Nanotechnology Industries Association

NIA Position on **Draft Commission Regulation (EU) XXX amending Regulation (EC) No 1907/2006 (REACH) as regards Annexes I, III, VI, VII, VIII, IX, X, XI and XII to address nanoforms of substances**

2017-11-06

Synopsis/Introduction

On 9th of October 2017, the European Commission published its proposal for amending the REACH Annexes to address nanoform substances (http://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-4925011_en).

The proposal is in the form of a Commission Regulation to amend Annexes I, III, VI, VII, VIII, IX, X, XI and XII. The Commission Regulation itself is only 3 Articles, and the main text changes for the REACH Annexes are provided in an Annex to the Commission Regulation. The Commission Regulation shall apply from 1 January 2020, while at the same time allowing users to comply before that date.

The NIA provide these comments by 6 November 2017, via the official feedback procedure at the following EC website: http://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-4925011_en

NIA position on the draft regulation

The NIA welcomes the draft proposal from the European Commission as it clarifies that nanomaterials are explicitly included in the REACH Regulation via specifics detailed in its Annexes. Following the extensive input by the EC, MS, industry and stakeholders in nanomaterials research projects over the last decade, and work performed e.g. at OECD, extensive knowledge has been generated on nanomaterials and their properties.

However, NIA also has comments and concerns outlined in this position paper under the headings below, corresponding to sections in the draft proposal and its annex.

General comments

It is not clear to us if this revision will require retrospective updates of existing registration dossiers, based on the REACH requirement (and related legislation e.g. EU-BPR) for all registrants to update their dossier as and when new information is available. This clarification would be helpful.

Whereas Clause 2 refers to the Recommendation for a Definition of a Nanomaterial (2011/696/EU) and states 'a nanomaterial can be a form of a substance or a distinct substance'. This statement is not in line with the Recommendation, as nanoform is not mentioned in the Recommendation. The sentence should therefore be removed from this whereas clause. The NIA, as well as others, are also aware of the ongoing revision process of the definition, and the process of revising the Draft Regulation to be aligned with any modifications should be clearly mentioned in this text.

Whereas Clause 4, and Annex VI: The term 'nanoform'
The reference to the 2011 EC Recommendation is appropriate, but the introduction of a new term 'nanoform' that for most practical aspects has the same meaning as the term 'nanomaterial' is confusing. The rationale for this new term is however understood, as several forms of the same nanomaterial might be registered, but it should be clearly explained in relation to the term nanomaterial.

Whereas Clause 6: states 'This should ensure a clear and effective implementation with proportionate costs and avoid adversely affecting innovation and competitiveness.' This is very important and should be retained, and form a strong basis for all modifications proposed. Unfortunately, this is contradicted in Whereas Clause 16, that thus needs to be rephrased.

Whereas Clause 7: The use of a nanoform, as well as a conventional substance, may result in its modification or even *de novo* formation of a new substance or nanoform. The requirement for downstream users to detect such potential transformations may be very limited as science is not fully developed to detect all possible modifications. The requirement for downstream users to transmit such information is therefore too far reaching and should be limited to relating information on its use scenarios. The paragraph needs to be rephrased to reflect this.

Whereas Clause 8, with regard to solubility, the statement that insolubility should be a surrogate for toxicity is not appropriate and needs to be rephrased. Insolubility may be an indication for developing a testing strategy.

As described in Whereas Clause 8, it is expected that the majority of nanoforms will be from phase-in substances. As such, existing data from such substances will available, and should be used ahead of generating new data with consequently potential additional use of animals and resources.

Whereas Clause 11 states that '… the information on volume,…. of the different nanoforms or sets of nanoforms…' 'should be provided separately…'; This whereas clause seems to indicate that the volume for the registered substance should be subdivided. This seems to contradict information in the REACH Regulation indicating that it is the total volume of the substance that triggers the registration.

A similar lack of precision is mentioned in the suggested addition in Annex VI, Section 3 (see comment below).

Whereas Clause 15 asks for information on dustiness, however Annex VII, 7.14 bis conditions this information based on exposure to granular forms over the life cycle. This should be mentioned also in the Whereas Clause.

Whereas Clause 16 asks for '…one or more other in vitro mutagenicity study(ies)…'. Asking for more than one study is not in line with the statement made in Whereas Clause 6 'This should ensure a clear and effective implementation with proportionate costs and avoid adversely affecting innovation and competitiveness.' The statement in Whereas Clause 6 is very important and should be retained, and form a strong basis for any modification proposed in the regulation.

Whereas Clause 18 asks for studies to investigate certain effects, and specifically for nanoforms to look at indirect genotoxicity as a result of persistent inflammation. The scientific justification for addressing indirect genotoxicity as a result of persistent inflammation only for nanoforms is not provided. Persistent inflammation is known to give rise to potential indirect genotoxicity, and this is not only applicable for nanomaterials. We suggest therefore to delete this here and remove it from the Annexes where it is mentioned, as the sentence in the Annexes starts with e.g. other appropriate studies may be performed. (See Annex VIII 8.6.1 and in Annex IX 8.6.2).

Secondly, the inclusion of the requirement related to histopathological determination is already included in relevant OECD Technical Guidance, and is therefore not required to be inserted here. The paragraph should therefore be rephrased/deleted.

Whereas Clause 19 addresses the toxicological profile and asks for assessment of the toxicokinetic behaviour. This is then mentioned in Annex VIII 8.8 and Section 8.8.1 states that 'Assessment…relevant available information'. However, this is then further detailed in the second column as 'For nanoforms… shall be proposed or may be required…'. The use of the word shall is too strong in this case, and should be removed.

Annex I (f): 0.11 bis paragraph: The use of an appropriate metric, as well as its justification is relevant for the CSA and CSR. However, current wording seems to require to also include this justification in a summarised form in the SDS. This requirement is unnecessary and should be removed.

Annex I (g): Adding the proposed sentence after the first line of 1.0.3 does not make sense as the first line ends with a colon mark. It would make more sense to add the sentence after the Step 4 line.

Annex I (r) 5.2.3: It may not always be possible to characterise aggregation, agglomeration and particle surface chemistry, and therefore we suggest to replace 'characterisation' with 'description'. This requirement also needs further description in guidance documents.

Annex III: The last sentence of b(ii) seems to indicate that all substance with nanoforms (except if soluble in biological or environmental media) fall under the criteria and thus a full Annex VII information is required. The rationale for including this broad range of nanomaterials is not clear and needs to be explained by the European Commission.

NIA would also point out that the use of the word 'soluble' is not defined in this legal text. While understanding that this will be clarified in guidance, and considering the very broad implication different interpretations of 'soluble' will have, NIA would like to stress that this is creating uncertainty already in the basic legal text which should be avoided. The criteria for solubility needs to be clear for registrants to understand the applicability of Annex III for their substances. The issue of solubility is mentioned several times in the Annexes and should therefore be reconsidered throughout.

Annex VI:
Guidance note on nanoform
The phrasing of this Guidance note is not optimal and is easily confused with the 2011 Commission Recommendation for a definition of nanomaterial. The first sentence is very long and ends with '…is a nanoform of a substance.' This is then followed by a sentence '… that has been **characterised** in accordance with section 2.4…'. The Guidance note then ends with a sentence similar to the second sentence with the following difference '…when one has been **defined** in accordance with section 2.4….'.
It is not clear if this Guidance note is this to be interpreted as a definition?

The last sentence of the first paragraph of the Guidance Note refers to differences in the parameters in points 2.4.2 to 2.4.5 but it is not clear what, or who, defines the possible differences.

Section 2.3 indirectly require Registrants of more or less any (solid/granular) substance to verify if their Registration covers nanomaterials. However, neither the Guidance note on nanoform, nor section 2.4 provides a clear indication of what does not constitute a nanoform nor how this should be proven (e.g. the 50 % number size distribution is not mentioned in section 2.4).

This section also states '…one of more nanoforms…', and it is our understanding that it is the Registrant that defines what constitutes a difference between one nanoform and another.

Section 2.4.2: The numbers size distribution does not include an upper limit. This difficulty is the same issue as already pointed out by several stakeholders for the application of the definition. It appears unwise to include this large imprecision in a legal text.

Section 3: It needs to be clear that a nanoform produced in less than 1 tonne per year does not require registration. The current wording can be interpreted such that a substance that has a nanoform and where the nanoform is below the 1 tonne threshold would still need to be registered and provide information required. Providing all information requirements for small volumes of nanoforms, as required for the volume of the total substance might quickly become prohibitively resource intensive and hamper innovation.

Does this mean that e.g. Annex IX testing has to be completed on every individual nanoform unless grouping/read-across etc. can be argued, simply because the tonnage of all the forms of the substance is over 100 tonnes even if less than one tonne of each nanoform is produced? This clarification should be provided.

It is our understanding that it is the registrant who decides on the substance identification of what is being registered in the dossier. This may imply that the 'one substance one registration' concept might not always be applicable, as it would be up to the registrant to decide on the appropriate boundaries that describes the registered substance. This concept should be fully clarified in the text to avoid uncertainties, and the practical approach on this might need to be further clarified/explained in guidance.

The usefulness of grouping and read across of nanoforms should be encouraged and this notion should be considered for inclusion in the Annex VI.

Section 5, the proposed amendments seems to indicate that the 'Guidance on Safe Use Concerning' should differentiate between bulk and nanoforms if appropriate. Would this mean that the registrant should provide separate SDS's for bulk and nanoforms of the same substance? This is currently not clear.

Annex VII:
7.7: The confounding effect of dispersions is not nanospecific, and the addition should therefore be removed, or rephrased to cover all forms of substances.

7.8: Same comment as for 7.7 above.

8.5.1: The possibility to perform another study with a more appropriate route of exposure needs to also clarify, that if such another study is performed, the oral study does not need to be performed.

Annex VIII:
8.6.1: The inclusion of the requirement related to histopathological determination is already included in relevant OECD Technical Guidance, and is therefore not required to be inserted here. The paragraph should therefore be deleted.

Indirect genotoxicity from persistent inflammation is not a clear indication. The parenthesis already starts with 'e.g.' and therefore further examples are not required, as they are implicit, and the proposed addition for nanoforms should be deleted.

8.8.1: The possibility for the Agency to propose or request a toxicokinetic study is too broad and needs to be clarified in much more detail when such a situation exists, as currently it creates a lot of uncertainty. However, the proposed addition is not required, based on the broad competencies already provided by the Agency following Articles 40 and 41. Therefore, this addition is not needed and should be deleted.

Annex IX:
8.6.2: Same comment as for Annex VIII section 8.6.1 above.

Annex XI:
8.6.2: Same comment as for Annex VIII.

Concluding remarks of editorial nature
Annex I (l): It is suggested to change the wording from '… justification *is* applied…' to '…justification *should be* applied…'

Whereas clause 22 and 25 are very similar in wording differing e.g. in the use of 'apply' vs 'comply with' and 'deadline for compliance' and 'date of applications'. It seems they comply the same information and it should be considered if one of them (e.g. whereas clause 22) should be deleted.

Annex VI, introductory text: Fifth paragraph uses quotation marks around 'grouped'. The need to quotation marks is questioned, and we suggest that they are removed.

Annex VI, Guidance note on nanoforms
Several footnotes (e.g. 1 and 2 in the Guidance note on nanoforms) are referred to in the text of Annex VI but cannot be found in the document.

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The NIA, Nanotechnology Industries Association, is the sector-independent, responsible voice for the industrial nanotechnologies supply chains; it proactively supports the ongoing innovation and commercialisation of nanotechnologies and promotes their safe and reliable advancement.

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