



TEXTS ADOPTED

P9_TA(2024)0316

Objection to a delegated act: Novel foods - the definition of 'engineered nanomaterials'

European Parliament resolution of 24 April 2024 on the Commission delegated regulation of 14 March 2024 amending Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods as regards the definition of 'engineered nanomaterials' (C(2024)01612 - 2024/2691(DEA))

The European Parliament,

- having regard to the Commission delegated regulation of 14 March 2024 amending Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods as regards the definition of 'engineered nanomaterials' (C(2024)01612),
- having regard to Article 290 of the Treaty on the Functioning of the European Union (TFEU),
- having regard to 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 1852/2001¹, and in particular Article 31 and Article 32(6) thereof,
- having regard to Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provisions of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission

¹ OJ L 327, 11.12.2015, p. 1.

Regulation (EC) No 608/2004¹, and in particular Article 18(3) thereof,

- having regard to Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives²,
 - having regard to the Union lists established by Commission Regulation (EU) No 1129/2011 of 11 November 2011 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives³ and Commission Regulation (EU) No 1130/2011 of 11 November 2011 amending Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives by establishing a Union list of food additives approved for use in food additives, food enzymes, food flavourings and nutrients⁴,
 - having regard to Commission Regulation (EU) No 257/2010 of 25 March 2010 setting up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives⁵,
 - having regard to Rule 111(3) of its Rules of Procedure,
 - having regard to the motion for a resolution of the Committee on the Environment, Public Health and Food Safety,
- A. whereas Article 18(3) of Regulation (EU) No 1169/2011) provides that all food ingredients present in the form of engineered nanomaterials are to be clearly indicated in the list of food ingredients to ensure consumer information; whereas, accordingly, Regulation (EU) No 1169/2011 defines ‘engineered nanomaterials’ as established by Article 3(2), point (f), of Regulation (EU) 2015/2283;
- B. whereas Article 31 of Regulation (EU) 2015/2283 empowers the Commission to adjust and adapt the definition of ‘engineered nanomaterials’ referred to therein to technical and scientific progress or to definitions agreed at international level, by means of delegated acts, for the purposes of achieving the objectives of that Regulation;
- C. whereas comprehensive Union lists established by Regulations (EU) No 1129/2011 and (EU) No 1130/2011 set out the food additives that were permitted for use prior to the entry into force of Regulation

¹ OJ L 304, 22.11.2011, p. 18.

² OJ L 354, 31.12.2008, p. 16.

³ OJ L 295, 12.11.2011, p. 1.

⁴ OJ L 295, 12.11.2011, p. 178.

⁵ OJ L 80, 26.3.2010, p. 19.

(EC) No 1333/2008 after a review of their compliance with the provisions thereof;

The definition consequences

- D. whereas the Commission delegated regulation's definition of 'engineered nanomaterial' will determine whether a food is to be labelled as '[nano]' in the list of ingredients, as referred to in Article 18(3) of Regulation (EU) No 1169/2011;
- E. whereas the Commission delegated regulation aims to address interpretation issues stemming from the current definition by introducing objective elements to determine whether a nanomaterial is 'engineered' or not, such as through replacing 'intentionally produced [material]' with 'manufactured';
- F. whereas the Commission delegated regulation precludes particles that are not in a solid state, such as micelles, liposomes, or nanoscale droplets in emulsion, and ingredients containing less than 50 % of particles less than 100 nm in size from being considered as nanomaterials in food;
- G. whereas the proposed default threshold value of 50 % or more particles at the nano-scale is arbitrary and less protective than the interpretation that has been given by some Member States, for example France, of the definition in Regulation (EU) 2015/2283; whereas that Regulation does not consider a size distribution threshold value for particles below 100 nm;
- H. whereas the proposed definition would potentially exclude many nano-substances from the scope of Regulation (EU) No 1169/2011, which would thus not be subject to the '[nano]' labelling obligation; whereas the Commission indicates in its explanatory memorandum point 3 that 'the number of materials used in foods that may contain a certain fraction of nanoparticles is limited and most if not all of these are materials are not novel' and that '[t]he potential impacts of the delegated act will therefore only concern a very limited number of materials';
- I. whereas, currently, it is precisely food additives that may be present as nanomaterials in food; whereas the French National Health and Safety Agency (ANSES) had listed 37 nano-substances used in more than 900 food products¹; whereas tests carried out by consumer organisations and non-governmental organisations (Agir pour

¹ <https://www.anses.fr/fr/nanomateriaux-alimentation-premiere-application-methodologie>.

l'Environnement¹, Que Choisir², 60 Millions de consommateurs³, AVICENN⁴ in France, Foodwatch⁵ and Bund⁶ in Germany, Testachats⁷ in Belgium and Altroconsumo⁸ in Italy and OCU in Spain⁹) have repeatedly shown the presence of food additives with a significant percentage of nanoparticles, for example, the food colouring iron oxide (E172) used in dairy products, baked goods, and some breakfast cereals, may contain nanoparticles below the 50 % threshold; whereas this shows that the lack of adequate labelling of certain food ingredients as '[nano]' is primarily due to a lack of enforcement of the current legislation, and much less so to interpretation issues;

- J. whereas a 2020 study commissioned by the European Chemicals Agency showed that citizens demand better labelling of everyday products containing nanomaterials¹⁰;

Contradictions with recommendations and new scientific advancements

- K. whereas in its resolution of 12 March 2014 on the Commission delegated regulation of 12 December 2013 amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers as regards the definition of 'engineered nanomaterials'¹¹, the European Parliament objected to a very similar definition, with the same 50 % threshold, which excluded all food additives, considering that the definition was 'contrary to the basic aim of the directive to pursue a high level of protection of consumers' health and interests by providing a basis for final consumers to make informed choices'; whereas the European

1 <https://www.agirpourenvironnement.org/communiqués-presse/enquete-exclusive-des-analyses-revelent-la-presence-de-nanoparticules-dans-3980/>.

2 <https://www.quechoisir.org/enquete-nanoparticules-taille-mini-doutes-maxi-n50748/>.

3 https://bibliotheque.60millions-mag.com/detail/publication/detail-top-right/561?issue_id=113421&switch_toc=archive.

4 <https://veillenanos.fr/wp-content/uploads/2023/01/Rapport-test-EN-20230113.pdf>.

5 <https://www.foodwatch.org/de/potenziell-krebserregender-farbstoff-in-backzutaten-von-dr-oetker>.

6 https://www.bund.net/fileadmin/user_upload_bund/publikationen/chemie/nanotechnologie_in_lebensmitteln_hintergrund.pdf.

7 <https://www.test-achats.be/sante/sante-au-quotidien/produits-testes/news/nanoparticules-affichage>.

8 <https://www.altroconsumo.it/alimentazione/sicurezza-alimentare/news/nanoparticelle>.

9 <https://www.ocu.org/toda-la-informacion?type=magazine-articles&magazine=ocu%20compra%20maestra&year=2019>.

10 <https://echa.europa.eu/-/what-do-eu-citizens-think-about-nanomaterials->.

11 OJ C 378, 9.11.2017, p. 92.

Parliament called on the Commission to submit a new delegated act which takes its position into account;

- L. whereas in its resolution of 8 October 2020 on the draft Commission regulation amending the Annex to Regulation (EU) No 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards specifications for titanium dioxide (E 171)¹, the European Parliament objected to a draft Commission regulation which authorised food grade titanium dioxide (E171) batches that contain fewer than 50 % of particles smaller than 100 nm;
- M. whereas the European Food Safety Authority recommended² that '[i]n 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';
- N. whereas academic organisations, public authorities, non-governmental consumer and environmental organisations and trade unions advocated in the consultation process of the Commission for a definition that would include all materials, be they manufactured, incidental or natural, and a default threshold of 10 % or more of particles in the number-based size distribution;
- O. whereas since 2014, new scientific advancements and knowledge confirm that nanomaterials can cross physiological barriers and are often more hazardous than substances in micro or macro states³;
- P. whereas ANSES published a detailed report in April 2023⁴ in which it states that the definition of nanomaterials set out in the Commission's Recommendation of 10 June 2022⁵, which has served as the basis for the revision of the definition of 'engineered nanomaterials' set out in Regulation (EU) 2015/2283, in sector-specific regulations, especially in food, would be detrimental to the prevention of health and environmental risks; whereas ANSES stressed that the nanoparticle number threshold of 50 % included in the horizontal '[nano]' definition 'is not based on sound scientific arguments', and recommended setting a lower value for that threshold;

¹ OJ C 395, 29.3.2021, p. 28.

² <https://www.efsa.europa.eu/sites/default/files/assets/corporatenanotechnology121003.pdf>.

³ <https://veillenanos.fr/en/dossier/nanos-and-health/nanos-health-risks/>.

⁴ Anses opinion (2023): Definition of nanomaterials: analysis, challenges and controversies, <https://www.anses.fr/en/system/files/AP2018SA0168RaEN.pdf>.

⁵ Commission Recommendation of 10 June 2022 on the definition of nanomaterial (OJ C 229, 14.6.2022, p. 1).

- Q. whereas detecting nano food ingredients based on a 10 % nanoparticle number threshold is feasible, since that is the cut-off value currently applied by the French Directorate General for Consumer Affairs, Competition and Fraud Control in its control activities¹;

Precautionary principle

- R. whereas Article 191(2) TFEU sets out the precautionary principle as one of the fundamental principles of the Union;
- S. whereas Article 168(1) TFEU states that ‘a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities’;
1. Objects to the Commission delegated regulation;
 2. Instructs its President to forward this resolution to the Commission and to notify it that the delegated regulation cannot enter into force;
 3. Considers that the Commission delegated regulation is not compatible with the aim and content of Regulation (EU) 2015/2283 and that it exceeds the delegated powers conferred on the Commission in Article 31 of that Regulation;
 4. Regrets that the proposed threshold of 50 % does not take into account technical and scientific progress;
 5. Calls on the Commission to apply the precautionary principle, to ensure consumer safety and information and to take into account the One Health approach;
 6. Instructs its President to forward this resolution to the Council and to the governments and parliaments of the Member States.

¹ Anses (2020) : Nanomatériaux dans les produits destinés à l'alimentation. Rapport d'expertise collective, <https://www.anses.fr/fr/system/files/ERCA2016SA0226Ra.pdf> (p. 86).