



2024/2766

31.10.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/2766

of 30 October 2024

concerning the non-approval of 1,3,7-trimethylxanthine (caffeine) as a basic substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market

(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 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ⁽¹⁾, and in particular Article 23(5) in conjunction with Article 13(2) thereof,

Whereas:

- (1) On 6 June 2018, the Commission received an application from the company Progarein ('the applicant') for the approval of 1,3,7-trimethylxanthine (caffeine) as a basic substance to be used in plant protection as insecticide in cabbage, potatoes and *Buxus* spp. and as molluscicide in all edible and non-edible crops.
- (2) The Commission received a revised application in June 2019, followed by further revised versions submitted in December 2019 and April 2020. The revised application, as received in April 2020, was accompanied by the information required under Article 23(3), second subparagraph, of Regulation (EC) No 1107/2009.
- (3) The Commission asked the European Food Safety Authority ('the Authority') for scientific assistance pursuant to Article 23(4) of Regulation (EC) No 1107/2009. The Authority provided the Commission with a technical report on 1,3,7-trimethylxanthine (caffeine) on 26 January 2021 ⁽²⁾. The Commission presented a review report ⁽³⁾ to the Standing Committee on Plants, Animals, Food and Feed on 5 July 2021.
- (4) The Commission invited the applicant to submit its comments on the technical report of the Authority and on the Commission's review report.
- (5) In August 2021, the applicant requested to put on hold the procedure for adopting a decision on the approval of 1,3,7-trimethylxanthine (caffeine) as a basic substance in order to prepare additional information supporting its application. The Commission accepted the request of the applicant.
- (6) In September 2022, the applicant provided an updated application for the approval of caffeine as a basic substance. The Commission distributed that application and the information attached to it to the Member States and the Authority for comments. Based on the information available in the revised application and the comments received, the Standing Committee on Plants, Animals, Food and Feed decided that renewed scientific assistance by the Authority was not needed.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1, ELI: <http://data.europa.eu/eli/reg/2009/1107/oj>.

⁽²⁾ EFSA (European Food Safety Authority), 2021. Technical report on the outcome of the consultation with Member States and EFSA on the basic substance application for approval of caffeine to be used in plant protection as insecticide in cabbage, potatoes and *buxus* and as molluscicide in all edible and non-edible crops. EFSA supporting publication 2021:EN-6423. 96 pp.; doi:10.2903/sp.efsa.2021.EN-6423.

⁽³⁾ Review report for the basic substance 1,3,7-trimethyl xanthine (caffeine) finalised by the Standing Committee on Plants, Animals, Food and Feed on 3 October 2024 in view of the non-approval of 1,3,7-trimethyl xanthine (caffeine) as basic substance in accordance with Regulation (EC) No 1107/2009.

- (7) According to the Union harmonised classification established in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council ⁽⁴⁾, caffeine is harmful to humans if swallowed (Acute Tox. 4). With regard to human health, the Authority also noted, on the basis of the scientific opinion of EFSA Panel on Dietetic Products, Nutrition and Allergies on the safety of caffeine ⁽⁵⁾, that caffeine has adverse effects on the cardiovascular system, hydration and body temperature in adults, as well as on the central nervous system (sleep, anxiety, behavioural changes) in adults and children, and an adverse birth weight-related outcome in pregnant women. Furthermore, due to the absence of data, the Authority could not conclude its assessment of non-dietary risks for operators, workers, bystanders and residents.
- (8) As regards the effect of caffeine on the environment, the Authority noted that the parametric drinking water limit of 0,1 µg/L that would be applicable to caffeine if approved as an active substance, would be significantly exceeded for the uses applied for in the application. According to the Authority, significant surface water exposure can also be expected. Moreover, the available data were not sufficient to demonstrate acceptable risk to non-target organisms.
- (9) The Commission presented an updated review report, concluding that in the case of 1,3,7-trimethylxanthine (caffeine) the approval criteria for basic substances are not fulfilled and that therefore it is not to be approved as a basic substance, as well as a draft Implementing Regulation regarding caffeine to the Standing Committee on Plants, Animals, Food and Feed on 23 May 2024 and on 11 July 2024, respectively.
- (10) The Commission invited the applicant to submit its comments on the Commission's updated review report in accordance with Article 13(1) of Regulation (EC) No 1107/2009. The applicant submitted its comments, which were taken into consideration.
- (11) However, despite the arguments put forward by the applicant, the concerns related to the safety of using this substance with regard to the protection of human health and environment could not be eliminated.
- (12) Consequently, it has not been established that the conditions laid down in Article 23 of Regulation (EC) No 1107/2009 are satisfied. It is therefore appropriate not to approve 1,3,7-trimethylxanthine (caffeine) as a basic substance.
- (13) This Regulation does not prevent the submission of a further application for the approval of 1,3,7-trimethylxanthine (caffeine) as a basic substance in accordance with Article 23(3) of Regulation (EC) No 1107/2009.
- (14) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Non-approval as a basic substance

The substance 1,3,7-trimethylxanthine (caffeine) is not approved as a basic substance.

⁽⁴⁾ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1, ELI: <http://data.europa.eu/eli/reg/2008/1272/oj>).

⁽⁵⁾ EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2015. Scientific Opinion on the safety of caffeine. EFSA Journal 2015;13(5):4102, 120 pp.; doi:10.2903/j.efsa.2015.4102.

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, 30 October 2024.

For the Commission
The President
Ursula VON DER LEYEN
