

## **Eurocolour's experiences and concerns from the registration of nanoforms under REACH**

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### **Our concerns**

- ❖ Information demands exceed the legal text basis of REACH by far. Guidance documents, IUCLID, and the first draft decisions by ECHA all ask for information without legal basis, nor scientific reason.
- ❖ Scientific justifications for formed sets of similar nanoforms or for the boundary composition of single nanoforms are not accepted without clear justification.
- ❖ Given time frames have been unrealistic and could not be met when sound scientific data needed to be generated. This is an especially high burden for SMEs who often do not have all the analytical equip in-house but have to rely on contract laboratories.
- ❖ The published Guidance Documents are of limited usefulness and applicability as they do not reflect the legal requirements and include many unclarities. Additionally, constant changes in IUCLID without any information for users hamper the submission of updated dossiers.

### **Our demands**

- ❖ Greater inclusion of industry's concerns in the development of legislation and guidance documents – industry's voice is not being heard. A token inclusion brings no benefit and is unacceptable.
- ❖ Higher acceptance of scientific data – science does not bend to political agendas
- ❖ Realistic timeframes necessary – Diligence and correctness must take precedence over time pressure and speed
- ❖ Facing and solving fundamental problems instead of case-by-case discussions

### **Our proposed actions**

- ❖ Align information requirements in guidance documents and in IUCLID with the legal text. A nanoform is defined by the characterizers laid down in REACH Annex VI, Note 2, subsection 2.4.2-2.4.5 and nothing else.
- ❖ Accept that materials with the same phys. chem. parameters also have the same hazard, exposure, and risk profile, thus, facilitating defining boundary compositions for individual nanoforms and justifications for sets of similar nanoforms.
- ❖ Improve communication with industry, e. g. by providing more transparency by publishing patch notes for IUCLID updates or by granting an appropriate deadline in case a dossier evaluation revealed the need to additional data to be generated

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