

Public consultation relating to the REACH Annexes on Nanomaterials

The questionnaire	
General information on the respondent	
1. On what basis are you responding to this public consultation exercise? -single choice reply- (compulsory)	As an individual citizen
7. Your email address for correspondence -open reply-(compulsory)	
10. How would you describe your knowledge of REACH? -single choice reply-(compulsory)	Excellent
11. How would you describe your knowledge of nanomaterials? -single choice reply-(compulsory)	Excellent
Problem definition	
12. What is your overall view of the current registration provisions and information requirements for the registration of nanomaterials? -single choice reply-(compulsory)	Unclear
a. Absence of a definition of nanomaterial until October 2011 -single choice reply-(compulsory)	Some impact on causing the problem
b. Determination of nanomaterial according to the current European Commission definition of nanomaterials -single choice reply-(compulsory)	No Effect
c. Current information requirements on how to describe the scope of registration -single choice reply-(compulsory)	Some impact on causing the problem
d. Current information requirements on Substance identification -single choice reply-(compulsory)	Strong impact on causing the problem
e. Current information requirements on physical-chemical properties -single choice reply-(compulsory)	Strong impact on causing the problem
f. Current information requirements on human health toxicity -single choice reply-(compulsory)	Strong impact on causing the problem
g. Current information requirements on ecotoxicity and environmental fate -single choice reply-(compulsory)	Strong impact on causing the problem
h. Current information requirements on Chemical Safety Assessment -single choice reply-(compulsory)	Strong impact on causing the problem

i. Current information requirements on use of grouping and category approaches for nanoforms and other adaptations of the testing regime. -single choice reply-(compulsory)	Strong impact on causing the problem
j. Current requirements on application of test methods and the relevance of results of tests performed on another form of material -single choice reply-(compulsory)	Strong impact on causing the problem
k. Lack of specific guidance -single choice reply-(compulsory)	No Effect
l. Other -single choice reply-(optional)	Strong impact on causing the problem
If you answered 'Other' to question 13 then please give details below: -open reply-(optional)	
14. Do you believe there are any other areas of potential uncertainty or lack of clarity? Please set out below: -open reply-(optional)	
The lack of clarity for the registration of nanomaterials is due also to the fact that the legal text allows nanomaterials to have a phase-in status. As a consequence, most nanomaterials will be registered much later in the process (in 2018) and this will have negative impacts on innovation. Indeed, without clarity on the safety of nanomaterials, the innovative potential of nanomaterials will be slowed down. Already now consumers are avoiding products containing nanomaterials and companies prefer to market articles that are nano-free.	
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? -single choice reply-(compulsory)	Lower costs of compliance for nanomaterials
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? -single choice reply-(compulsory)	Significantly lower comparative safety for nanomaterials
a. More specific ECHA tools and guidance for nanomaterials -single choice reply-(compulsory)	No difference
b. Application of the Commission's definition of Nanomaterials -single choice reply-(compulsory)	Increase clarity
c. Introduction of specific requirements in the REACH Annexes -single choice reply-(compulsory)	Significantly increase clarity
d. Other -single choice reply-(optional)	Significantly increase clarity
If you answered 'Other' to question 17 then	Lowering of volume thresholds for nanomaterials to 10kg, the performance of a CSA for all nanomaterials, separate registration of nano and bulk.

please give details below: -open reply-(optional)

Policy options

Option 2 – Clarity option

a. Explicitly require registrants to describe the scope of the registration dossier -single choice reply-(compulsory)	Have no impact on the cost of compliance
b. Explicitly require registrants to provide more detailed characterisation of nanomaterials/nanoforms -single choice reply-(compulsory)	Have no impact on the cost of compliance
c. * Require that nanoforms are explicitly addressed in the endpoint sections -single choice reply-(compulsory)	Increases the cost of compliance
d. * Require detailed description of the test material / sample and sample preparation -single choice reply-(compulsory)	Have no impact on the cost of compliance
e. * Require scientific justifications for grouping / read across / QSAR and other non-testing approaches for different forms -single choice reply-(compulsory)	Have no impact on the cost of compliance
f. ** Require considerations of most appropriate / relevant metric with preferable presentation in several metrics -single choice reply-(compulsory)	Have no impact on the cost of compliance
g. Require that bioaccumulation is addressed specifically for the nanoform -single choice reply-(compulsory)	Increases the cost of compliance
h. Specify that absorption/desorption behaviour of nanomaterials should not be assessed based on K_d values derived from K_{oc} and K_{ow} -single choice reply-(compulsory)	Have no impact on the cost of compliance
i. Require identification of uses and exposure assessment of the nanoform. -single choice reply-(compulsory)	Increases the cost of compliance
j. When considered together what do you believe the impact of the measures outlined above would be? -single choice reply-(compulsory)	Have no impact on the cost of compliance
a. Explicitly require registrants to describe the scope of the registration dossier -single choice reply-(compulsory)	Significantly increase the safe use of nanomaterials
b. Explicitly require registrants to provide more detailed characterisation of nanomaterials/nanoforms -single choice reply-(compulsory)	Significantly increase the safe use of nanomaterials

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

several metrics -single choice reply-(compulsory)	nanomaterials
g. Require that bioaccumulation is addressed specifically for the nanoform -single choice reply-(compulsory)	Higher overall efficiency for the regulation of nanomaterials
h. Specify that absorption/desorption behaviour of nanomaterials should not be assessed based on K_d values derived from K_{oc} and K_{ow} -single choice reply-(compulsory)	Higher overall efficiency for the regulation of nanomaterials
i. Require identification of uses and exposure assessment of the nanoform -single choice reply-(compulsory)	Significantly higher overall efficiency for the regulation of nanomaterials
j. When considered together what do you believe the impact of the measures outlined above would be? -single choice reply-(compulsory)	Significantly higher overall efficiency for the regulation of nanomaterials
Option 3 – Soft law	
a. Development of further ECHA guidance and other ...? -single choice reply-(compulsory)	Have no impact on the cost of compliance
b. Enhanced use of the Directors Contact Group -single choice reply-(compulsory)	Have no impact on the cost of compliance
c. Initiatives to enhance information and dissemination at EU and Member State level -single choice reply-(compulsory)	Have no impact on the cost of compliance
d. When considered together what do you believe the impact of the measures outlined above would be? -single choice reply-(compulsory)	Have no impact on the cost of compliance
a. Development of further ECHA guidance and other ...? -single choice reply-(compulsory)	Have no impact on the safe use of nanomaterials
b. Enhanced use of the Directors Contact Group -single choice reply-(compulsory)	Significantly reduces the safe use of nanomaterials
c. Initiatives to enhance information and dissemination at EU and Member State level -single choice reply-(compulsory)	Have no impact on the safe use of nanomaterials
d. When considered together what do you believe the impact of the measures outlined above would be? -single choice reply-(compulsory)	Have no impact on the safe use of nanomaterials
a. Development of further ECHA guidance and other ...? -single choice reply-(compulsory)	Significantly lower overall efficiency for the regulation of nanomaterials
b. Enhanced use of the Directors Contact Group -single choice reply-(compulsory)	Significantly lower overall efficiency for the regulation of nanomaterials
c. Initiatives to enhance information and	No difference in relation to the overall efficiency between

dissemination at EU and Member State level -single choice reply-(compulsory)	nanomaterials and other materials
d. When considered together what do you believe the impact of the measures outlined above would be? -single choice reply-(compulsory)	Significantly lower overall efficiency for the regulation of nanomaterials
Option 4	
a. Include information on dustiness -single choice reply-(compulsory)	Have no impact on the cost of compliance
b. Require acute toxicity data for the most relevant route of exposure -single choice reply-(compulsory)	Increases the cost of compliance
c. Change 'particles' to '(nano)particles' for repeated dose toxicity studies (inhalation) -single choice reply-(compulsory)	Increases the cost of compliance
d. Require non-bacterial in vitro gene mutation study -single choice reply-(compulsory)	Increases the cost of compliance
e. * Consider water solubility in relation to test waiving -single choice reply-(compulsory)	Have no impact on the cost of compliance
f. * Specify that long term testing should not be waived based on lack of short term toxicity -single choice reply-(compulsory)	Increases the cost of compliance
g. Specify that algae testing should not be waived based on insolubility -single choice reply-(compulsory)	Increases the cost of compliance
h. Require that testing on soil and sediment organisms is prioritised -single choice reply-(compulsory)	Increases the cost of compliance
i. ** Require consideration of most appropriate / relevant metric with preferable presentation in several metrics -single choice reply-(compulsory)	Have no impact on the cost of compliance
j. When considered together what do you believe the impact of the measures outlined above would be? -single choice reply-(compulsory)	Increases the cost of compliance
a. Include information on dustiness -single choice reply-(compulsory)	Significantly increase the safe use of nanomaterials
b. Require acute toxicity data for the most relevant route of exposure -single choice reply-(compulsory)	Significantly increase the safe use of nanomaterials
c. Change 'particles' to '(nano)particles' for repeated dose toxicity studies (inhalation) -single choice reply-(compulsory)	Significantly increase the safe use of nanomaterials
d. Require non-bacterial in vitro gene mutation study -single choice reply-(compulsory)	Significantly increase the safe use of nanomaterials

e. * Consider water solubility in relation to test waiving -single choice reply-(compulsory)	Significantly increase the safe use of nanomaterials
f. * Specify that long term testing should not be waived based on lack of short term toxicity -single choice reply-(compulsory)	Significantly increase the safe use of nanomaterials
g. Specify that algae testing should not be waived based on insolubility -single choice reply-(compulsory)	Significantly increase the safe use of nanomaterials
h. Require that testing on soil and sediment organisms is prioritised -single choice reply-(compulsory)	Significantly increase the safe use of nanomaterials
i. ** Require consideration of most appropriate / relevant metric with preferable presentation in several metrics -single choice reply-(compulsory)	Significantly increase the safe use of nanomaterials
j. When considered together what do you believe the impact of the measures outlined above would be? -single choice reply-(compulsory)	Significantly increase the safe use of nanomaterials
a. Include information on dustiness -single choice reply-(compulsory)	Significantly higher overall efficiency for the regulation of nanomaterials
b. Require acute toxicity data for the most relevant route of exposure -single choice reply-(compulsory)	Significantly higher overall efficiency for the regulation of nanomaterials
c. Change 'particles' to '(nano)particles' for repeated dose toxicity studies (inhalation) -single choice reply-(compulsory)	Significantly higher overall efficiency for the regulation of nanomaterials
d. Require non-bacterial in vitro gene mutation study -single choice reply-(compulsory)	Significantly higher overall efficiency for the regulation of nanomaterials
e. * Consider water solubility in relation to test waiving -single choice reply-(compulsory)	Significantly higher overall efficiency for the regulation of nanomaterials
f. * Specify that long term testing should not be waived based on lack of short term toxicity -single choice reply-(compulsory)	Significantly higher overall efficiency for the regulation of nanomaterials
g. Specify that algae testing should not be waived based on insolubility -single choice reply-(compulsory)	Significantly higher overall efficiency for the regulation of nanomaterials
h. Require that testing on soil and sediment organisms is prioritised -single choice reply-(compulsory)	Significantly higher overall efficiency for the regulation of nanomaterials
i. ** Require consideration of most appropriate / relevant metric with preferable presentation in several metrics -single choice reply-(compulsory)	Significantly higher overall efficiency for the regulation of nanomaterials

<p>j. When considered together what do you believe the impact of the measures outlined above would be? -single choice reply-(compulsory)</p>	<p>Significantly higher overall efficiency for the regulation of nanomaterials</p>
<p>Option 5</p>	
<p>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 -single choice reply-(compulsory)</p>	<p>Have no impact on the cost of compliance</p>
<p>b. Specify that nanoform specific information is required only when an insoluble or poorly soluble nanoform put on the market is classified hazardous/ dangerous -single choice reply-(compulsory)</p>	<p>Increases the cost of compliance</p>
<p>c. Specify that a coated nanomaterial is considered as a special mixture e.g. in classification and labelling as accepted e.g. alloys -single choice reply-(compulsory)</p>	<p>Increases the cost of compliance</p>
<p>d. Specify that the granulometry concept in 7.14 of Annex VII includes also shape and surface area of nanomaterials -single choice reply-(compulsory)</p>	<p>Increases the cost of compliance</p>
<p>e. Specify that the information on dustiness is required for nanoforms only where relevant for the worker safety assessment -single choice reply-(compulsory)</p>	<p>Increases the cost of compliance</p>
<p>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 -single choice reply-(compulsory)</p>	<p>Increases the cost of compliance</p>
<p>g. Specify that the use of non-testing methods (e.g. read across, grouping, categorisation etc. methods) is a priority for nanoforms -single choice reply-(compulsory)</p>	<p>Have no impact on the cost of compliance</p>
<p>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</p>	<p>Have no impact on the cost of compliance</p>

polymer forms, or otherwise used in closed systems or controlled conditions -single choice reply-(compulsory)	
i. Specify that absorption/desorption behaviour of nanoforms can be based on biological surface adsorption index, affinity coefficient or other relevant parameters -single choice reply-(compulsory)	Increases the cost of compliance
j. No specific obligations for nanoforms in 1-10 tonnage band -single choice reply-(compulsory)	Have no impact on the cost of compliance
k. No specific obligations for nanoforms in 10-100 tonnage band -single choice reply-(compulsory)	Have no impact on the cost of compliance
l. No nanomaterial specific obligations for 2nd exposure route at 10-100 tonnage band for acute toxicity -single choice reply-(compulsory)	Have no impact on the cost of compliance
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 -single choice reply-(compulsory)	Have no impact on the cost of compliance
n. A nanoform consisting of aggregates is considered same as bulk form and the same endpoint information for (eco)toxicological and environmental fate apply -single choice reply-(compulsory)	Have no impact on the cost of compliance
o. No specific obligations for nanoforms to provide ecotoxicological and environmental fate information -single choice reply-(compulsory)	Have no impact on the cost of compliance
p. Create presumption that non-testing methods are valid for nanomaterials in all endpoints -single choice reply-(compulsory)	Don't know
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 -single choice reply-(compulsory)	Increases the cost of compliance
r. Specify explicitly that coating agents of nanoforms are registered separately in line with practices already accepted for e.g. alloys -single choice reply-(compulsory)	Have no impact on the cost of compliance
s. Reduce the set of combined methods for nanomaterial determination (Nanomaterial definition, EU/2011/696) to only one (e.g. DLS)	Reduce the costs of compliance

-single choice reply-(compulsory)	
t. For the purposes of REACH, consider aggregates as constituent particle (primary particle) in the nanomaterial definition (EU/2011/696) -single choice reply-(compulsory)	Have no impact on the cost of compliance
u. Omit mutagenicity and acute toxicity tests in lower tonnages. No skin irritation, skin corrosion or <i>in vivo</i> eye irritation information required for 10-100 t/y if the assessments in 1-10 t/y has been negative -single choice reply-(compulsory)	Reduce the costs of compliance
v. When considered together what do you believe the impact of the measures outlined above would be? -single choice reply-(compulsory)	Increases the cost of compliance
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 -single choice reply-(compulsory)	Increase the safe use of nanomaterials
b. Specify that nanoform specific information is required only when an insoluble or poorly soluble nanoform put on the market is classified hazardous/ dangerous -single choice reply-(compulsory)	Significantly reduces the safe use of nanomaterials
c. Specify that a coated nanomaterial is considered as a special mixture e.g. in classification and labelling as accepted e.g. alloys -single choice reply-(compulsory)	Significantly reduces the safe use of nanomaterials
d. Specify that the granulometry concept in 7.14 of Annex VII includes also shape and surface area of nanomaterials -single choice reply-(compulsory)	Significantly reduces the safe use of nanomaterials
e. Specify that the information on dustiness is required for nanoforms only where relevant for the worker safety assessment -single choice reply-(compulsory)	Significantly reduces the safe use of nanomaterials
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 -single choice reply-(compulsory)	Significantly reduces the safe use of nanomaterials
g. Specify that the use of non-testing methods (e.g. read across, grouping, categorisation etc. methods) is a priority for nanoforms -single choice reply-(compulsory)	Significantly reduces the safe use of nanomaterials

<p>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 -single choice reply-(compulsory)</p>	<p>Significantly reduces the safe use of nanomaterials</p>
<p>i. Specify that absorption/desorption behaviour of nanoforms can be based on biological surface adsorption index, affinity coefficient or other relevant parameters -single choice reply-(compulsory)</p>	<p>Significantly reduces the safe use of nanomaterials</p>
<p>j. No specific obligations for nanoforms in 1-10 tonnage band -single choice reply-(compulsory)</p>	<p>Significantly reduces the safe use of nanomaterials</p>
<p>k. No specific obligations for nanoforms in 10-100 tonnage band -single choice reply-(compulsory)</p>	<p>Significantly reduces the safe use of nanomaterials</p>
<p>l. No nanomaterial specific obligations for 2nd exposure route at 10-100 tonnage band for acute toxicity -single choice reply-(compulsory)</p>	<p>Significantly reduces the safe use of nanomaterials</p>
<p>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 -single choice reply-(compulsory)</p>	<p>Significantly reduces the safe use of nanomaterials</p>
<p>n. A nanoform consisting of aggregates is considered same as bulk form and the same endpoint information for (eco)toxicological and environmental fate apply -single choice reply-(compulsory)</p>	<p>Significantly reduces the safe use of nanomaterials</p>
<p>o. No specific obligations for nanoforms to provide ecotoxicological and environmental fate information -single choice reply-(compulsory)</p>	<p>Significantly reduces the safe use of nanomaterials</p>
<p>p. Create presumption that non-testing methods are valid for nanomaterials in all endpoints -single choice reply-(compulsory)</p>	<p>Significantly reduces the safe use of nanomaterials</p>
<p>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 -single choice reply-(compulsory)</p>	<p>Significantly reduces the safe use of nanomaterials</p>
<p>r. Specify explicitly that coating agents of nanoforms are registered separately in line with</p>	<p>Significantly reduces the safe use of nanomaterials</p>

practices already accepted for e.g. alloys -single choice reply-(compulsory)	
s. Reduce the set of combined methods for nanomaterial determination (Nanomaterial definition, EU/2011/696) to only one (e.g. DLS) -single choice reply-(compulsory)	Significantly reduces the safe use of nanomaterials
t. For the purposes of REACH, consider aggregates as constituent particle (primary particle) in the nanomaterial definition (EU/2011/696) -single choice reply-(compulsory)	Significantly reduces the safe use of nanomaterials
u. Omit mutagenicity and acute toxicity tests in lower tonnages. No skin irritation, skin corrosion or in vivo eye irritation information required for 10-100 t/y if the assessments in 1-10 t/y has been negative -single choice reply-(compulsory)	Significantly reduces the safe use of nanomaterials
v. When considered together what do you believe the impact of the measures outlined above would be? -single choice reply-(compulsory)	Significantly reduces the safe use of nanomaterials
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 -single choice reply-(compulsory)	Higher overall efficiency for the regulation of nanomaterials
b. Specify that nanoform specific information is required only when an insoluble or poorly soluble nanoform put on the market is classified hazardous/ dangerous -single choice reply-(compulsory)	Significantly lower overall efficiency for the regulation of nanomaterials
c. Specify that a coated nanomaterial is considered as a special mixture e.g. in classification and labelling as accepted e.g. alloys -single choice reply-(compulsory)	Significantly lower overall efficiency for the regulation of nanomaterials
d. Specify that the granulometry concept in 7.14 of Annex VII includes also shape and surface area of nanomaterials -single choice reply-(compulsory)	Significantly lower overall efficiency for the regulation of nanomaterials
e. Specify that the information on dustiness is required for nanoforms only where relevant for the worker safety assessment -single choice reply-(compulsory)	Significantly lower overall efficiency for the regulation of nanomaterials
f. Specify that waiving of endpoint specific information requirements for classified insoluble or poorly soluble nanoforms applies as for any	Significantly lower overall efficiency for the regulation of nanomaterials

other forms and also when nanoforms do not significantly differ from each other in specific endpoints -single choice reply-(compulsory)	
g. Specify that the use of non-testing methods (e.g. read across, grouping, categorisation etc. methods) is a priority for nanoforms -single choice reply-(compulsory)	Significantly lower overall efficiency for the regulation of nanomaterials
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 -single choice reply-(compulsory)	Significantly lower overall efficiency for the regulation of nanomaterials
i. Specify that absorption/desorption behaviour of nanoforms can be based on biological surface adsorption index, affinity coefficient or other relevant parameters -single choice reply-(compulsory)	Significantly lower overall efficiency for the regulation of nanomaterials
j. No specific obligations for nanoforms in 1-10 tonnage band -single choice reply-(compulsory)	Significantly lower overall efficiency for the regulation of nanomaterials
k. No specific obligations for nanoforms in 10-100 tonnage band -single choice reply-(compulsory)	Significantly lower overall efficiency for the regulation of nanomaterials
l. No nanomaterial specific obligations for 2nd exposure route at 10-100 tonnage band for acute toxicity -single choice reply-(compulsory)	Significantly lower overall efficiency for the regulation of nanomaterials
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 -single choice reply-(compulsory)	Significantly lower overall efficiency for the regulation of nanomaterials
n. A nanoform consisting of aggregates is considered same as bulk form and the same endpoint information for (eco)toxicological and environmental fate apply -single choice reply-(compulsory)	Significantly lower overall efficiency for the regulation of nanomaterials
o. No specific obligations for nanoforms to provide ecotoxicological and environmental fate information -single choice reply-(compulsory)	Significantly lower overall efficiency for the regulation of nanomaterials
p. Create presumption that non-testing methods are valid for nanomaterials in all endpoints -single choice reply-(compulsory)	Significantly lower overall efficiency for the regulation of nanomaterials

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 -single choice reply-(compulsory)	Significantly lower overall efficiency for the regulation of nanomaterials
r. Specify explicitly that coating agents of nanoforms are registered separately in line with practices already accepted for e.g. alloys -single choice reply-(compulsory)	Significantly lower overall efficiency for the regulation of nanomaterials
s. Reduce the set of combined methods for nanomaterial determination (Nanomaterial definition, EU/2011/696) to only one (e.g. DLS) -single choice reply-(compulsory)	Significantly lower overall efficiency for the regulation of nanomaterials
t. For the purposes of REACH, consider aggregates as constituent particle (primary particle) in the nanomaterial definition (EU/2011/696) -single choice reply-(compulsory)	Significantly lower overall efficiency for the regulation of nanomaterials
u. Omit mutagenicity and acute toxicity tests in lower tonnages. No skin irritation, skin corrosion or in vivo eye irritation information required for 10-100 t/y if the assessments in 1-10 t/y has been negative -single choice reply-(compulsory)	Significantly lower overall efficiency for the regulation of nanomaterials
v. When considered together what do you believe the impact of the measures outlined above would be? -single choice reply-(compulsory)	Significantly lower overall efficiency for the regulation of nanomaterials
Option 6	
a. Apply clear rules on when nanoforms can be in one dossier or in separate ones based on possibility for data sharing -single choice reply-(compulsory)	Have no impact on the cost of compliance
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 -single choice reply-(compulsory)	Have no impact on the cost of compliance
c. Information requirements for substances covered by Annex III (b) must also apply to nanoforms -single choice reply-(compulsory)	Increases the cost of compliance
d. For nanoforms, require all information on potential alterations of hazard due to operational conditions upstream the exposure situation is considered -single choice reply-(compulsory)	Have no impact on the cost of compliance
e. For nanoforms, require all available	Increases the cost of compliance

information on the use is considered, even when the use would not be covered by the registration -single choice reply-(compulsory)	
f. For nanoforms, require additional physico-chemical characterisation along the particle's fate when particle properties impacts on hazard -single choice reply-(compulsory)	Have no impact on the cost of compliance
g. Phys-chem, (eco)tox and CSA documented separately for each nanoform -single choice reply-(compulsory)	Increases the cost of compliance
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 -single choice reply-(compulsory)	Increases the cost of compliance
i. Require adapted DNEL setting based on different routes through the value chain / specific uses -single choice reply-(compulsory)	Have no impact on the cost of compliance
j. Add to the SDS information relevant to Nano registries in Member States -single choice reply-(compulsory)	Have no impact on the cost of compliance
k. Specify that list of substances in Annexes IV and V does not cover nanoforms of these substances -single choice reply-(compulsory)	Increases the cost of compliance
l. Choose inhalation as the appropriate route of exposure in repeated dose toxicity study unless such exposure can be excluded. -single choice reply-(compulsory)	Have no impact on the cost of compliance
m. Perform toxicokinetic screening -single choice reply-(compulsory)	Increases the cost of compliance
n. For nanoforms, request 28 day repeated dose toxicity in Annex VII -single choice reply-(compulsory)	Increases the cost of compliance
o. When considered together what do you believe the impact of the measures outlined above would be? -single choice reply-(compulsory)	Increases the cost of compliance
a. Apply clear rules on when nanoforms can be in one dossier or in separate ones based on possibility for data sharing -single choice reply-(compulsory)	Significantly increase the safe use of nanomaterials
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 -single choice reply-(compulsory)	Significantly increase the safe use of nanomaterials

c. Information requirements for substances covered by Annex III (b) must also apply to nanoforms -single choice reply-(compulsory)	Significantly increase the safe use of nanomaterials
d. For nanoforms, require all information on potential alterations of hazard due to operational conditions upstream the exposure situation is considered -single choice reply-(compulsory)	Significantly increase the safe use of nanomaterials
e. For nanoforms, require all available information on the use is considered, even when the use would not be covered by the registration -single choice reply-(compulsory)	Significantly increase the safe use of nanomaterials
f. For nanoforms, require additional physic-chemical characterisation along the particle's fate when particle properties impacts on hazard -single choice reply-(compulsory)	Significantly increase the safe use of nanomaterials
g. Phys-chem, (eco)tox and CSA documented separately for each nanoform -single choice reply-(compulsory)	Significantly increase the safe use of nanomaterials
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 -single choice reply-(compulsory)	Significantly increase the safe use of nanomaterials
i. Require adapted DNEL setting based on different routes through the value chain / specific uses -single choice reply-(compulsory)	Significantly increase the safe use of nanomaterials
j. Add to the SDS information relevant to Nano registries in Member States -single choice reply-(compulsory)	Significantly increase the safe use of nanomaterials
k. Specify that list of substances in Annexes IV and V does not cover nanoforms of these substances -single choice reply-(compulsory)	Significantly increase the safe use of nanomaterials
l. Choose inhalation as the appropriate route of exposure in repeated dose toxicity study unless such exposure can be excluded. -single choice reply-(compulsory)	Significantly increase the safe use of nanomaterials
m. Perform toxicokinetic screening -single choice reply-(compulsory)	Significantly increase the safe use of nanomaterials
n. For nanoforms, request 28 day repeated dose toxicity in Annex VII -single choice reply-(compulsory)	Significantly increase the safe use of nanomaterials
o. When considered together what do you believe the impact of the measures outlined above would be? -single choice reply-(compulsory)	Significantly increase the safe use of nanomaterials
a. Apply clear rules on when nanoforms can be	Significantly higher overall efficiency for the regulation of

in one dossier or in separate ones based on possibility for data sharing -single choice reply-(compulsory)	nanomaterials
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 -single choice reply-(compulsory)	Significantly higher overall efficiency for the regulation of nanomaterials
c. Information requirements for substances covered by Annex III (b) must also apply to nanoforms -single choice reply-(compulsory)	Significantly higher overall efficiency for the regulation of nanomaterials
d. For nanoforms, require all information on potential alterations of hazard due to operational conditions upstream the exposure situation is considered -single choice reply-(compulsory)	Significantly higher overall efficiency for the regulation of nanomaterials
e. For nanoforms, require all available information on the use is considered, even when the use would not be covered by the registration -single choice reply-(compulsory)	Higher overall efficiency for the regulation of nanomaterials
f. For nanoforms, require additional physic-chemical characterisation along the particle's fate when particle properties impacts on hazard -single choice reply-(compulsory)	Significantly higher overall efficiency for the regulation of nanomaterials
g. Phys-chem, (eco)tox and CSA documented separately for each nanoform -single choice reply-(compulsory)	Significantly higher overall efficiency for the regulation of nanomaterials
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 -single choice reply-(compulsory)	Significantly higher overall efficiency for the regulation of nanomaterials
i. Require adapted DNEL setting based on different routes through the value chain / specific uses -single choice reply-(compulsory)	Significantly higher overall efficiency for the regulation of nanomaterials
j. Add to the SDS information relevant to Nano registries in Member States -single choice reply-(compulsory)	Significantly higher overall efficiency for the regulation of nanomaterials
k. Specify that list of substances in Annexes IV and V does not cover nanoforms of these substances -single choice reply-(compulsory)	Significantly higher overall efficiency for the regulation of nanomaterials
l. Choose inhalation as the appropriate route of exposure in repeated dose toxicity study unless such exposure can be excluded. -single choice reply-(compulsory)	Significantly higher overall efficiency for the regulation of nanomaterials

m. Perform toxicokinetic screening -single choice reply-(compulsory)	Significantly higher overall efficiency for the regulation of nanomaterials
n. For nanoforms, request 28 day repeated dose toxicity in Annex VII -single choice reply-(compulsory)	Significantly higher overall efficiency for the regulation of nanomaterials
o. When considered together what do you believe the impact of the measures outlined above would be? -single choice reply-(compulsory)	Significantly higher overall efficiency for the regulation of nanomaterials
36. Are there other policy measures that should be considered? -open reply-(optional)	

Overall Assessment of Options

a. Do Nothing (Option 1) -single choice reply-(compulsory)	Significantly lower overall efficiency for the regulation of nanomaterials
b. Option 2 -single choice reply-(compulsory)	No difference in relation to the overall efficiency between nanomaterials and other materials
c. Option 3 -single choice reply-(compulsory)	Significantly lower overall efficiency for the regulation of nanomaterials
d. Option 4 -single choice reply-(compulsory)	Higher overall efficiency for the regulation of nanomaterials
e. Option 5 -single choice reply-(compulsory)	Significantly lower overall efficiency for the regulation of nanomaterials
f. Option 6 -single choice reply-(compulsory)	Significantly higher overall efficiency for the regulation of nanomaterials

38. What is your preferred option? Explain why? -open reply-(compulsory)

Option 6 which includes options 2 and 4, is by far the best option to obtain the goals of the REACH Regulation, not only in terms of safety and environmental protection but even more to increase innovation on nanomaterials. Through option 6 a thorough risk assessment of the nanoforms of substances are individually assessed and that a clear distinction is made between nano and bulk form. As concluded by the Regulatory review on nanomaterials, these substances may be, as any other chemicals, hazardous or not. Only through the collection of the information that would derive from option 6 a comprehensive hazard and risk assessment would be possible to allow decision makers but also companies to understand the extend to which these substances are safe or not. With a thorough assessment of the safety of each nano form, companies could decide to invest on a chemical. The present uncertainty has a negative effect on innovation as consumers, retailers and article manufacturers are becoming more and more skeptical of nanomaterials and through a demonstration of their safety, this negative trend for innovation can be stopped.