

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

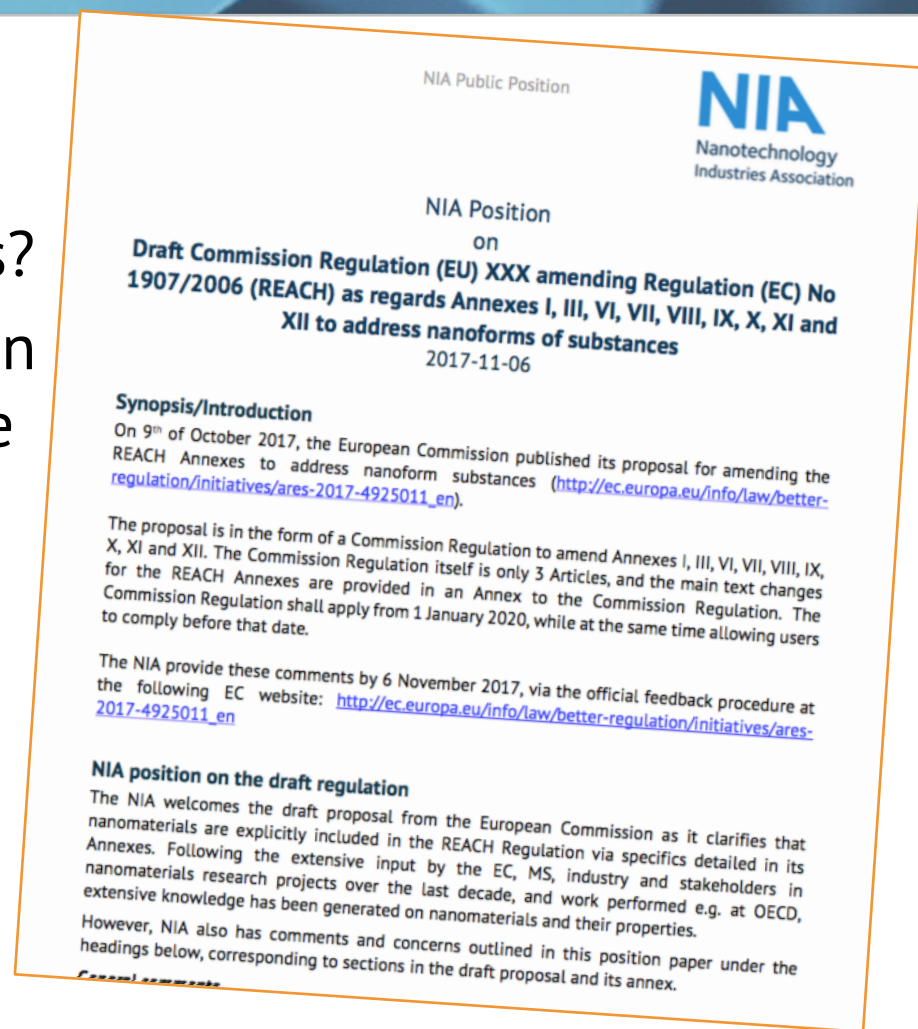
Brussels, 10 April, 2018

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NIA Director Regulatory Affairs

- **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...

Selected snippets:

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



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

Guidance note on nanoforms:

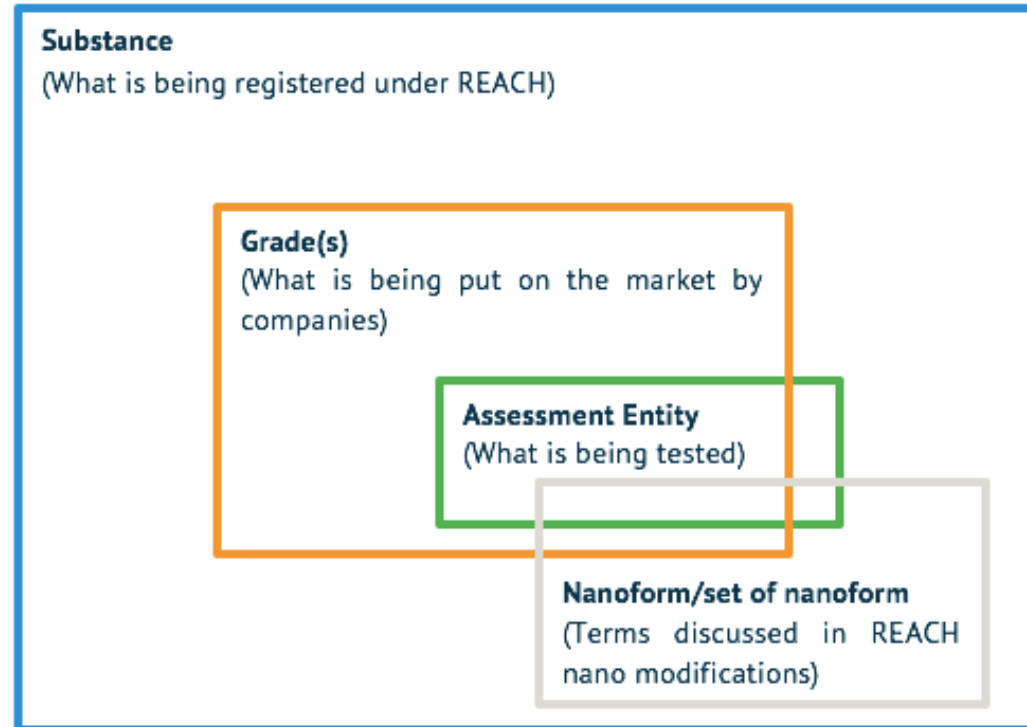
- In accordance with the Commission Recommendation of 18 October 2011 on the definition of nanomaterial, a form of a natural or **manufactured substance containing particles**, in an unbound state or as an aggregate or as an agglomerate and where, for **50 % or more of the particles** in the **number 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]

- ‘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]

- 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**'



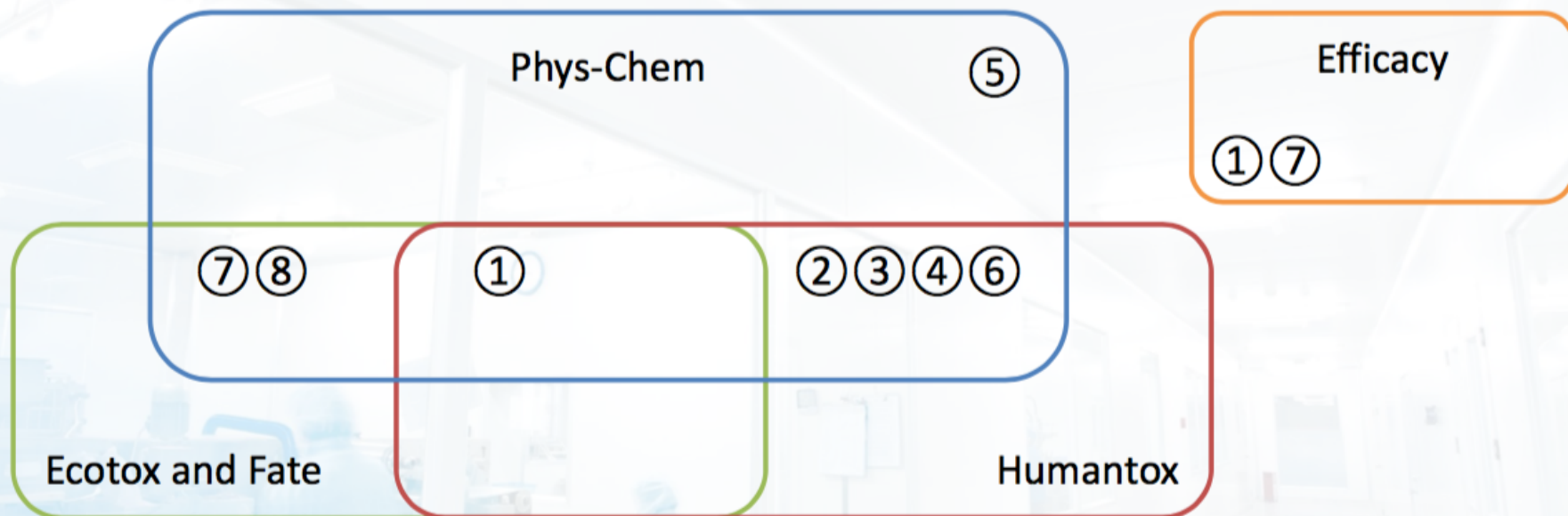
- Drafting a paper, based on information on the wording in the current EC proposal!
 - **NB! This is likely to change!**
- Several examples provided (currently) focusing on **size** as the endpoint parameter
 - *Situation 1: Size and one nanoform of a substance where 100% is in 1-100 nm*
 - *Situation 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

- 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

- 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!

Data use scheme

Sorted in main groups of endpoints



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