

Challenges foreseen with nanoforms and the work of the NIA Global Regulatory Working Group

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Nano-specific modifications of Annexes

General clarification

- If nanoforms are covered by the registration, they must be addressed, assessment and conclusions documented and appropriate risk management measures identified
- Introduction of requirements to provide information on nanoforms in Annexes I, III, VI-XII
 - For characterisation: 'Size, Shape, Surface modification'
 (Name, particle number size distribution, surface functionalization/treatment, shape, aspect ratio, morphology, surface area, analytical methods)
 - Specify test conditions
 - Confounding effects related to dispersion
 - Cancel waiving of testing based on high solubility in water alone
 - Dustiness information etc...



NIA comments to EC proposal

Selected snippets:

- Retrospective updates of existing registration dossiers?
- Should substance information requirements due to tonnage triggers be subdivided?
- The word 'soluble' is not defined
- Nanoform not yet clear!

NIA Public Position



NIA Position

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 $9^{\circ\circ}$ 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-

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

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-

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.

[http://nanotechia.org/news/nia-comments-reach-annexes-submitted-ec]



What is a nanoform? From EC proposal

Guidance note on nanoforms:

In accordance with the Commission Recommendation of 18 October 2011 on the definition of nanomaterial, a form of a natural or manufactured substance containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm, including also by derogation, fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm, is a nanoform of a substance. The term 'nanoform', when it is referred to in the other Annexes, shall relate to a nanoform or a set of **nanoforms** that has been characterised in accordance with section 2.4 below. A substance may have one or more different nanoforms, based on differences in the parameters in points 2.4.2 to 2.4.5.

[From EC proposal]



What is a nanoform? Characterisation

 'Characterisation of nanoforms of a substance: For any of the characteristics, the information provided may be applicable to individual nanoforms or sets of similar nanoforms provided that the boundaries of the sets are clearly specified. A justification shall be provided to demonstrate why the sets are appropriate for the hazard assessment, exposure assessment and risk assessment of the individual nanoforms that are manufactured and placed on the market.'

[From EC proposal]

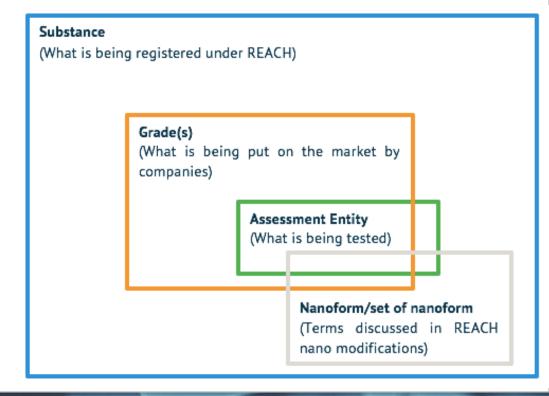


What is a nanoform?

 A common understanding what is considered a 'nanoform' is not clear in the proposed regulatory text, and this cause uncertainties in the application of the regulatory

text

 Guidance note on nanoforms in regulatory proposal, includes also 'set of nanoforms'





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- Drafting a paper, based on information on the wording in the current EC proposal!
 - NB! This is likely to change!
- Several examples provided (currently) focusing on size as the endpoint parameter
 - Situation 1: Size and one nanoform of a substance where 100% is in 1-100 nm
 - Situation 2: Size and a set of nanoforms of a substance where 100% is in 1-100 nm
 - Situation 3: Size and a set of nanoforms of a substance where not 100% is in 1-100 nm
- Also, surface functionalization, shape, surface area examples expected to be developed



NIA Global Regulatory Working Group

- Aim is to develop a practical understanding for industries how to work and understand the nanoform concept based on examples.
- The document will also outline a position on the industry views of the nanoform concept and its practical implications.
- Document will form a discussion basis to be shared and discussed with interested stakeholder



Upcoming joint Industry ECHA meeting

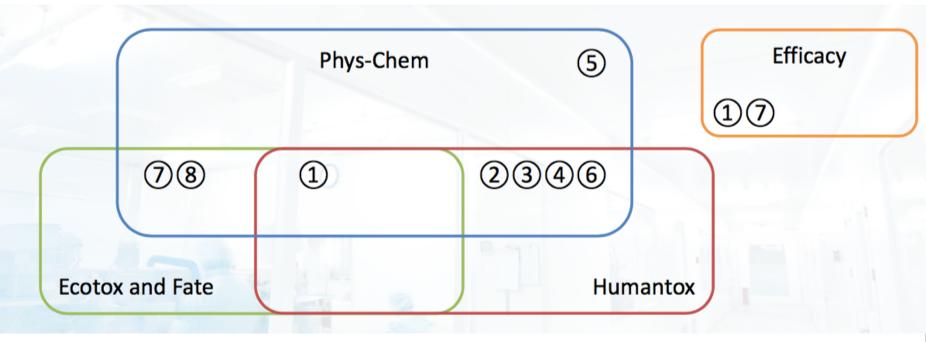
- A dedicated meeting is being prepared with ECHA and Industries to have a joint discussion on the nanoform concept and its implications
- Likely in June/September 2018
- NIA is one of the organisers of this meeting!



Example from NIA Member

Data use scheme

Sorted in main groups of endpoints





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http://nanotechia.org/membership

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