European Food Safety Authority

SCIENTIFIC COMMITTEE UNIT

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Mrs Paola Testori Coggi
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European Commission
Health and Consumer Directorate-General
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Subject: Application of the Definition on nanomaterial to food and feed

Dear Mrs Testori Coggi,

The European Commission adopted on 18 October 2011 a Recommendation on a definition of nanomaterial[1] which is addressed to Member States, economic operators and Union agencies. The EFSA in consultation with its Scientific Committee and its Network for anomaterials in food and feed, considered the definition and the consequences in terms of risk assessment when applying it to food and feed.

As point 6 of the recommendation foresees a review of the definition by December 2014 based on experiences gained by the addressed instances, please find here below the findings of the EFSA consultations on this issue:

[1] The commission Recommendation of 18 October 2011 on the definition of nanomaterial (2011/696/EU), EN L 275/40 Official Journal of the European Union 20.10.2011: *"Nanomaterial" means a natural, incidental or manufactured material containing particles (i.e. minute pieces of matter with defined physical boundaries), in an unbound state or as an aggregate (i.e. particles comprising of strongly bound or fused particles) or as an agglomerate (i.e. collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components) and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm. In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50 % may be replaced by a threshold between 1 and 50 %.". "Where technically feasible and requested in specific legislation, compliance with this definition may be determined on the basis of the specific surface area by volume. A material should be considered as falling under this definition where the specific surface area by volume of the material is greater than 60 m^2 /cm 3. However, a material which, based on its number size distribution, is a nanomaterial should be considered as complying with this definition [as above] even if the material has a specific surface area lower than 60 m^2 /cm^3. "By derogation [of what has been stated above], fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials"*

1. Currently, the only EU definition of engineered nanomaterial, relevant to food/feed applications and used by EFSA for risk assessment, is provided under point (t) of Article 2(2) of the Food Information Regulation (Regulation (EU) No 1169/2011). However, a provision in the Article 18(5) of Regulation (EU) No 1169/2011 also makes a future adjustment of the definition possible in view of technical and scientific progress, or a definition agreed at international level. In due course, other relevant regulatory frameworks may also adopt nanomaterial definition in view of the criteria provided in the Recommendation.

2. While the EFSA Scientific Committee did not adopt, in its opinion in 2011, any specific definition for the term 'nanomaterial', the understanding is that the 'nanomaterial' to be assessed consists of particles with at least one size measurement between approximately 1 and 100 nm. The recent Commission Recommendation for a definition, however, clearly considers a nanomaterial to be composed of particles in unbound state as well as when in aggregate or agglomerate forms. It also proposes a threshold of 50% or more in terms of particle number distribution in the nano-scale (i.e. one or more external dimensions between 1 nm-100 nm). Furthermore, it proposes by derogation a lower threshold between 1 and 50%, where warranted by concerns for the environment, health, safety or competitiveness.

3. The feedback from the Member States and Scientific Committee broadly welcomed the criteria laid out in the proposed Recommendation for nanomaterial definition. A few suggestions were made, such as:
    a. Extend the term 'internal structure' to 'internal structure with a possibility of nanoparticle release', because some conventional (e.g. porous) materials may also have an internal structure at the nanoscale but without the possibility of releasing nanoparticles.
    b. Consider for food related applications a lower cutoff for nanoparticles, rather than the 50% threshold proposed in the Recommendation, as a basis for nanomaterial definition. As an example, one proposal was to use 0.15% of particle number distribution in nanoscale as suggested by SCENIHR (2010).
    c. Consider all the new data that becomes available by 2014 while revising the Recommendation in 2014.

4. Feedback on the potential implications of adopting the Recommendation on risk assessment suggested that thorough characterisation of nanomaterials was the key consideration for nanomaterials. It was stressed that any toxicological data for use in risk assessment should be gathered with special attention to possible agglomeration and aggregation of nanoparticles in the actual testing media at relevant concentrations. This is in view of the distinctive agglomeration/aggregation behavior of nanoparticles that may jeopardise the outcome of toxicological investigations due to effect on the uptake, bioavailability/kinetics, biological interactions and effects of nanoparticles. For this, the measurement of size distribution of free nanoparticles, as well as their aggregates and agglomerates, in the target cells/tissues, was seen as an important element for the interpretation of test results. Other factors considered important in this regard include shape and surface coating, as they may affect penetration of nanoparticles through membrane barriers, as well as their bioavailability, kinetics, distribution, and persistence in the organism, and toxic effects.

5. Feedback on the question whether risk assessment should focus on monodispersed materials or also include mixtures of nanoparticles noted that nanomaterials used as food/feed additives in real-life applications are likely to have a wider size distribution of nanoparticles. Therefore, relevant testing could use monodispersed nanomaterials in initial scientific investigations to obtain basic data on properties, behavior and effects, but must also use polydispersed materials, and mixtures of nanoparticles of different compositions and sizes, to account for more realistic situations.

6. It was also noted that nanoparticles may manifest toxic effects differently from the conventional forms. For example, unlike conventional substances, nanoparticles may impart a disproportionate or exacerbated toxic effect at lower concentrations than at higher concentrations. This is because higher concentrations of nanoparticles are likely to increase the possibility of agglomeration/aggregation or saturation of test systems, which may prevent nanoparticle uptake and thus mask toxicological effects.

7. The main actions identified as a follow-up of the EC Recommendation on nanomaterial definition stressed the need for more public dialogue and education, and the development of validated techniques for particle number measurement and nanomaterial characterisation.

In consideration of the above views, the EFSA Scientific Committee proposes that the EC considers the following when revising the Recommendation as is foreseen in point 6 of the Recommendation:

i). A major current challenge in ensuring the safety of nanomaterials is how to detect and characterise them in different complex matrices, for instance food or feed. There is a current lack of validated analytical methods for nanomaterials in general, and in complex matrices in particular. This is because foodstuffs for instance contain a range of natural structures, some of which in the nano-scale, which makes it difficult to differentiate between natural nano-structures and engineered nanomaterials. Therefore, scientific progress and state-of-the-art in terms of availability and validation of analytical technology should be considered when adopting the Recommendation under any of the food related regulatory frameworks, and when revising the Recommendation in 2014.

ii). In the context of food related applications, the term ‘natural, incidental or manufactured’ should be restricted to ‘incidental or manufactured’ because of the likely presence of natural nano-structures in foodstuffs, or their generation from larger food structures during processing.

iii). In view of the current uncertainties over safety, a lower nanoparticle number threshold, e.g. 10%, should be considered for food related applications instead of the currently proposed (50%) in the Recommendation.

iv). For the purpose of food related applications, consideration should be given to include only those materials in the definition that are insoluble, partially-soluble, and persistent or stable enough in final products and/or in the body to allow interaction with biological systems at the local or systemic levels.

v). Depending on the number and nature of applications for substances in nanoform, and any relevant regulatory developments, EFSA may consider revising the Opinion of 2011 on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain.

We remain at your disposal to monitor and inform about any further scientific or technological development relevant to the definition of nanomaterial. One important EFSA activity in this regard is the FEEDAP procurement contract to make an inventory of reasonably foreseen applications of nanotechnology in food and feed. We thank your services for their kind mutual cooperation in this field.

Yours sincerely,

[SIGNED]

Catherine Geslain-Lanéelle

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Mr Q. Chaudhry, Mr A. Hardy (Chair EFSA SC)
Mr H. Deluyker, Mr D. Liem, Ms R. Schoonjans (EFSA SCOM Unit)

ANNEX 1

Feedback from EFSA on applying the recommended definition of nanomaterial on food

Each of the scientific and technological aspects of the recommended definition were reviewed in detail by the EFSA Scientific Committee. The EFSA Scientific Committee 2012-2015 that became operational on 23 July 2012, built further on the work of the EFSA Scientific committee 2009-2012 and the EFSA internal taskforce with scientists from all concerned Units. Also the national risk assessors of the EFSA Network for nanotechnology in food and feed were consulted and are acknowledged for their input. The following is the brief outcome of the EFSA consultations on this issue: