EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR INTERNAL MARKET, INDUSTRY, ENTREPRENEURSHIP AND SMES
Ecosystems I: Chemicals, Food, Retail
F.2 – Bioeconomy, Chemicals & Cosmetics

Brussels
GROW.F.2/SJ

Mr Philippe Bourlitio
AVICENN

E-mail:
mathilde.detcheverry@veillenanos.fr

Dear Mr Bourlitio,

Thank you for your letter of 14 March 2023 in which you inform us about the recent testing results relating to the presence of nanomaterials in consumer products and advocate the need for better information and enforcement of existing measures relating to nanomaterials.

Ensuring that products we use daily, including cosmetics, food and hygiene products, containing substances in nanoforms are safe in terms of human health and do not have a negative impact on the environment, remains our priority. To that end, both REACH and sector legislations in food and cosmetics contain strict provisions for the characterisation, assessment and labelling of nanomaterials.

We share and agree with the need for increased knowledge, transparency and vigilance on nanomaterials raised in the recommendations and questions of your letter.

In the ISO/TS 80004-1:2015(en) standard, nanomaterial is defined as the “material with any external dimension in the nanoscale (2.1) or having internal structure or surface structure in the nanoscale" with nanoscale defined as the "length range approximately from 1 nm to 100 nm". This is a very generic definition leading to different approaches on the market and raising various issues of compliance.

The 2022 Recommendation on the definition on nanomaterials (the “2022 Recommendation”) ([1]) is the result of extensive knowledge and experience, gained with the definition of the Commission Recommendation 2011/696/EU (the “2011 Recommendation”) ([2]), which enabled the Commission to conclude that the default threshold particle fraction value of 50 % threshold is a pragmatic and scientifically sound

([1]) Commission Recommendation of 10 June 2022 on the definition of nanomaterial, OJ C 229, 14.6.2022, p. 1–5.
([2]) Commission Recommendation of 18 October 2011 on the definition of nanomaterial, OJ L 275, 20.10.2011, p. 38–40.

Commission européenne/Europese Commissie, 1049 Bruxelles/Brussel, BELGIQUE/BELGIË – Tel. +32 22991111
Office: N105 08/090 – Tel. direct line +32 229-84121

Sylwia.JACZEWSKA@ec.europa.eu

criterion for which the review did not identify systemic and scientifically underpinned reasons to deviate from. ([3])

The Staff Working Document ([4]) points to the insufficient knowledge, and a too large physicochemical variety among nanomaterials to justify "*carving out all-inclusive criteria and still be both implementable and not lead to 'false positive' classifications (i.e. include a significant number of materials for which scrutiny might not have been warranted)*".

The 2022 Recommendation proposes a definition of nanomaterial that is appropriate in the general context of Union policy and legislation to aim for a coherent approach that upholds legal certainty. However, the Commission has recognised (recital 23 of the Recommendation), that it may be necessary in some cases to exclude certain materials from the scope of application of specific legislation even if they are nanomaterials under this Recommendation and likewise there might be a need to subject certain materials to the regulatory provisions foreseen for nanomaterials, even if they do not fall under the definition of nanomaterial in accordance with the Recommendation.

The requirements in REACH Regulation (EU) 1907/2006 ([5]) on industrial chemicals, requiring since 2018 specific registration for substances in nanoform, follows the nanomaterial definition in the 2011 Recommendation applying already as fixed its default 50% threshold. As the 2022 Recommendation replaced the previous definition, the nanoform definition in REACH will be revised accordingly ([6]) to maintain full adherence to the harmonized definition. The implementation experience since 2018 is still building, as nanoforms have been registered for 177 substances ([7]). Tools like substance evaluation use information on nanoforms alongside information on other forms e.g. powder and massive forms of substances, to ensure comprehensive understanding of the properties of (different forms of) substances.

As regards cosmetics, one of the objectives of the targeted revision of the Cosmetic Products Regulation ([8]) is to align the definition of nanomaterial with the definition recommended in the 2022 Recommendation. The Commission will not propose changing the existing empowerment which enables adjusting the definition of nanomaterial to technical and scientific progress and to definitions subsequently agreed at international level (Article 2(3) of the Cosmetic Products Regulation).

The 2022 Recommendation and the technical and scientific knowledge and experience underpinning it, are also the basis for the revision of the 'engineered nanomaterial' definition

([3]) Recital 13 of the 2022 Recommendation.
([4]) Commission Staff Working Document "Review of the Commission Recommendation 2011/696/EU on the definition of nanomaterial accompanying the document Commission Recommendation on the definition of nanomaterial", SWD(2022) 150 final, 10 June 2022, page 25.
([5]) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (Text with EEA relevance)Text with EEA relevance (OJ
([6]) Changes to nanoform provisions are planned as part of an ongoing REACH revision; Commission proposal is planned for last quarter of 2023.
([7]) Search with EUON – European Observatory for nanomaterials, March 2023
([8]) Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, OJ L 342, 22.12.2009, p. 59–209.

enshrined in Regulation (EU) 2015/2283 on novel foods ([9]). As with cosmetics, and applying the flexibility that the June 2022 definition allows for, the Commission will consider all pertinent elements that may be applicable in revising the 'engineered nanomaterial' definition.

With regards to plastic food packaging and other food contact materials, specific authorisation of substances in the nanoform has been required since more than a decade. The on-going revision of the legislation on food contact materials will aim to ensure a harmonised approach for all materials, including paper and board, rubbers, coatings and inks. The revision should facilitate a much higher transparency for substances that are used in food contact materials, including nanomaterials.

The **enforcement** of the requirements laid down in the sectoral Union legislation relies on the national authorities. The Commission supports their efforts by providing them a platform, in the form of expert groups, to discuss problems and to enable exchange of good practices, where necessary also in the form of coordinated action on a specific issue.

In the area of cosmetic products, the sub-group on Definition of Nanomaterials follows the developments in the EU and in the Member States as regards nanomaterials and their impact on cosmetics. The Platform of European Market Surveillance Authorities for Cosmetics (PEMSAC) assists national authorities in their enforcement actions. In addition, the national surveillance authorities can benefit from the Single Market Programme and participate in Joint Actions which facilitate the organisation of cross-border testing of products of their choice.

In the food area, the Joint Research Centre of the Commission, at the request of the Directorate general for Health and Food Safety, is training and assisting Member State laboratories in the development and validation of methods to identify and characterise engineered nanomaterials in foods.

We continue believing that the **registration of products containing nanomaterials and the rules for labelling** for such products should remain sector specific. We do not consider developing additional nano-specific registries or labels. We are committed to facilitate maximum transparency regarding the presence of nanomaterials on the European market (in terms of products and uses) as well as future trends through the EU Observatory for Nanomaterials (EUON). Across the sectors, the adequate assessments considering potential specificity of hazard or risk of different (nano)forms is actively pursued so that it can be adequately followed by corresponding hazard labelling and other appropriate risk management measures. Impact of form on parameters linked to sustainability or circularity is also being considered both in the assessments and in the development of associated data generation, reporting and information bases.

Before a cosmetic product can be placed on the EU market, the responsible person has to notify to the Commission the presence of substances in nanoform including, among others, their identification, specifications, their toxicological profile, the safety data and the reasonably foreseeable exposure conditions (Article 13 and 16 of the Cosmetic Products Regulation). The information on a label of a cosmetic has to indicate which ingredients are

([9]) Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327, 11.12.2015, p. 1).

present in the form of nanomaterials (the word "nano" has to follow such ingredient) (Article 19(1) of the Cosmetic Products Regulation).

Similarly, provisions for the risk assessment of engineered nanomaterials as defined in Regulation (EU) 2015/2283 on novel foods, and of materials in nanoform as referred to in plastic food contact materials ([10]) or in food additives ([11]) regulations are in place. Engineered nanomaterials or materials in nanoform used in foods must be appropriately identified on the product label (word 'nano' next to the ingredient name).

Such labelling in food and cosmetics serves only information purposes and it does not imply any hazard or risk linked to the presence of a nanomaterial in a product concerned.

In addition, at the request of the Commission, the European Food Safety Authority (EFSA) has developed guidance documents to ensure that not only engineered nanomaterials and materials in nanoform but also materials which, although they do not meet the definition of engineered nanomaterial, may contain a fraction of small particles including nanoparticles used in foods, are properly assessed for safety.

Finally, we appreciate your choice to refer to one of the studies performed under the umbrella of the EU Observatory for Nanomaterials, created by the European Commission and operated by the European Chemicals Agency. Indeed, the study showed that the awareness on the nature, characteristics and properties of nanomaterials is low, but increasing. It also confirmed that the availability of information on nanomaterials reduces the concerns about the safety of using them in everyday products. We look forward to collaborating with you on an improved information and communication on nanomaterials.

Yours sincerely,

Electronically signed

Hans Ingels
Head of Unit

([10]) Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (OJ L 12, 15.1.2011, p. 1).

([11]) Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16).