumers are not exposed at this stage of manufacturing. A nanomaterial register would not provide any added value in controlling risk. Risks about nanomaterials should be linked to the REACH registration information and analysis process.**	

Section V – Consumer trust

1. In case information on the presence of nanomaterials in specific products were made available, what impact do you think this would have on consumers? (Please tick all that would apply)

[11] **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

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: This is not a very objective question. For example, would people stop drinking coffee, if information indicated that a nano liquid was contained in it? Furthermore, the question is misleading as it does not clearly make the distinction between natural nanomaterials and manufactured nanomaterials.	

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	
Comments: **N/A – This depends entirely on the source of the information.**	

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)	NO
b) have no significant impact on innovation	
c) hamper innovation in the EU (e.g. through concerns about confidential business information or through additional costs related to providing information)	YES
Comments:	

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	NO
b) enhance the competitiveness of European companies against extra-EU companies	NO
c) have no significant impact on intra-EU competitiveness	
d) have no significant impact on the competitiveness of European companies against extra-EU companies	NO
e) hamper intra-EU competitiveness	YES
f) hamper the competitiveness of European companies against extra-EU companies	YES
Please explain: **A nanomaterial registry would hamper competitiveness and innovation of European companies and may help non-EU competitors. Unless such a registry were applied to non-EU competitors they would benefit from information freely available from such a registry. This may mean EU companies forgoing any competitive advantage.**	

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

Not applicable

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.

Notification per use would be very bureaucratic with no obvious added value in doing this. If a registry is considered, it should start with a notification per nanomaterial. Notification should focus on upstream suppliers where nanomaterials are manufactured rather than downstream users.

If you have a nano variant of a substance, it would be more logical to follow these nanomaterials from the source i.e. the supplier and importer. Therefore, a top-down approach is preferential similar to the REACH methodology. Information regarding MNM should start at the top level at the production phase of MNM e.g. supplier level. REACH is the existing instrument to achieve this.

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

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

Please explain:

Downstream users should not be subject to notification requirements because they do not have the information indicating if a substance or article contains nanomaterials. Notification should focus on upstream suppliers where nanomaterials are manufactured rather than downstream users.

It is impossible to control whether or not a product is containing nanomaterials. It would be a gigantic purely administrative burden for downstream users to be subjected to such notification requirements.
A top-down approach is preferential similar to the REACH methodology. It is better to follow these nanomaterials from the source i.e. the supplier and importer.

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

a) Substances	
b) Mixtures containing nanomaterials	
c) Articles with intended release of nanomaterials	

d) Articles containing nanomaterials without intended release	
Please explain: **Downstream users do not have the resources and capacity to know all the properties of substances and articles containing nanomaterials they use.**	

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

Yes, certain types of nanomaterials should be exempted from a notification system	
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.)	
Comments: REACH regulation along with Health and Safety workplace legislation should be the route to facilitate any potential human and environmental risk from nanomaterials. All types of nanomaterials should be exempt from a registration system, but could be subject to the REACH methodology.	

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.)	
Exempt many naturally occurring nanomaterials which are known not to cause any ill-health	

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	X
d) Information concerning products containing nanomaterials	X
e) Information on the hazards and risks of nanomaterials	X
f) Other	X
If other, please explain or add any comment: **We generally support the idea of a nanomaterials observatory. It should be voluntary in nature and work in tandem closely with SCOEL (Scientific Committee on Occupational Exposure Limits) and ECHA (European Chemicals Agency).**	

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

Working closely with SCOEL and ECHA, such information could be presented as a chapter in data safety sheets which concern nano particles.

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	
b) Enforcement of worker protection	
c) Promotion of safe use of nanomaterials in products	
d) Development of strategies to ensure the safe use of nanomaterials	
e) Informed purchasing decisions by consumers	
f) General education of the public	
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):

CEEMET does not think a registry system would contribute to the goals set out.

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

None

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

The idea of a nano observatory is an interesting proposal and warrants more investigation. **Overall, CEEMET believes that regulatory simplification and a universal approach to hazardous chemical substances is urgently needed at EU Level** **There is an imperative to establish a single EU regulatory framework which covers both occupational health and safety and environmental exposure to chemical substances and materials. The existing EU framework is confusing, is overlapping and is not coordinated. It is too complex for most employers, especially SME's, to understand.** **In the area of worker H&S, employers must currently comply with the following five different**

pieces of EU chemicals legislation: REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) Regulation, Chemical Agents Directive (CAD), Carcinogens and Mutagens Directive (CMD), the Seveso Directive and the Classification, Labelling and Packaging (CLP) Regulations.

Simplifying and consolidating the existing regulatory framework will have the added value of reducing administrative burdens and compliance costs, thus improving EU competitiveness globally. It is also vital that there is joint policy coordination between the Commission's Directorates-General to create a unified EU hazardous substances framework encompassing all elements of CAD, CMD, CLP, Seveso and REACH, as part of the on-going REFIT programme.

Thank you very much for answering our questions.