COMMISSION IMPLEMENTING REGULATION (EU) 2023/612

of 17 March 2023

amending Implementing Regulation (EU) No 307/2012 as regards certain procedures for the Union assessment of the safety of a substance or group of substances under scrutiny

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods ([1]), and in particular Article 8(6) thereof,

Whereas:

(1) Regulation (EC) No 1925/2006 harmonises the national rules in Member States on the addition of vitamins and minerals and of certain other substances to foods.

(2) Commission Implementing Regulation (EU) No 307/2012 ([2]) lays down, in particular, implementing rules for the application of the procedure referred to in Article 8(4) and (5) of Regulation (EC) No 1925/2006 concerning the safety assessment by the European Food Safety Authority ('the Authority') of the substances under scrutiny listed in Part C of Annex III thereto.

(3) To demonstrate the safety of a particular substance under scrutiny contained in the list in Part C of Annex III to Regulation (EC) No 1925/2006, food business operators and other interested parties may submit to the Authority within 24 months from the entry into force of a decision listing the substance in Part C of that Annex, a file containing the scientific data for evaluation.

(4) Under Article 6(1) of Regulation (EU) No 307/2012, the Authority is to give its opinion on the submitted files within 9 months from the date of receipt of a valid file. Where multiple files are submitted for the evaluation of the same substance or group of substances, and since each file is assessed independently from the other files, the Authority may not be able to consider the totality of the safety data submitted for the assessment of that substance or group of substances placed under scrutiny. The individual assessment of each file may therefore lead to several incomplete and possibly inconsistent opinions on the same substance or group of substances. In view of the above, it is necessary to amend Regulation (EU) No 307/2012, to allow the Authority to initiate the risk assessment on a substance or group of substances listed in Part C of Annex III to Regulation (EC) No 1925/2006 only at the end of the 24-month period following the entry into force of the decision listing that substance or group of substances in Part C of that Annex and to issue a single opinion on files submitted as regards the same substance or group of substances.

(5) Regulation (EU) No 307/2012 should therefore be amended accordingly.

(6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

([1]) OJ L 404 30.12.2006, p. 26.

([2]) Commission Implementing Regulation (EU) No 307/2012 of 11 April 2012 establishing implementing rules for the application of Article 8 of Regulation (EC) No 1925/2006 of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods (OJ L 102, 12.4.2012, p. 2).

HAS ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EU) No 307/2012

Article 6 of Regulation (EU) No 307/2012 is replaced by the following:

'*Article 6*

Opinion of the Authority

1. The Authority shall assess the validity of each file submitted under Article 5 of this Regulation within 30 days from its receipt.

2. The Authority shall give its opinion on the files it considers valid under Article 5 of this Regulation within nine months from the end of the 24-month period referred to in Article 5(2) of this Regulation.

3. Where multiple files on the same substance or group of substances are submitted in accordance with Article 5 of this Regulation, the Authority shall issue a single opinion on those files.

4. The Authority may request from the food business operator or the interested party to provide additional information to their file within 15 days from the date of receipt of the Authority's request.

Where the Authority requests additional information, including information with regard to the conditions of use of the substance in a food or in a category of foods and the purpose of that use, it may extend the time limit referred to in paragraph 2.

The time limit may be extended only once by up to three months. That time limit shall include the time set in the first subparagraph for the food business operator or any interested party to provide the requested information.

5. Where the Authority extends the time limit in accordance with paragraph 4, it shall inform thereof all food business operators or interested parties that have submitted the file with regard to the same substance or group of substances and the Commission.

The Authority shall make the additional information provided in accordance with paragraph 4 available to the Commission and to the Member States.'

Article 2

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 17 March 2023.

For the Commission
The President
Ursula VON DER LEYEN