Open Letter to the European Commission:

- **DG GROW:** Kerstin Jorna, cc Hans Ingels
- **DG ENV** : Florika Fink-Hooijer, cc Cristina de Avila
- Cc **DG SANTE** : Sandra Gallina

8 February 2022

Civil society concerns and demands regarding the EC "nanomaterial" definition

We, the undersigned, are writing to you regarding the ongoing process of revising the recommendation[1] on the definition of the term "nanomaterial". The much smaller size of nanomaterials compared to bulk substances also makes them dramatically more mobile, reactive, and thus potentially toxic. We are particularly concerned about the revision's process and potential consequences, and we would like to ask you to put in place a number of measures in order to guarantee that it delivers in a health and environment-protective way.

Some of our organisations took part in the online consultation conducted in May-June 2021. However, the latter was put forward on a very short notice, with limited allocated time to respond[2], which favoured the participation of industry stakeholders over others[3]. Above all, the lack of clarity on the purposes, rationales and impacts for the proposed changes[4] made it close to impossible to provide informed responses. Besides, modifications proposed in the consultation are problematic: if implemented as such, they would very likely lead to the exclusion of substances that were covered by the 2011 recommendation. In a context of the Zero Pollution ambition and the objective for a toxic-free environment and strong citizens' desire for increased information about nanomaterials[5], this would be extremely counterproductive.
Finally, in light of the continuing under-registration of nanomaterials within REACH[6], under-labelling and large use of unauthorised nanomaterials across consumer products[7], the proposed modifications come across as an attempt to "break the thermometer to address the fever".

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[1] Commission recommendation of 18 October 2011 on the definition of nanomaterial (2011/696/EU) https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32011H0696

[2] Expected to last twelve weeks, it was shortened to only eight weeks, with only a week ahead notice, while it was expected since 2014

[3] Cf. https://ec.europa.eu/environment/pdf/chemicals/nanotech/TSC_Nanodefinition_PublicExcerpt.xlsx

[4] For example, the proposal to get rid of the possibility to lower the 50% threshold is not backed by any sanitary, scientific and analytical rationale nor by any evidence that this would effectively limit innovation possibilities for market operators or put the safety of consumers at risk. As a matter of fact, specific properties of nanomaterials – as well as the toxicity that may result from them – do not "magically" disappear below 50% or above 100 nm.

[5] Cf. Understanding the public's perception of nanomaterials and how their safety is perceived in the EU, ECHA / EUON, November 2020

[6] To date, only 150 nanoforms are registered in REACH, half as much as in the French register r-nano

[7] Tests carried out by civil society organisations and national authorities alike are regularly showing the wide presence of unlabelled nanoparticles and/or unauthorised nanomaterials. Cf. "French authorities detect high rate of non-compliance on nanomaterials in cosmetics", Chemical Watch, 25 November 2021

With this letter, we thus call on you to properly and collectively scrutinise the ins and outs of the changes that the Commission has proposed (as well as those that have not been considered) in order to:

- clarify and justify proposed modifications with real-world examples of shortcomings in the existing definition;
- explain how the proposed modifications would address the prior challenges and assess their full impacts (including by monitoring their potential adverse effects);
- allow for a transparent discussion through the organisation of public Q&A sessions, with presentations and discussions based on concrete cases, contradictory insights and contributions from stakeholders and independent experts of various fields (physical chemistry, toxicology, metrology, law, etc.), in order to eventually deliver a clearer common understanding of which materials should (or not) fall off the revised definition, under which conditions, etc.

Only a transparent, inclusive, and iterative process will ensure buy-in from all stakeholders as well as a legally and scientifically reliable revised definition.

- From a legal standpoint, a flawed revised recommendation would be detrimental to the objectives of EU regulations in which it would be integrated (REACH, Cosmetics, BPR, Novel Foods, Medical Device, ...), with or without adaptations. Bringing appropriate and relevant clarifications upstream would spare additional laborious discussions and tedious work downstream, and would thus be much more effective and efficient.
- From a scientific standpoint, the guarantees we are asking would ensure that the process is based on the latest scientific evidence in the field. For example, a recent EFSA guidance, which was published after the end of the online consultation, focuses on materials with more than 10% of the particles (number-based) with at least one external dimension smaller than 500 nm[8]. By aiming at guaranteeing minimum adverse effects on human health and ecosystems, such evidence-based consideration[9] is also in line with recommendations made by national authorities (e.g. Sweden, France and Belgium, ...) and the Zero Pollution Ambition of the Chemicals Strategy for Sustainability.

We look forward to your response and would welcome the opportunity to hold an exchange on those important matters.

Yours sincerely,

Philippe Bourlitio,
President, AVICENN

On behalf of:

- Association de veille et d'information civique sur les enjeux des nanosciences et nanotechnologies (AVICENN)
- Bund für Umwelt und Naturschutz Deutschland (BUND)
- ChemSec
- the Center for International Environmental Law (CIEL)
- ClientEarth
- Environmental Coalition on Standards (ECOS)
- European Environmental Bureau (EEB)
- France Nature Environnement (FNE)
- Générations futures
- Health Care Without Harm (HCWH)
- Health and Environment Alliance (HEAL)
- Sciences citoyennes
- Women engage for a common future (WECF) International & France
- ZERO - Associação Sistema Terrestre Sustentável
- Zero Waste Europe (ZWE)

Please note that this letter will be made publicly available considering that this matter is of public interest.

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[8] Cf. Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles, EFSA, June 2021

[9] The 500 nm limit is based on the fact that a particle uptake from physiological barrier has been found to be possible for sizes up to 250 nm, with an uncertainty factor of 2 which has been applied to account for the limitations of available screening techniques for size measurements (see EFSA, 2021, above-cited, page 21).
The 10% threshold is a technical threshold based on the measurement uncertainty that can be achieved under typical conditions with the currently available EM methods (see EFSA, 2021, above-cited, page 24).