



Nanomaterials state of the art: the consequences of the adopted Annexes

REACH Conference 2018

3 – 4 September 2018, Bratislava

Dr. Erwin Annys (thanks to Blanca Serrano)



Nanomaterials definition



- Delay in one step before last : public consultation
- After 12 weeks consultation, analysis of feedback
- Decision on revision and its individual elements
- Following Commission's adoption
- Uptake in respective regulations (own processes)
 - REACH will include definition from 2011/696/EU. If recommendation is changed, uptake in REACH will require committee procedure. Implementation impact will be checked
- Further conditions might still apply
 - In REACH 'limited' by what is registered (substance)

Source: EU Commission

Nanomaterials definition: Principal elements to be consulted upon...



Similar but not the exactly the same...

- Materials, not products or components
- Definition based on (sizing of) identifiable constituent solid particles, external size 1-100nm
- Nanostructured materials excluded
- Particle number size distribution, 50% threshold (only)
- Supplementary definitions (particle, agglomerates, aggregates)

Source: EU Commission

Nanomaterials definition

Further changes



- Volume specific surface area (VSSA)
 - As way to exclude material as nanomaterial ($<5 \text{ m}^2/\text{cm}^3$)
 - Guidance decision tree may include VSSA as a way to demonstrate material is a nanomaterial
- Materials explicitly included (options):
 - a) replace existing derogation (fullerenes, graphene flakes and single wall carbon nanotubes) with inclusion of counting also thin ($1 < \text{nm}$) particles of elongated or plate-like shapes; b) leave it as it is, or c) eliminate current derogation
 - Views on this solution (or its alternatives) will be sought in the consultation, including
 - Identification of thus 'newly' included materials and their use
 - Impact of such inclusion, based on uptake in the regulation (e.g. cosmetics)

Adaptation of REACH Annexes to nanomaterials



Process – modification of REACH

- 2012/13: Announcement of possible revision
- 2013-17: Proposal development, impact assessment
- Public consultation, discussions with stakeholders
- 9 October 2017: Commission draft proposal
- **26 April 2018: Committee vote (unanimous)**
- 3 months EP and EC scrutiny, then Commission adoption
- [1 Jan 2020] Mandatory application

Annexes content



Elements I.

- Fulfilling information requirements [Annexes VI, III & VII-XI]
 - Definition of nanoform [NF] and nanoform characterisation requirements
- Clarification statements [Annex I,VI,XII]
 - NF covered by the registration must be addressed
 - Assessment & conclusions documented and appropriate risk management measures identified
- Specific scientific-technical considerations [VII-XI]
 - Make the existing information requirements in Annexes VI to XI effective and applicable for NF
- Annex II (Safety Data Sheets): Not now
 - In 2018, planned jointly with changes coming from GHS

Annexes content



Elements II.

- Changes from initial COM proposal
 - Consider dissolution rate in water, environment and biological media (under water solubility 7.7)
 - Consider dispersion stability when Kow not applicable (under Kow 7.8)
 - Inhalation route for acute toxicity also default under Annex VII (instead of oral route)
 - Long term ecotox (9.1.1,9.1.3) : for NF to be considered also in case of low dissolution rate
 - Additional physchem parameter : new info requirement now under Annex VIII (not IX)

- Discussion in Committee
 - Is 'set of similar nanoforms' a required concept?
 - Final text : YES.

Annex VI (introductory guidance, nanoform)



Fulfilling information requirements for substances with nanoforms (Annexes VI-XI)

- Link the concept of nanoform, based on the Commission recommendation of the definition of nanomaterial*, with the existing information requirements for substances
- Include minimum characterisation information on size, shape, surface treatment and surface area of the nanoparticles as part of substance identification for nanoform or set of nanoforms.

Also enables to establish relevance and adequate scope of the hazard information and chemical assessment

*2011/696/EU. Review in progress. To be replaced by the revised Recommendation as soon as available

Implementation Annexes



- Identification of nanoform(s) for registration
 - Definition
 - Characterisation
 - Identification of uses
- Defining sets of similar nanoforms
 - Justification

Implementation Annexes



- Existing datasets - relevance, identification of gaps
- (Intelligent) testing strategy + grouping/read-across
- Dossier preparation/update
- Support needed
 - Guidance
 - Methods under development

Guidance update



Revision of REACH Annexes for NM

- Modifications to include nanomaterials and nanoforms explicitly into the Annexes, and to adapt the information requirements to nanoforms
- Voted at REACH Committee on 26 April 2018
- Entry into application January 2020
- Triggers need for update/development of guidance to align it with the updated legal text

Guidance on nanoforms:



Update needs:

- The conversion of the Practical Guide into a guidance document
- Revision of the legal justification for the requirements;
- Redraft of the general sections and the terminology of the REACH Annexes is different from the one used in the current practical guide (i.e. sets of nanoforms);
- Amendments to the sections regarding size, shape and surface chemistry of the nanoforms;
- Development of a new section on specific surface area (SSA) to follow the requirements of Annex VI;
- Inclusion of information on characterisation for size, shape surface chemistry and VSSA;
- Explanations on Annex III and general issues on information requirements.

Guidance on read-across



Minor update of one section to be aligned with definition of nanoforms in the revised REACH

Guidance on IR for phys-chem endpoints



Update needs

- Revision of the section on water solubility (incl. limitation of the waiving possibilities for nanomaterials);
- Alignment for the relevant endpoints;
- Revision of the information requirements on granulometry;
- Development of a new section on dissolution rate (relevant for human health and the environment);
- Partition coefficient octanol/water;
- Development of a new section for dustiness;
- Development of a new section on further information for physchem properties.

Guidance on environmental endpoints



Update needs

- General update of several sections to include waiving limitations: e.g. hydrolysis as a function of the pH, adsorption desorption, ecotoxicology testing etc...
- Revision of the sections on transformation make clear testing transformation, coating degradation etc. is mandatory (now recommended in guidance)
- Revision of the section on bioaccumulation to strengthen the message on waving limitations, and when possible provide advice on testing for bioaccumulation

Guidance on human health endpoints



Update needs

- Most of the sections would only need minor alignment (except toxicokinetics and to some extent indirect genotoxicity)

