# Public consultation relating to the REACH Annexes on Nanomaterials

## The questionnaire

### General information on the respondent

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| 1. On what basis are you responding to this public consultation exercise? -single choice reply-(compulsory) | On behalf of an organisation |
| 2. Please specify the organisation you represent -single choice reply-(compulsory) | Government authority |
| 3. In which Member State is your organisation principally based? -single choice reply-(compulsory) | Netherlands |
| 5. The principle activity(ies[1]) of the organisation you are responding on behalf of...<br><br>[1] Multiple answers should be possible<br>-multiple choices reply-(compulsory) | Other |
| If you answered 'Other' to question 5 then please give details below: -open reply-(optional) | Ministry of Infrastructure and the Environment |
| 6. Your role within the organisation you are responding on behalf of... -single choice reply-(compulsory) | Administrator |
| 7. Your email address for correspondence -open reply-(compulsory) | hans.meijer@minienm.nl; monique.bosman@minienm.nl |
| 8. What involvement has your organisation had within the last three years in relation to REACH? -single choice reply-(compulsory) | Directly involved |
| 9. What involvement has your organisation had within the last three years in relation to the regulation of nanomaterials? -single choice reply-(compulsory) | Directly involved |
| 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

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| 12. What is your overall view of the current registration provisions and information requirements for the registration of nanomaterials? -single choice reply-(compulsory) | Very unclear |

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| a. Absence of a definition of nanomaterial until October 2011 -single choice reply-(compulsory) | Strong impact on causing the problem |
| b. Determination of nanomaterial according to the current European Commission definition of nanomaterials -single choice reply-(compulsory) | Some impact on causing the problem |
| c. Current information requirements on how to describe the scope of registration -single choice reply-(compulsory) | Strong 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) | Strong impact on causing the problem |
| 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) | The definition of nanomaterials as published October 2011 is still not legally binding to materials covered by REACH. The tonnage based information requirements might be inappropriate as nanomaterials are small in size and potentially more reactive than other materials. REACH only requests information on exposure in case a substance is classified as hazardous, therefore information on exposure is lacking for almost all nanomaterials, despite the fact that it is generally agreed upon that information on exposure is of utmost importance to assess the potential human health and environmental risk. Information requirements are insufficient to characterise and assess the hazardous properties and risks of nanomaterials. Adequate information on coated materials is lacking. |
| 14. Do you believe there are any other areas of potential uncertainty or lack of clarity? Please set out below: -open reply-(optional) | |

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| As mentioned above (under 13), the current information requirements on the characterisation of nanomaterials is inadequate for nanomaterials and as a consequence: - The same applies for the identifiers for the characterisation of nanomaterials - The tonnage level linked information requirements need to be adjusted for nanomaterials - The route of exposure needs to be reconsidered for nanomaterials - It is essential that relevant information on exposure is not only mandatory in case the substance is classified as hazardous, but relevant exposure information needs to be provided for all substances to allow a proper risk assessment Next to the absence of relevant information and instruments to request relevant information on nanomaterials, the current legislation is absolutely inadequate to assess the potential hazard and risk of coated materials. Since these coatings can dramatically change the – toxicological and ecotoxicological– properties of a substance, this lack of information seriously affects the hazard and risk assessment of nanomaterials. Further to the definition, there appears to be consensus that harmonization of the definitions in different European types of legislation should be aimed for, to ensure that nanomaterials are treated in a harmonized and consistent manner in all legislation. If different definitions were to exist for the various regulatory frameworks, this would result in materials that in one framework are defined as a nanomaterial whereas in another are not defined as a nanomaterial. This could lead to unequal treatment of producers and/or importers and will hamper transparency for workers and consumers, as well as regulators and risk assessors. The EU Recommendation forms a good basis for such harmonization (Bleeker et al 2012, 2013) | |
| 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) | No difference in relation to the cost of compliance between nanomaterials and other materials |
| 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) | Increase clarity |
| b. Application of the Commission's definition of Nanomaterials -single choice reply-(compulsory) | Significantly 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 please give details below: -open reply-(optional) | Appropriate characterisation would help to assess which substances we are talking about; Change in the linkage between tonnage level and information requirements; Mandatory information on exposure for all substances, and not only in case a substance is considered/approved to be hazardous on basis of extensive in vivo studies that are essential to establish the hazardous properties of a substances under the Regulation for Classification, Labelling and Packaging (CLP); Characterisation and toxicological information on coated materials is considered of importance to assess the risk of these coated materials |

## Policy options

## Option 2 – Clarity option

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| 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) | Have no impact on 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) | Have no impact on 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) | Have no impact on the safe use of nanomaterials |
| b. Explicitly require registrants to provide more detailed characterisation of nanomaterials/nanoforms -single choice reply-(compulsory) | Have no impact on the safe use of nanomaterials |
| c. * Require that nanoforms are explicitly addressed in the endpoint sections -single choice reply-(compulsory) | Have no impact on the safe use of nanomaterials |
| d. * Require detailed description of the test | Have no impact on the safe use of nanomaterials |

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| material / sample and sample preparation -single choice reply-(compulsory) | |
| 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 safe use of nanomaterials |
| f. ** Require considerations of most appropriate / relevant metric with preferable presentation in several metrics -single choice reply-(compulsory) | Have no impact on the safe use of nanomaterials |
| g. Require that bioaccumulation is addressed specifically for the nanoform -single choice reply-(compulsory) | Have no impact on 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) | Have no impact on 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) | Increase the safe use of nanomaterials |
| a. Explicitly require registrants to describe the scope of the registration dossier -single choice reply-(compulsory) | No difference in relation to the overall efficiency between nanomaterials and other materials |
| b. Explicitly require registrants to provide more detailed characterisation of nanomaterials/nanoforms -single choice reply-(compulsory) | 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) | 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) | No difference in relation to the overall efficiency between nanomaterials and other materials |
| f. ** Require considerations of most appropriate / relevant metric with preferable presentation in several metrics -single choice reply-(compulsory) | No difference in relation to the overall efficiency between nanomaterials and other materials |
| g. Require that bioaccumulation is addressed specifically for the nanoform -single choice reply-(compulsory) | Higher overall efficiency for the regulation of nanomaterials |

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| 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) | 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) | Have no impact on 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) | No difference in relation to the overall efficiency between nanomaterials and other materials |
| b. Enhanced use of the Directors Contact Group -single choice reply-(compulsory) | No difference in relation to the overall efficiency between nanomaterials and other materials |
| c. Initiatives to enhance information and dissemination at EU and Member State level -single choice reply-(compulsory) | No difference in relation to the overall efficiency between 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) | No difference in relation to the overall efficiency between nanomaterials and other materials |

## Option 4

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| 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) | Have no impact on the cost of compliance |
| c. Change 'particles' to '(nano)particles' for repeated dose toxicity studies (inhalation) -single choice reply-(compulsory) | Have no impact on 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) | Have no impact on the cost of compliance |
| g. Specify that algae testing should not be waived based on insolubility -single choice reply-(compulsory) | Have no impact on the cost of compliance |
| h. Require that testing on soil and sediment organisms is prioritised -single choice reply-(compulsory) | Have no impact on 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) | Have no impact on the cost of compliance |
| a. Include information on dustiness -single choice reply-(compulsory) | Have no impact on the safe use of nanomaterials |
| b. Require acute toxicity data for the most relevant route of exposure -single choice reply-(compulsory) | Have no impact on the safe use of nanomaterials |
| c. Change 'particles' to '(nano)particles' for repeated dose toxicity studies (inhalation) -single choice reply-(compulsory) | Have no impact on the safe use of nanomaterials |
| d. Require non-bacterial in vitro gene mutation study -single choice reply-(compulsory) | Increase the safe use of nanomaterials |
| e. * Consider water solubility in relation to test waiving -single choice reply-(compulsory) | 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) | Have no impact on the safe use of nanomaterials |
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| g. Specify that algae testing should not be waived based on insolubility -single choice reply-(compulsory) | Increase the safe use of nanomaterials |
| h. Require that testing on soil and sediment organisms is prioritised -single choice reply-(compulsory) | Increase the safe use of nanomaterials |
| i. ** Require consideration of most appropriate / relevant metric with preferable presentation in several metrics -single choice reply-(compulsory) | 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) | Increase the safe use of nanomaterials |
| a. Include information on dustiness -single choice reply-(compulsory) | No difference in relation to the overall efficiency between nanomaterials and other materials |
| b. Require acute toxicity data for the most relevant route of exposure -single choice reply-(compulsory) | No difference in relation to the overall efficiency between nanomaterials and other materials |
| c. Change 'particles' to '(nano)particles' for repeated dose toxicity studies (inhalation) -single choice reply-(compulsory) | No difference in relation to the overall efficiency between nanomaterials and other materials |
| d. Require non-bacterial in vitro gene mutation study -single choice reply-(compulsory) | Higher overall efficiency for the regulation of nanomaterials |
| e. * Consider water solubility in relation to test waiving -single choice reply-(compulsory) | 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) | No difference in relation to the overall efficiency between nanomaterials and other materials |
| g. Specify that algae testing should not be waived based on insolubility -single choice reply-(compulsory) | Higher overall efficiency for the regulation of nanomaterials |
| h. Require that testing on soil and sediment organisms is prioritised -single choice reply-(compulsory) | 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) | 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) | Higher overall efficiency for the regulation of nanomaterials |
| Option 5 | |
| a. Describe whether and which different nanoforms are covered in the chemical safety assessment, including a statement when and | Don't know |

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| how information on one form is used to demonstrate safety of other forms -single choice reply-(compulsory) | |
| 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) | Don't know |
| 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) | Don't know |
| d. Specify that the granulometry concept in 7.14 of Annex VII includes also shape and surface area of nanomaterials -single choice reply-(compulsory) | Don't know |
| e. Specify that the information on dustiness is required for nanoforms only where relevant for the worker safety assessment -single choice reply-(compulsory) | Don't know |
| 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) | Don't know |
| 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) | Don't know |
| 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) | Don't know |
| 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) | Don't know |
| j. No specific obligations for nanoforms in 1-10 tonnage band -single choice reply-(compulsory) | Don't know |

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| k. No specific obligations for nanoforms in 10-100 tonnage band -single choice reply-(compulsory) | Don't know |
| l. No nanomaterial specific obligations for 2nd exposure route at 10-100 tonnage band for acute toxicity -single choice reply-(compulsory) | Don't know |
| 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) | Don't know |
| 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) | Don't know |
| o. No specific obligations for nanoforms to provide ecotoxicological and environmental fate information -single choice reply-(compulsory) | Don't know |
| 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) | Don't know |
| 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) | Don't know |
| 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) | Don't know |
| t. For the purposes of REACH, consider aggregates as constituent particle (primary particle) in the nanomaterial definition (EU/2011/696) -single choice reply-(compulsory) | Don't know |
| 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) | Don't know |
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| **v. When considered together what do you believe the impact of the measures outlined above would be?** -single choice reply-(compulsory) | 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 -single choice reply-(compulsory) | Have no impact on 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 nanomatrials |
| 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 nanomatrials |
| 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 nanomatrials |
| 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 nanomatrials |
| 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 nanomatrials |
| 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 nanomatrials |
| 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 reduces the safe use of nanomatrials |
| i. Specify that absorption/desorption behaviour | Significantly reduces the safe use of nanomatrials |

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| of nanoforms can be based on biological surface adsorption index, affinity coefficient or other relevant parameters -single choice reply-(compulsory) | |
| j. No specific obligations for nanoforms in 1-10 tonnage band -single choice reply-(compulsory) | Significantly reduces the safe use of nanomatrials |
| k. No specific obligations for nanoforms in 10-100 tonnage band -single choice reply-(compulsory) | Significantly reduces the safe use of nanomatrials |
| l. No nanomaterial specific obligations for 2nd exposure route at 10-100 tonnage band for acute toxicity -single choice reply-(compulsory) | Significantly reduces the safe use of nanomatrials |
| 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 reduces the safe use of nanomatrials |
| 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 reduces the safe use of nanomatrials |
| o. No specific obligations for nanoforms to provide ecotoxicological and environmental fate information -single choice reply-(compulsory) | Significantly reduces the safe use of nanomatrials |
| p. Create presumption that non-testing methods are valid for nanomaterials in all endpoints -single choice reply-(compulsory) | Significantly reduces the safe use of nanomatrials |
| 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 reduces the safe use of nanomatrials |
| 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 reduces the safe use of nanomatrials |
| 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 nanomatrials |
| t. For the purposes of REACH, consider aggregates as constituent particle (primary particle) in the nanomaterial definition | Significantly reduces the safe use of nanomatrials |

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| (EU/2011/696) -single choice reply-(compulsory) | |
| 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 nanomatrials |
| **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 nanomatrials |
| 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) | No difference in relation to the overall efficiency between nanomaterials and other materials |
| 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 other forms and also when nanoforms do not significantly differ from each other in specific endpoints -single choice reply-(compulsory) | Significantly lower overall efficiency for the regulation 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 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 | Significantly lower overall efficiency for the regulation of nanomaterials |

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| 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) | |
| 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 |
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| 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) | Increases the cost of compliance |
| c. Information requirements for substances covered by Annex III (b) must also apply to nanoforms -single choice reply-(compulsory) | Have no impact on 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) | Increases the cost of compliance |
| 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) | Increases the cost of compliance |
| f. For nanoforms, require additional physic-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) | Have no impact on the cost of compliance |

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| 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) | Have no impact on 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) | Increases 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) | Have no impact on 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 | Significantly increase the safe use of nanomaterials |

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| -single choice reply-(compulsory) | |
| 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) | Have no impact on 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) | 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 in one dossier or in separate ones based on possibility for data sharing -single choice reply-(compulsory) | Significantly higher overall efficiency for the regulation 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 higher overall efficiency for the regulation of nanomaterials |
| c. Information requirements for substances | Significantly higher overall efficiency for the regulation of |

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| covered by Annex III (b) must also apply to nanoforms -single choice reply-(compulsory) | 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) | Significantly 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) | Lower 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) | |

- Make the definition of nanomaterials legally binding to REACH - Change the tonnage related information for nanomaterials as these might exhibit certain characteristics at lower tonnage (depending on the number of particles rather than weight) - Exposure information should be provided for all nanomaterials and not only once a substance is classified as hazardous - Request specific information on surface coated materials

## Overall Assessment of Options

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| a. Do Nothing (Option 1) -single choice reply-(compulsory) | Lower overall efficiency for the regulation of nanomaterials |
| b. Option 2 -single choice reply-(compulsory) | Lower overall efficiency for the regulation of nanomaterials |
| c. Option 3 -single choice reply-(compulsory) | Lower overall efficiency for the regulation of nanomaterials |
| d. Option 4 -single choice reply-(compulsory) | Lower 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) | No difference in relation to the overall efficiency between nanomaterials and other materials |

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

As a general remark to the questionnaire: Assessing costs and benefits as requested was seriously hampered by uncertainty to what represents the baseline. Many of the elements proposed seem to be part of the baseline already. The answers to such elements in this questionnaire have therefore been assessed as neutral on both costs and benefits. Based on the information at this moment and our understanding of this consultation, option 6 is the preferred option because it appears to be the one that is most specific as to the information to be delivered. Such additional information is essential to enable adequate risk assessment of nanomaterials. Second best option is option 4. Very important is to include exposure information as specified in option 2, even in those cases a material has not been classified as hazardous. Option 5, on the other hand, seems to require less information and seems as such incompatible with REACH and unfit to provide for more information. It was not possible to assess impact on cost of the different elements as these seem to require an amendment of REACH first which has been explicitly out-ruled. In the overall assessment of options (Q37), even when options 2, 3 and 4 provide for improvements, only a combination of these with option 6 seems to provide a similar level of efficiency for REACH to regulate regular chemicals and nanomaterials. At this moment, REACH is clearly less efficient for nanomaterials. However, to ensure that REACH will actually be as efficient for nanomaterials, amending the REACH annexes should be followed by: - Making the definition of nanomaterials legally binding for REACH as well - Assess whether the requirements related to tonnage levels are adequate for nanomaterials - Request specific information on surface coated materials.