POSITION STATEMENT

September 2013

AmCham EU's response to DG ENVI's public consultation relating to the REACH Annexes on Nanomaterials

Questions marked with * require an answer to be given

General information on the respondent

1. **On what basis are you responding to this public consultation exercise?***

As an individual citizen	
On behalf of an organisation	X

2. **Please specify the organisation you represent***

Private company	X
Government authority	
Academic/research institution	
Non-governmental organisation	
Industrial or trade association	
Consumer association	
Other	

If you answered 'Other' to question 2 then please give details below:

3. **In which Member State is your organisation principally based?** *

Austria		Germany		Poland	
Belgium	X	Greece		Portugal	
Bulgaria		Hungary		Romania	

American Chamber of Commerce to the European Union
Avenue des Arts/Kunstlaan 53, 1000 Brussels, Belgium
Telephone 32-2-513 68 92 Fax 32-2-513 79 28
Email: info@amchameu.eu

Secretariat Point of Contact: Julie Linde Kjeldsen ; jlk @amchameu.eu +32 2 289 1015

Croatia		Ireland		Slovakia	
Cyprus		Italy		Slovenia	
Czech Republic		Latvia		Spain	
Denmark		Lithuania		Sweden	
Estonia		Luxembourg		United Kingdom	
Finland		Malta		None of the above	
France		Netherlands			

4. How many employees does your company have? *

Large: >250	
Small: <50	X
Medium: <250	
Micro: <10	

5. The principle activity(ies) of the organisation you are responding on behalf…

Multiple answers should be possible*

Manufacturing/importing chemicals	X
Manufacturing/importing nanomaterials	X
Using chemicals	X
Using nanomaterials	X
Research institution	
Consumer organisation	
Environmental NGO	
Other	Trade association

If you answered 'Other' to question 5 then please give details below:

AmCham EU speaks for American companies committed to Europe on trade, investment and competitiveness issues.

6. Your role within the organisation you are responding on behalf of…*

Board Director / Senior Manager	
Manager	
Researcher/Scientist	
Administrator	
Other	Policy Officer

If you answered 'Other' to question 6 then please give details below:

Policy Officer in charge of the AmCham EU Environment Committee and Nano Working Group

7. Your email address for correspondence*

jlk@amchameu.eu

8. What involvement has your organisation had within the last three years in relation to REACH? *

Directly involved	X
Indirectly involved	
Not involved	

9. What involvement has your organisation had within the last three years in relation to the regulation of nanomaterials? *

Directly involved	
Indirectly involved	X
Not involved	

10. How would you describe your knowledge of REACH? *

Excellent	X
Good	
Fair	
Bad	
None at all	

11. How would you describe your knowledge of nanomaterials? *

Excellent	X
Good	
Fair	
Bad	
None at all	

Problem definition

In this next section we would like to establish your view of how nano materials are currently treated within REACH. It is important to stress that the focus is on the current registration provisions and information requirements for registration of nanomaterials.

12. What is your overall view of the current registration provisions and information requirements for the registration of nanomaterials? *

Very clear	
Clear	
Unclear	X
Very unclear	
Don't know	

13. If in Question 12 unclear requirements have been acknowledged, what do you consider is causing this? Can you assess the possible impacts of the suggested causes listed below?

	Strong impact on causing the problem	Some impact on causing the problem	No effect	Don't know
a. Absence of a definition of nanomaterial until October 2011*	X			
b. Determination of nanomaterial according to the current European Commission definition of nanomaterials*	X			
c. Current information requirements on how to describe the scope of registration*		X		
d. Current information requirements on substance identification*	X			
e. Current information requirements on physical-chemical properties*		X		

f. Current information requirements on human health toxicity*		X		
g. Current information requirements on ecotoxicity and environmental fate*		X		
h. Current information requirements on chemical safety assessment*		X		
i. Current information requirements on use of grouping and category approaches for nanoforms and other adaptation of the testing regime*	X			
j. Current requirements on application of test methods and the relevance of results of tests performed on another form of material*	X			
k. Lack of specific guidance*		X		
l. Other	X			

If you answered 'Other' to question 13 then please give details below:

Due to the absence of validated measurement techniques, it is very difficult to determine conclusively and unambiguously whether a substance is a nanomaterial.

14. Do you believe there are any other areas of potential uncertainty or lack of clarity? Please set out below: (maximum 2000 characters)

The definition also covers not intentionally manufactured nanomaterials. This requires testing all powdered material to identify the percentage of nano. The inclusion of aggregates and agglomerates of primary nanoparticles in the definition and the lack of validated universal methods make this determination in real life situation unreliable.

15. In the next two questions we would like you compare the information requirements for nanomaterials with the information requirements for other forms of a substance under REACH. How would you compare the costs (money, time and administration) arising from the information requirements within the registration process for nanomaterials when compared to the costs for other forms of a substance? *

Significantly higher cost for nanomaterials	X (already due to determination whether the substance is nano)
Higher cost of compliance for nanomaterials	
No difference in relation to the cost of compliance between nanomaterials and other materials	
Lower cost of compliance for nanomaterials	
Significantly lower the cost of compliance for nanomaterials	
Don't know	

16. How would you compare the impact on the safety of nanomaterials arising from the information requirements within the registration process for nanomaterials when compared to that for other forms of a substance? *

Significantly higher comparative safety for nanomaterials	
Higher comparative safety for nanomaterials	
No difference in relation to the safety of nanomaterials and other materials	X
Lower overall safety for nanomaterials	
Significantly lower comparative safety for nanomaterials	
Don't know	

17. What do you believe would be the impact of the following measures on clarity for registrants?

	Significantly increase clarity	Increase clarity	No difference	Reduce clarity	Significantly reduce clarity	Don't know
a. More specific ECHA tools and guidance for nanomaterials*		X				
b. Application of the Commission's definition of Nanomaterials*					X	
c. Introduction of specific requirements in the REACH Annexes*		X				
d. Other	X					

If you answered 'Other' to question 17 then please give details below:

Restriction of the definition to only cover intentionally engineered nanomaterials would clarify the requirements. Identification of nano size related characteristics that are already mature enough and measurable to use as regulatory requirement would add clarity. REACH should not be misused to gather data l'art pour l'art for future research.

The European Commission's definition of nanomaterials

This section is focused on the impact of the European Commission's definition of nanomaterials.

18. Has the Commission's definition on nanomaterials changed the number of nanomaterials in your company's portfolio?

Pursuant to the definition the number of nanomaterials in your company's portfolio has…*

Significantly increased	
Increased	X
No change	
Decreased	
Significantly decreased	
Don't know	

Not applicable	

19. Has the Commission's definition on nanomaterials caused changes to your safety assessment or dossier preparation/update in your company?

How would you range the change in your safety assessment or dossier preparation/update for nanoforms covered by the definition*

Significantly changed	
Changed	X
No difference	
Don't know	
Not applicable	

20. If you answered 'Significantly changed' or 'Changed' to question 19 then please give details below:*

Better characterization	X
Specific consideration of different forms (e.g. relevance of test results)	X
Separate safety consideration of different forms	
Anticipation of specific regulatory provisions	X
Other?	X

If you answered 'Other' to question 20 then please give details below:

It depends whether the nanoform is a well characterised existing substance just 'caught' by the definition or an existing substance intentionally engineered in the nanoform.

Policy options

The focus for this section is to get your assessment as to the potential impact of five broad potential changes in the information requirements for the registration of nanomaterials under REACH. For each option we would like you to consider the potential impact on cost, safety and overall efficiency of the regulatory process.

The options will be measured against a 'baseline'. In the impact assessment the baseline will be titled 'option 1'. The baseline is a description of the current situation under REACH assuming no new policy actions but implementation based on what currently is known i.e. including the guidance update from April 2012 and full use of the Commission Recommendation on the definition of Nanomaterial. Moreover the baseline must make certain assumptions of how the current situation may develop over time when dossiers are brought into

compliance through updates, evaluation decisions, etc.

Option 2 – Clarity option

Currently many dossiers are of a quality falling below the baseline obligations. This is believed to be the case for several reasons including the lack of definition on Nanomaterialand specific guidance at the time of registration as well as that the existing information requirements are rather general and thus not targeting nanomaterials or even just multiplicity of forms within one dossier. This option therefore would introduce changes to certain Annex provisions clarifying what companies are expected to do in accordance with the registration obligations of REACH and the specific guidance which takes into account CA/59/2008 and the RIPoN 2 and 3 reports from 2011.

The measures are targeting more precise description of the scope of the dossier, clarification of requirements for nanoform specific information in a number of specific end-point sections, and clarification of how data is to be reported.

The measures needing clarification in this option are based on the advice the Commission requested from ECHA and the response given by ECHA in the context of the Nano-support project for this impact assessment. This option would not change any existing obligations as they are understood to exist, but it would provide companies with a clearer understanding on what information they must provide in the registration dossier. This would be a help to companies and ECHA alike.

A measure marked with '*****' is supposed to be introduced in the REACH Annexes for substance identification, physico-chemical properties, human health hazards, environmental fate and environmental hazards. A measure marked with '******' refers to human health hazards, environmental fate and environmental hazards only.

In the next three questions we would like you to consider the different impacts of measures taken under the Option 2.

21. Considering firstly the potential impact of the following measures on the cost of providing information to register nanomaterials under the provisions of REACH

	Significantly increase the cost of compliance	Increases the cost of compliance	Have no impact on the cost of compliance	Reduce the costs of compliance	Significantly reduce the cost of compliance	Don't know
a. Explicitly require registrants to describe the scope of the registration dossier*		X				
b. Explicitly require	X					

registrants to provide more detailed characterization of nanomaterials/nanoforms*						
c. *Require that nanoforms are explicitly addressed in the endpoint sections*	X					
d. *Require detailed description of the test material / sample and sample preparation*	X					
e. *Require scientific justifications for grouping / read across / QSAR and other non-testing approaches for different forms*		X				
f. **Require considerations of most appropriate / relevant metric with preferable presentation in several metrics*		X				
g. Require that bioaccumulation is addressed specifically for the nanoform*	X					
h. Specify that absorption/desorption behavior of nanomaterials should not be assessed based on K_d values derived fromK_{oc} and K_{ow}*	X					
i.Require identification of uses and exposure assessment of the nanoform*	X					
j. When considered together what do you believe the impact of the measures outlined above would be? *	X					

22. Secondly considering the potential impact of the following measures on the safety of nanomaterials

	Significantly	Increase the	Have no	Reduce the	Significantly	Don't

	increase the safe use of nanomaterials	safe use of nanomaterials	impact on the safe use of nanomaterials	safe use of nanomaterials	reduces the safe use of nanomaterials	know
a. Explicitly require registrants to describe the scope of the registration dossier*			X			
b. Explicitly require registrants to provide more detailed characterization of nanomaterials/nanoforms*			X			
c. *Require that nanoforms are explicitly addressed in the endpoint sections*			X			
d. *Require detailed description of the test material / sample and sample preparation*			X			
e. *Require scientific justifications for grouping / read across / QSAR and other non-testing approaches for different forms*		X				
f. **Require considerations of most appropriate / relevant metric with preferable presentation in several metrics*		X				
g. Require that bioaccumulation is addressed specifically for the nanoform*			X			
h. Specify that absorption/desorption behavior of nanomaterials should not be assessed based on K_d values derived from K_{oc} and K_{ow}*			X			
i. Require identification of uses and exposure assessment of the nanoform*	X					
j. When considered together what do you			X			

believe the impact of the measures outlined above would be? *						

23. Finally considering the overall potential impact of the following measures on the <u>efficiency</u> of the regulatory process within REACH in terms of striking a balance between appropriate demonstration of safe use and the cost (money, time and administration) ti will take to do it.

	Significantly higher overall efficiency for the regulation of nanomaterials	Higher overall efficiency for the regulation of nanomaterials	No difference in relation to the overall efficiency between nanomaterials and other materials	Lower overall efficiency for the regulation of nanomaterials	Significantly lower overall efficiency for the regulation of nanomaterials	Don't know
a. Explicitly require registrants to describe the scope of the registration dossier*			X			
b. Explicitly require registrants to provide more detailed characterization of nanomaterials/nanoforms*			X			
c. *Require that nanoforms are explicitly addressed in the endpoint sections*			X			
d. *Require detailed description of the test material / sample and sample preparation*			X			
e. *Require scientific justifications for grouping / read across / QSAR and other non-testing approaches for different forms*			X			
f. **Require considerations of most appropriate / relevant metric with preferable presentation in several metrics*			X			
g. Require that bioaccumulation is			X			

addressed specifically for the nanoform*						
h. Specify that absorption/desorption behavior of nanomaterials should not be assessed based on K_d values derived from K_{oc} and K_{ow}*			X			
i. Require identification of uses and exposure assessment of the nanoform*			X			
j. When considered together what do you believe the impact of the measures outlined above would be? *			X			

Option 3 – Soft law

This option introduces measures of a non-legally binding nature with a view to provide moreclarity. Measures could include updates of guidance, FAQs, CARACAL documents, Directors Contact Group and all other sorts of actions that can take place without changing any legalprovisions.Soft law is the term applied to EU measures, such as guidelines, declarations and opinions, which, in contrast to **Directives**, **Regulations** and decisions, are not binding on those to whom they are addressed. However, soft law can produce some legal effects.

In the next three questions we would like you to consider the different impacts of measures taken under the Option 3.

24. Considering firstly the potential impact of the following measures on the cost of providing information to register nanomaterials under the provisions of REACH.

	Significantly increase the cost of compliance	Increases the cost of compliance	Have no impact on the cost of compliance	Reduce the costs of compliance	Significantly reduce the cost of compliance	Don't know
a. Development of further ECHA guidance and other…?*			X			
b. Enhanced use of the			X			

Directors Contact Group*						
c. Initiatives to enhance information and dissemination at EU and Member State level*	X					
d. When considered together what do you believe the impact of the measures outlined above would be? *		X				

25. Secondly considering the potential impact of the following measures on the safety of nanomaterials

	Significantly increase the safe use of nanomaterials	Increase the safe use of nanomaterials	Have no impact on the safe use of nanomaterials	Reduce the safe use of nanomaterials	Significantly reduces the safe use of nanomaterials	Don't know
a. Development of further ECHA guidance and other…?*		X				
b. Enhanced use of the Directors Contact Group*			X			
c. Initiatives to enhance information and dissemination at EU and Member			X			

State level*						
d. When considered together what do you believe the impact of the measures outlined above would be? *			X			

26. Finally considering the overall potential impact of the following measures on the efficiency of the regulatory process within REACH in terms of striking a balance between appropriate demonstration of safe use and the cost (money, time and administration) it will take to do it.

	Significantly higher overall efficiency for the regulation of nanomaterials	Higher overall efficiency for the regulation of nanomaterials	No difference in relation to the overall efficiency between nanomaterials and other materials	Lower overall efficiency for the regulation of nanomaterials	Significantly lower overall efficiency for the regulation of nanomaterials	Don't know
a. Development of further ECHA guidance and other…?*	X					
b. Enhanced use of the Directors Contact Group*			X			
c. Initiatives to enhance information and dissemination at EU and Member State level*				X		
d. When considered			X			

together what do you believe the impact of the measures outlined above would be? *						

Option 4

The option contains additional measures that are generally – from a scientific or technical perspective - recommended to demonstrate safe use in cases where the existing information requirements in REACH are not tailored for nanomaterials or where specific considerations are required for nanomaterials. **The option is assuming fullimplementation of Option 2**.

The measures in this option are based on the advice the Commission requested from ECHA and the response given by ECHA in the context of the Nano-support project for this impact assessment. Measures are likely to be; revised or additional endpoints for, nanomaterials, e.g. in low tonnages; inhalation exposure route for acute toxicity and repeated dose toxicity studies; and a non-bacterial gene mutation study (in vitro); in all annexes exclusion of waiving possibility on the basis of insolubility or lack of short term toxicity, and a priority for test on soil and sediment organisms.Most provisions are listed as applicable to nanoforms. This limits the scope of the measure to be applicable to nanomaterials only.

A measure marked with '*' is supposed to be introduced in the REACH Annexes for environmental fate and environmental hazards. A measure marked with '**' on the other hand refers to exposure assessment and risk characterisation.

In the next three questions we would like you to consider the different impacts of measures taken under the Option 4.

27. **Considering firstly the potential impact of the following measures on the cost of providing information to register nanomaterials under the provisions of REACH**

	Significantly increase the cost of compliance	Increases the cost of compliance	Have no impact on the cost of compliance	Reduce the costs of compliance	Significantly reduce the cost of compliance	Don't know
a.Include information on dustiness*			X			
b. Require acute		X				

toxicity data for the most relevant route of exposure*						
c. Change 'particles' to '(nano)particles' for repeated dose toxicity studies (inhalation) *	X					
d. Require non-bacterial in vitro gene mut*ation study		X				
e. *Consider water solubility in relation to test waiving*		X				
f. *Specify that long term testing should not be waived based on lack of short term toxicity*		X				
g. Specify that algae testing should not be waived based on insolubility*		X				
h. Require that testing on soil and sediment organisms is prioritized*	X					
i.**Require consideration of most appropriate / relevant metric with preferable presentation in several metrics*		X				
j. When		X				

considered together what do you believe the impact of the measures outlined above would be? *						

28. Secondly considering the potential impact of the following measures on the safety of nanomaterials

	Significantly increase the safe use of nanomaterials	Increase the safe use of nanomaterials	Have no impact on the safe use of nanomaterials	Reduce the safe use of nanomaterials	Significantly reduces the safe use of nanomaterials	Don't know
a. Include information on dustiness*		X				
b. Require acute toxicity data for the most relevant route of exposure*			X			
c. Change 'particles' to '(nano)particles' for repeated dose toxicity studies (inhalation) *			X			
d. Require non-bacterial in vitro gene mutation study*		X				
e. *Consider water solubility in relation to test waiving*			X			
f. *Specify that long term testing should not be waived based on lack of short term toxicity*			X			
g. Specify that algae testing		X				

should not be waived based on insolubility*						
h. Require that testing on soil and sediment organisms is prioritized*			X			
i.**Require consideration of most appropriate / relevant metric with preferable presentation in several metrics*			X			
j. When considered together what do you believe the impact of the measures outlined above would be? *			X			

29. Finally considering the overall potential impact of the following measures on the efficiency of the regulatory process within REACH in terms of striking a balance between appropriate demonstration of safe use and the cost (money, time and administration) it will take to do it.

	Significantly higher overall efficiency for the regulation of nanomaterials	Higher overall efficiency for the regulation of nanomaterials	No difference in relation to the overall efficiency between nanomaterials and other materials	Lower overall efficiency for the regulation of nanomaterials	Significantly lower overall efficiency for the regulation of nanomaterials	Don't know
a. Include information on dustiness*			X			
b. Require acute toxicity data for the most relevant route of				X		

exposure*						
c. Change 'particles' to '(nano)particles' for repeated dose toxicity studies (inhalation) *				X		
d. Require non-bacterial in vitro gene mutation study*			X			
e. *Consider water solubility in relation to test waiving*			X			
f. *Specify that long term testing should not be waived based on lack of short term toxicity*				X		
g. Specify that algae testing should not be waived based on insolubility*			X			
h. Require that testing on soil and sediment organisms is prioritized*				X		
i.**Require consideration of most appropriate / relevant metric with preferable presentation in several metrics*			X			
j. When considered together what do you believe				X		

the impact of the measures outlined above would be? *						

Option 5

In light of the economic and innovation potential of nanomaterials, this option aims to enhance competitiveness and innovation of companies by providing greater specificity to core implementation issues and by reducing the economic burden for complying with REACH. The proposed measures foresee tailored information requirements for nanomaterials placed on the market, reduce certain information requirements, clarify regulatory provisions, maximize the use of non-testing methods and exposure categorisation, and maintain openness to flexible solutions.

In the next three questions we would like you to consider the different impacts of measures taken under the Option 5.

30. Considering firstly the potential impact of the following measures on the cost of providing information to register nanomaterials under the provisions of REACH

	Significantly increase the cost of compliance	Increases the cost of compliance	Have no impact on the cost of compliance	Reduce the costs of compliance	Significantly reduce the cost of compliance	Don't know
a. Describe whether and which different nanoforms are covered in the chemical safety assessment, including a statement when and how information on one form is used to demonstrate safety of other forms*		X				
b. Specify that nanoform specific information is required only when an insoluble or poorly soluble nanoform put on the market is classified hazardous/dangerous*					X	
c. Specify that a				X		

coated nanomaterial is considered as a special mixture e.g. in classification and labeling as accepted e.g. alloys*						
d. Specify that the granulometry concept in 7.14 of Annex VII includes also shape and surface area of nanomaterials*	X					
e. Specify that the information on dustiness is required for nanoforms only where relevant for the worker safety assessment*			X			
f. Specify that waiving of endpoint specific information requirements for classified insoluble or poorly soluble nanoforms applies as for any other forms and also when nanoforms do not significantly differ from each other in specific endpoints*				X		
g. Specify that the use of non-testing methods (e.g. read across, grouping, categorisation etc. methods) is a priority for nanoforms*					X	
h. Specify and require explicitly that waiving of testing on the basis of exposure conditions and categories applies also for nanoforms, in particular when nanoforms are completely reacted					X	

(cured), incorporated or embedded into a completely cured matrix or permanent solid polymer forms, or otherwise used in closed systems or controlled conditions*						
i. Specify that absorption/desorption behavior of nanoforms can be based on biological surface adsorption index, affinity coefficient or other relevant parameters*				X		
j. No specific obligations for nanoforms in 1-10 tonnage band*			X			
k. No specific obligations for nanoforms in 10-100 tonnage band*				X		
l. No nanomaterial specific obligation for 2nd exposure route at 10-100 tonnage band for acute toxicity*				X		
m. Specify that information generated according to existing test guidelines and/or test methods is sufficient for the purposes of hazard assessment of nanomaterials under REACH*					X	
n. A nanoform consisting of aggregates is considered same as bulk form and the same endpoint					X	

information for (eco)toxicological and environmental fate apply*						
o. No specific obligations for nanoforms to provide ecotoxicological and environmental fate information*					X	
p. Create presumption that non-testing methods are valid for nanomaterials in all endpoints*				X		
q. Amend the granulometry information requirements in Annex VII (1-10 tonnage band) for nanomaterials in line with Annex II, Section 9.1.a of REACH on Safety Data Sheet and respective ECHA Guidance on Compilation of Safety Data Sheets*			X			
r. Specify explicitly that coating agents of nanoforms are registered separately in line with practices already accepted for e.g. alloys*					X	
s. Reduce the set of combined methods for nanomaterials determination (Nanomaterial definition, EU/2011/696) to only one (e.g. DLS) *					X	
t. For the purposes of REACH, consider aggregates as					X	

constituent particle (primary particle) in the nanomaterial definition (EU/2011/696) *						
u. Omit mutagenicity and acute toxicity tests in lower tonnages. No skin irritation, skin corrosion or *in vitro* eye irritation information required for 10-100 t/y if the assessments in 1-10 t/y has been negative*					X	
v. When considered together what do you believe the impact of the measures outlined above would be? *					X	

31. Secondly considering the potential impact of the following measures on the safety of nanomaterials

	Significantly increase the safe use of nanomaterials	Increase the safe use of nanomaterials	Have no impact on the safe use of nanomaterials	Reduce the safe use of nanomaterials	Significantly reduces the safe use of nanomaterials	Don't know
a. Describe whether and which different nanoforms are covered in the chemical safety assessment, including a statement when and how information on one form is used to demonstrate safety of other forms*		X				
b. Specify that nanoform specific information is required only when an insoluble or poorly soluble nanoform put on the market is classified hazardous/dangerous*			X			

c. Specify that a coated nanomaterial is considered as a special mixture e.g. in classification and labeling as accepted e.g. alloys*			X			
d. Specify that the granulometry concept in 7.14 of Annex VII includes also shape and surface area of nanomaterials*			X			
e. Specify that the information on dustiness is required for nanoforms only where relevant for the worker safety assessment*			X			
f. Specify that waiving of endpoint specific information requirements for classified insoluble or poorly soluble nanoforms applies as for any other forms and also when nanoforms do not significantly differ from each other in specific endpoints*			X			
g. Specify that the use of non-testing methods (e.g. read across, grouping, categorisation etc. methods) is a priority for nanoforms*			X			
h. Specify and require explicitly that waiving of testing on the basis of exposure conditions and categories applies also for nanoforms, in particular when nanoforms are			X			

completely reacted (cured), incorporated or embedded into a completely cured matrix or permanent solid polymer forms, or otherwise used in closed systems or controlled conditions*						
i. Specify that absorption/desorption behavior of nanoforms can be based on biological surface adsorption index, affinity coefficient or other relevant parameters*			X			
j. No specific obligations for nanoforms in 1-10 tonnage band*			X			
k. No specific obligations for nanoforms in 10-100 tonnage band*			X			
l. No nanomaterial specific obligation for 2nd exposure route at 10-100 tonnage band for acute toxicity*			X			
m. Specify that information generated according to existing test guidelines and/or test methods is sufficient for the purposes of hazard assessment of nanomaterials under REACH*			X			
n. A nanoform consisting of aggregates is considered same as bulk form and the			X			

same endpoint information for (eco)toxicological and environmental fate apply*						
o. No specific obligations for nanoforms to provide ecotoxicological and environmental fate information*			X			
p. Create presumption that non-testing methods are valid for nanomaterials in all endpoints*				X		
q. Amend the granulometry information requirements in Annex VII (1-10 tonnage band) for nanomaterials in line with Annex II, Section 9.1.a of REACH on Safety Data Sheet and respective ECHA Guidance on Compilation of Safety Data Sheets*			X			
r. Specify explicitly that coating agents of nanoforms are registered separately in line with practices already accepted for e.g. alloys*			X			
s. Reduce the set of combined methods for nanomaterials determination (Nanomaterial definition, EU/2011/696) to only one (e.g. DLS) *		X				
t. For the purposes of REACH, consider			X			

aggregates as constituent particle (primary particle) in the nanomaterial definition (EU/2011/696) *						
u. Omit mutagenicity and acute toxicity tests in lower tonnages. No skin irritation, skin corrosion or *in vitro* eye irritation information required for 10-100 t/y if the assessments in 1-10 t/y has been negative*			X			
v. When considered together what do you believe the impact of the measures outlined above would be? *			X			

32. Finally considering the overall potential impact of the following measures on the <u>efficiency</u> of the regulatory process within REACH in terms of striking a balance between appropriate demonstration of safe use and the cost (money, time and administration) it will take to do it.

	Significantly higher overall efficiency for the regulation of nanomaterials	Higher overall efficiency for the regulation of nanomaterials	No difference in relation to the overall efficiency between nanomaterials and other materials	Lower overall efficiency for the regulation of nanomaterials	Significantly lower overall efficiency for the regulation of nanomaterials	Don't know
a. Describe whether and which different nanoforms are covered in the chemical safety assessment, including a statement when and how information on one form is used to demonstrate safety of other forms*		X				
b. Specify that		X				

nanoform specific information is required only when an insoluble or poorly soluble nanoform put on the market is classified hazardous/dangerous*						
c. Specify that a coated nanomaterial is considered as a special mixture e.g. in classification and labeling as accepted e.g. alloys*		X				
d. Specify that the granulometry concept in 7.14 of Annex VII includes also shape and surface area of nanomaterials*				X		
e. Specify that the information on dustiness is required for nanoforms only where relevant for the worker safety assessment*		X				
f. Specify that waiving of endpoint specific information requirements for classified insoluble or poorly soluble nanoforms applies as for any other forms and also when nanoforms do not significantly differ from each other in specific endpoints*		X				
g. Specify that the use of non-testing methods (e.g. read across, grouping, categorisation etc. methods) is a priority		X				

for nanoforms*						
h. Specify and require explicitly that waiving of testing on the basis of exposure conditions and categories applies also for nanoforms, in particular when nanoforms are completely reacted (cured), incorporated or embedded into a completely cured matrix or permanent solid polymer forms, or otherwise used in closed systems or controlled conditions*	X					
i. Specify that absorption/desorption behavior of nanoforms can be based on biological surface adsorption index, affinity coefficient or other relevant parameters*		X				
j. No specific obligations for nanoforms in 1-10 tonnage band*		X				
k. No specific obligations for nanoforms in 10-100 tonnage band*			X			
l. No nanomaterial specific obligation for 2nd exposure route at 10-100 tonnage band for acute toxicity*			X			
m. Specify that information generated according to existing test guidelines and/or test methods is sufficient for the		X				

purposes of hazard assessment of nanomaterials under REACH*						
n. A nanoform consisting of aggregates is considered same as bulk form and the same endpoint information for (eco)toxicological and environmental fate apply*	X					
o. No specific obligations for nanoforms to provide ecotoxicological and environmental fate information*		X				
p. Create presumption that non-testing methods are valid for nanomaterials in all endpoints*		X				
q. Amend the granulometry information requirements in Annex VII (1-10 tonnage band) for nanomaterials in line with Annex II, Section 9.1.a of REACH on Safety Data Sheet and respective ECHA Guidance on Compilation of Safety Data Sheets*			X			
r. Specify explicitly that coating agents of nanoforms are registered separately in line with practices already accepted for e.g. alloys*		X				
s. Reduce the set of		X				

combined methods for nanomaterials determination (Nanomaterial definition, EU/2011/696) to only one (e.g. DLS) *						
t. For the purposes of REACH, consider aggregates as constituent particle (primary particle) in the nanomaterial definition (EU/2011/696) *	X					
u. Omit mutagenicity and acute toxicity tests in lower tonnages. No skin irritation, skin corrosion or *in vitro* eye irritation information required for 10-100 t/y if the assessments in 1-10 t/y has been negative*		X				
v. When considered together what do you believe the impact of the measures outlined above would be? *		X				

Option 6

With this option additional emphasis is put on generation of targeted information with the objective of reduction of uncertainty considering that knowledge is still under development regarding the influence of particle and nanomaterial specific properties on risk. Information generated should also facilitate development of category approaches with all the associated impacts.

Physico-chemical characterisation of different forms covered by the dossier and all their uses, with particular attention given to materials where the forms could change, would be diligently pursued. More specific information will then be requested to be organised separately in the registration dossier with a view to make it easily accessible upon review.

Option 6 assumes full implementation of the measures described in

Option 4, and therefore also the complete Option 2.

In the next three questions we would like you to consider the different impacts of measures taken under the Option 6.

33. Considering firstly the potential impact of the following measures on the cost of providing information to register nanomaterials under the provisions of REACH

	Significantly increase the cost of compliance	Increases the cost of compliance	Have no impact on the cost of compliance	Reduce the costs of compliance	Significantly reduce the cost of compliance	Don't know
a. Apply clear rules on when nanoforms can be in one dossier or in separate ones based on possibility for data sharing *		X				
b. Introduce rules to ensure mandatory separation between nanoforms identified and addressed in the dossier whenever they differ in coating, shape, crystalline form or prescribed classes of particle size distribution*	X					
c. Information requirements for substances covered by Annex III (b) must also apply to nanoforms*		X				
d. For nanoforms, require all	X (Impractical)					

information on potential alterations of hazard due to operational conditions upstream the exposure situation is considered*						
e. For nanoforms, require all available information on the use in considered, even when the use would not be covered by the registration*	X (Impractical)					
f. For nanoforms, require additional physic-chemical characterization along the particle's fate when particle properties impacts on hazard*	X					
g. Phys-chem, (eco)tox and CSA documented separately for each nanoform*	X					
h. For nanoforms, explicitly limit the potential for use of non-testing approaches for		X				

hazard and exposure where science is not consolidated, but encourage its parallel application and documentation*						
i.Require adapted DNEL setting based on different routes through the value chain / specific uses*	X					
j. Add to the SDS information relevant to Nano registries in Member States*	X					
k. Specify that list of substances in Annexes IV and V does not cover nanoforms of these substances*	X					
l. Choose inhalation as the appropriate route of exposure in repeated dose toxicity study unless such exposure can be excluded*	X					
m. Perform toxicokinetic screening*		X				
n. For nanoforms, request 28 day	X					

repeated dose toxicity in Annex VII*						
o. When considered together what do you believe the impact of the measures outlined above would be? *	X					

34. Secondly considering the potential impact of the following measures on the safer handling of nanomaterials

	Significantly increase the safe use of nanomaterials	Increase the safe use of nanomaterials	Have no impact on the safe use of nanomaterials	Reduce the safe use of nanomaterials	Significantly reduces the safe use of nanomaterials	Don't know
a. Apply clear rules on when nanoforms can be in one dossier or in separate ones based on possibility for data sharing*			X			
b. Introduce rules to ensure mandatory separation between nanoforms identified and addressed in the dossier whenever they differ in coating, shape, crystalline form or prescribed classes of particle size distribution*			X			
c. Information requirements for substances			X			

covered by Annex III (b) must also apply to nanoforms*						
d. For nanoforms, require all information on potential alterations of hazard due to operational conditions upstream the exposure situation is considered*			X			
e. For nanoforms, require all available information on the use in considered, even when the use would not be covered by the registration*			X			
f. For nanoforms, require additional physic-chemical characterization along the particle's fate when particle properties impacts on hazard*			X			
g. Phys-chem, (eco)tox and CSA documented separately for each nanoform*			X			

h. For nanoforms, explicitly limit the potential for use of non-testing approaches for hazard and exposure where science is not consolidated, but encourage its parallel application and documentation*			X			
i. Require adapted DNEL setting based on different routes through the value chain / specific uses*			X			
j. Add to the SDS information relevant to Nano registries in Member States*			X			
k. Specify that list of substances in Annexes IV and V does not cover nanoforms of these substances*			X			
l. Choose inhalation as the appropriate route of exposure in repeated dose toxicity study unless such exposure can be excluded*			X			

m. Perform toxicokinetic screening*			X			
n. For nanoforms, request 28 day repeated dose toxicity in Annex VII*			X			
o. When considered together what do you believe the impact of the measures outlined above would be? *			X			

35. Finally considering the overall potential impact of the following measures on the <u>efficiency</u> of the regulatory process within REACH in terms of striking a balance between appropriate demonstration of safe use and the cost (money, time and administration) it will take to do it.

	Significantly higher overall efficiency for the regulation of nanomaterials	Higher overall efficiency for the regulation of nanomaterials	No difference in relation to the overall efficiency between nanomaterials and other materials	Lower overall efficiency for the regulation of nanomaterials	Significantly lower overall efficiency for the regulation of nanomaterials	Don't know
a. Apply clear rules on when nanoforms can be in one dossier or in separate ones based on possibility for data sharing*				X		
b. Introduce rules to ensure mandatory separation between nanoforms identified and					X	

addressed in the dossier whenever they differ in coating, shape, crystalline form or prescribed classes of particle size distribution*						
c. Information requirements for substances covered by Annex III (b) must also apply to nanoforms*				X		
d. For nanoforms, require all information on potential alterations of hazard due to operational conditions upstream the exposure situation is considered*			X			
e. For nanoforms, require all available information on the use in considered, even when the use would not be covered by the registration*					X	
f. For nanoforms, require additional physic-chemical characterization		X				

along the particle's fate when particle properties impacts on hazard*						
g. Phys-chem, (eco)tox and CSA documented separately for each nanoform*				X		
h. For nanoforms, explicitly limit the potential for use of non-testing approaches for hazard and exposure where science is not consolidated, but encourage its parallel application and documentation*					X	
i. Require adapted DNEL setting based on different routes through the value chain / specific uses*					X	
j. Add to the SDS information relevant to Nano registries in Member States*					X	
k. Specify that list of substances in Annexes IV and V does not cover					X	

nanoforms of these substances*						
l. Choose inhalation as the appropriate route of exposure in repeated dose toxicity study unless such exposure can be excluded*		X				
m. Perform toxicokinetic screening*		X				
n. For nanoforms, request 28 day repeated dose toxicity in Annex VII*					X	
o. When considered together what do you believe the impact of the measures outlined above would be? *					X	

36. Are there other policy measures that should be considered? (maximum 2000 characters)

We strongly recommend that any measure specifically addressing the nano forms of existing substances should be based on the potential for exposure to this form.
We also recommend of introducing measures which are harmonized with the US requirements for the same substances.

Overall Assessment of Options

Finally we would like you to consider the potential impact of each of the options set out above.

37. Considering the overall potential impact of each of the options on the efficiency of the regulatory process within REACH in terms of striking a balance between appropriate demonstration of safe use and the cost (money, time and administration) it will take to do it.

	Significantly higher overall efficiency for the regulation of nanomaterials	Higher overall efficiency for the regulation of nanomaterials	No difference in relation to the overall efficiency between nanomaterials and other materials	Lower overall efficiency for the regulation of nanomaterials	Significantly lower overall efficiency for the regulation of nanomaterials	Don't know
a. Do nothing (option 1) *			X			
b. Option 2*			X			
c. Option 3*				X		
d. Option 4*				X		
e. Option 5*		X				
f. Option 6*					X	

38. What is your preferred option? Explain why? (maximum 2000 characters)*

We prefer Option 5, as this is the only option that considers exposure as a basis for waiving testing requirements. We also prefer in this option the ability to assess coated nanomaterials as a special mixture of the core substance and the coating component and to consider aggregates as similar to the bulk form. However, instead of accepting Option 5 as it is, we envisage an option that combines certain elements of Option 5, together with elements of other options where the efficiency of the measure was rated significantly higher or higher; offering an optimal cost/benefit (safety) ratio.