9 September 2013

Cefic side letter on public consultation for REACH options

Cefic welcomes the Commission's initiative to launch the public consultation in order to set out an efficient and balanced approach for a potential adaptation of REACH Annexes and guidance documents to cover nanomaterials.

Cefic considers the option 5 as relevant for industry being aimed at enhancing competitiveness and innovation, and at the same time maintaining a high level of safety.

We are concerned that the multiple choice questionnaire provided by DG ENV does not include sufficient space to fully elaborate our views, and that its use alone might even lead to misinterpretations.

Therefore, we have decided to accompany our replies to the internet consultation by this side letter and ask that these additional points are taken into consideration:

Generic comments

Firstly, we would like to stress that although there is an overarching definition in place, the lack of validated and certified measurement techniques is hampering efforts to better address nanomaterials in REACH.

We support the Commission in improving the EC Recommendation of a definition of nanomaterial and we look forward to discussing the implications of the Commission's Recommendation in the context of REACH.

Secondly, the context for regulatory control of nanomaterials must include the increasing understanding of leading scientists that a nano-specific toxicity does not exist and that conventional data are useful and relevant to the evaluation of nanoparticle hazard[1].

Furthermore, we have to bear in mind that the antithesis to Article 5 of REACH "no data, no market", does not automatically mean that ***more data*** means ***more market*** or even ***more safety*** but rather it has the potential to restrict competition. With regard to animal protection, the safety testing should be limited to only meaningful and necessary studies.

In the light of registration obligations, Cefic shares the view of the Commission communicated in its 2nd Regulatory Review on Nanomaterials that under REACH, different forms can be considered within a single registration of a substance.

[1] Donaldson/Poland, Current Opinion in Biotechnology 2013, 24:1–11
Kenneth Dawson at the EuroNanoForum in Dublin 2013

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In addition, Cefic is committed to working with both industry and stakeholder experts to develop solutions for effective application of the existing legislative tools to nanomaterials.

Specific comments

Taking into consideration the complexity of nanomaterials and that there are a number of ambiguities in the phrasing of the questionnaire, Cefic requests that for more clarity and consistency, additional points must be considered, and offers the following comments and recommendations:

Option 2 – clarity option:

- The measures in this option are already REACH requirements. If clarification was needed, it should be addressed in the guidance, and not in REACH Annexes.
- Changes to the REACH Annexes need to be carefully considered, and be implemented **only if needed**. Furthermore, following analysis of the items under this option, we believe there is certainly the case of a "magic triangle" of safety, cost and efficiency where improving one characteristic means a negative impact in another. In order to avoid unnecessary high cost, trade barriers and excessive animal testing, we recommend the use of scientifically valid methods for assessing a respective nanoform considering grouping approaches for similar nanoforms.
- That said, in our previous comments on the Nano Support Task II Final Report, with regard to the measures ***b*** *(detailed characterization)* and ***c*** *(endpoints section)*, we have stated that if the information given for physicochemical and (eco)toxicological endpoints reflects the full spectrum of all identified forms of the substance then, pursuant to REACH, different forms can be covered in the same registration dossier. Certainly, providing full characterisation for all endpoints per each individual nanoform will drastically increase the costs without any improvement of safety *("Impact Assessment of the RIPoN1"*, Cefic/RPA study 2011). Therefore, Cefic considers a pragmatic approach, whereby if physicochemical and (eco)toxicological information (as specified under the measures ***b***, ***c***, ***e*** *(scientific justification)* and ***i*** *(uses and exposure assessment)*) is provided for a representative nanoform then read-across is scientifically justified for other forms. For the measure **i** *(uses and exposure assessment)*, the provision of data would be required **only if appropriate** according to REACH requirements.
- For the measures ***g*** *(bioaccumulation)* and ***h*** *(adsorption/desorption)*, these are not nano-specific and, in our opinion, the same rules (general rules of REACH) should apply for both nanomaterials and bulk materials.

Option 4:

- Cefic regards as appropriate the measure ***a*** *(dustiness)* (to be required only if applicable to and relevant for the workplace and must be measurable in the context of defined standards and measurement techniques) and the measure **d** *(require non-bacterial in vitro gene mutation study).*
- On the measure ***c*** *(inhalation)*, we consider that this is technically not always feasible or relevant for realistic exposure assessment. That is because there is a very strong tendency for nanoparticles to agglomerate and aggregate and thus atmospheres containing individual nano-particles cannot be generated.

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- The relevance and validity of algae studies (measure **g**) with particulate test substances is questionable and validated test guidelines are missing. Furthermore, testing on soil and sediment organisms (measure **h**) should only be required if relevant exposure scenarios exist otherwise these data do not support the safety assessment of nanomaterials.

Option 6:

- Since to date, a nano-specific toxicity could not be demonstrated, this option overestimates the relevance of the nano-size for risk assessment without any scientific justification. Requiring data for non-relevant exposure conditions and endpoints that do not depend on particle size but rather on the material's intrinsic properties would significantly increase the costs for registration without any commensurate improvement in safety.
- The measure ***a*** *(one dossier or separate dossiers)* should be discussed and agreed in the SIEF since it is very case specific, depending on the company's decision (for example, due to chemical composition differences, CBI, other interests, etc.). However, a substance having the same chemical identity for the bulk and nanoform should be a priori registered in one dossier.
- Cefic does not share the opinion expressed in the measure ***m*** *(perform toxicokinetic screening)* due to lack of knowledge about ADME (absorption, distribution, metabolism and elimination) relevance for nanomaterials, and thus believes that the request should not be mandatory.

Finally the REACH regulation should consider that the (eco)toxicological effects of nanomaterials rather depend on the intrinsic (eco)toxicological properties of the material itself than on the particle size. Thus, data requirement should be scientifically justified with relevance for realistic usages and exposure scenarios.

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