EUROPEAN ENVIRONMENTAL CITIZENS ORGANISATION FOR STANDARDISATION
ORGANISATION EUROPÉENNE ENVIRONNEMENTALE CITOYENNE POUR LA NORMALISATION
ECOS

ECOS welcomes the publication of the European Commission's official proposal for REACH Annex revisions to address nanomaterials. Nonetheless, ECOS wants to signal the unacceptably late publication of this revision. Work began in 2011, when another option for adequate regulation of nanomaterials also included the creation of a nano-specific legislation to supplement REACH's horizontal addressing of chemicals. At that time, the European Commission proposed that the quickest, and therefore most appropriate, option for establishing chemicals legislation that explicitly addressed nanomaterials was by revising REACH Annexes. Given numerous delays to the development of the proposed revisions, the specific nano requirements for nanomaterials will not be available for the last REACH registration deadline of 2018 and substances in the nanoform will therefore continue to reach the market without ECHA having adequate data to assess their safety.

ECOS therefore provides the following comments to both the political and technical aspects of this proposal.

Political:

ECOS deplores the European Commission's – particularly DG GROW's – maladministration of governance in two ways.

First, it has taken 6 years to produce the official proposal, with no apparent public consideration for missing of the REACH 2018 registration deadline. This delay was never explained or justified beyond mere mentions of the technical complexity of the issue. This demonstrates contempt for citizens and Member States concerns, as well as an obvious prioritisation of industry registrant concerns over EU citizen's health.

Second, DG GROW's and therefore the European Commission's, handling of this dossier has consistently undermined co-regulators' and other stakeholders' contributions to what has become the official proposal:

- The majority of revisions worked on at CASG Nano meetings have not been incorporated into the official proposal;
- There has been no presentation to or discussion of the official proposal in the CASG Nano group; political discussion with the REACH Committee was begun without informing CASG Nano representatives and leaving CASG Nano in the dark about decision-making processes; and
- REACH Committee discussions on the file has so far been restricted to procedural issues.

Such unilateral handling of such an important file does not create trust, faith or good will amongst stakeholders and has no place in democratic decision-making in a "united, stronger and more democratic Union".

Technical:

Definition: It is our understanding that the Annex revision will include a definition of nanoforms. While we welcome this inclusion, we believe that as a matter of clarity, this definition should be included in the core text of REACH rather than in the Annexes.

No future-proofing included: Preamble 8 states that "As the majority of nanomaterials are expected to be nanoforms of phase-in substances…". This statement appears to place the official proposal in developments in nanomaterials back several years. Indeed, in addition to the multiplication of nanoforms with no bulk counterpart, there will still likely be nano-forms of phase-in substances, but with new properties and functionalities requiring clear data requirements. Work delivered by consultants for the European Commission's potential 3rd regulatory review of nanomaterials addressed 'advanced materials', which can include active materials capable of modifying particular properties depending on external stimuli. Given the long gestation period for this official proposal, the lack of future-proofing for new materials is misguided in that it almost guarantees that the revision proposed will become obsolete in the short term.

Tonnage thresholds: The proposed 100t/y threshold needs to be clarified in relation to registrations for purely nanomaterial substances and combined bulk and nanoform substances. Preamble 20 requires that registrants of substances with production volumes of more than 100t/y should provide information on properties beyond those physico-chemical properties used to distinguish a nanoform or sets of nanoforms. The tonnage threshold is suggested for 'workability and proportionality'. Given on-going scientific knowledge gaps, this information should be required for all nanomaterials.

Requirement for "justification" should be a requirement for "*scientific* justification": Various justifications are required throughout the legal text and Annexes, varying between scientific justification, justification and adequate justification. Given ongoing gaps in scientific knowledge on various aspects and impacts of nanomaterials, these justifications should clearly be science-based and therefore all should require *scientific* justification. We do not reference all instances in our response where justification is currently proposed in this text, but rather we clarify that the only two non-scientific justifications acceptable are: in relation to that regarding a registrant's declaration that certain information submitted in the registration dossier is commercially sensitive; and in a substance's high insolubility not being a justification for waiving certain tests set out in Annex VII. These two instances are the only one where the use of the term justification instead of scientific justification is acceptable. In all other instances, and in particular where the Annex modification appears to allow the use of read-across between substances based on a 'justification' (e.g.: Annex I Sub-section 0.4), it should be replaced by a requirement for a scientific justification.

QSARs: Preamble 10 states that 'a justification' has to be provided for why the sets are appropriate for hazard, exposure and risk assessments of individual nanoforms. As indicated above, the preamble should specify *scientific* justification to ensure a science-based decision. Most importantly, the actual requirements to justify the use of QSARs (introductory text proposed as a modification to Annexes VII, VIII, IX and X), only requires a ***description*** "of the range of materials characteristics/properties to which the evidence can be applied."

Given the current knowledge gaps uncertainties about the use of read across, QSARs and grouping, and in order to guarantee that the information provided is adequate for all nanoforms registered, the sentence should be replaced in all four instances by the following: "*Where QSARs are used or evidence is obtained by means other than testing, a scientific justification shall be provided for the range of material characteristics / properties to which the evidence can be applied*".

Grouping and characterisation: As repeated numerous times by several stakeholders and experts in CASG Nano for the past 5 years, in the present state of knowledge, it is impossible to systematically group nanoforms for toxicity and ecotoxicity assessment. Because basic characterisation information is key to bridge this knowledge gap, ALL nanoforms should be fully characterised.

Tests for the environmental fate and environmental hazards should consider the surface functionalisation of nano-objects: Similarly, the absence of specific requirements to distinguish nanoforms depending on their surface treatment and assess them separately (despite Subsection 2.4.3 of guidance note which includes 'Description of surface functionalization or treatment and identification of each agent including IUPAC name and CAS or EC number') is a serious gap that should be addressed in future versions.

Solubility is not a surrogate for potential (eco)toxicity: There are several contradictions on whether solubility is a potential surrogate for (eco)toxicity. Preamble 8 suggests that insolubility should be applied as a surrogate for nanoforms, given the inadequacy of existing tools. Yet, Annex VII features various mentions that high insolubility in water alone cannot serve as justification for waiving specific tests (e.g. short-term toxicity on invertebrates, growth inhibition on aquatic plants). Current levels of scientific knowledge do not allow for (in)solubility to be used as a surrogate for nanoforms and should therefore be deleted from Preamble 8. Similarly, the sentence "unless those nanoforms are soluble in biological and environmental media" in paragraph (b) (ii) of Annex III should be deleted.

Inadequate use of partition co-efficient in relation to nanomaterials: Partition coefficients are mentioned in both the legal text and Annex text. These are not acceptable in the case of nanomaterials as they have been shown to flux in and out of different phases rather than going into equilibrium between different phases e.g. octanol and water and air. Therefore, Preamble 14 should not include partition coefficient. Annex VII,

Subsection 7.8 Partition coefficient n-octanol/water should be deleted. Annex VIII Point 9.3.1 and Annex IX 9.3.2 should not reference partition coefficient.

Preamble 7 confusing wording: The first sentence of Preamble 7 is grammatically incorrect and confusing. Preamble 7 also states that the chemical safety report should describe which nanoforms are covered 'by the assessment'. The first (confusing) sentence mentions that the registrant should "assess … the necessary information and document in the CSR". It is unclear whether this assessment relates to the risk assessment mentioned in Preamble 6 or to the assessment of the documents in the CSR mentioned in the first sentence of preamble 7.

Clarification needed for use of 'where relevant': There are many instances of 'where relevant' that lead to legal uncertainty. It is furthermore unclear who determines when this is relevant and how, so all instances of "where relevant" should be deleted. Examples include Annex I Section 5.2.2 in relation to exposure assessment of nanoforms compared to non-nanoforms; Annex I Section 5 introductory text relating to Safety Date Sheet information. It is our view that such information generation and provision should be systematic for non-nano and nano-forms.

Safety Data Sheet requirements need strengthening: No specific duties have been introduced to improve the existing (poor) information provision in SDSs. We propose clearer wording that requires an SDS to include information on nanomaterials and nanoforms in the following categories: composition, handling, exposure controls, physical and chemical properties, and toxicological information.