



2024/2197

5.9.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/2197

of 4 September 2024

concerning the non-approval of eggshell powder 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 13(2) in conjunction with Article 23(5) thereof,

Whereas:

- (1) On 25 June 2020, the Commission received an application from SAMO ('the applicant') for the approval of eggshell powder as a basic substance to be used in plant protection as a fungifuge on grapevine.
- (2) A first revision of the application was received by the Commission on 12 September 2021. After the final admissibility check, the application, as received on 4 March 2022, was accompanied by the information required under Article 23(3), second subparagraph, of Regulation (EC) No 1107/2009.
- (3) Several relevant evaluations, carried out in accordance with other Union legislation, as referred to in Article 23(2) of Regulation (EC) No 1107/2009, were available. A number of conclusions from the European Food Safety Authority ('the Authority') on the peer review of the pesticide risk assessment were available as well as different Scientific Opinions from the ANS Panel, the CEP Panel, the CONTAM Panel, the FAF Panel and the NDA Panel from the Authority ⁽²⁾. The outcome of these evaluations have been taken into account by the Authority as well as by the Commission.
- (4) The Commission asked 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 eggshell powder on 31 October 2023 ⁽³⁾.
- (5) With regard to the identity of the product, the Authority stated that the exact parameters of the production process are unclear. The Authority noted that depending on the temperature applied and the duration of the heating, materials with different compositions and respectively different properties will be produced (e.g. pH). The main components (around 50 %) of the intended basic substance are calcium carbonate/calcium oxide (CaCO₃/CaO) at different proportions depending on the conditions of the manufacturing process. CaCO₃ is an approved active substance ⁽⁴⁾ according to Regulation (EU) No 1107/2009. CaO is classified as causing serious eye damage Category 1 depending on the pH, causing skin irritation, and may cause respiratory irritation.

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

⁽²⁾ The references to these evaluations are available in the EFSA Conclusion. EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS); EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (CEP); EFSA Panel on Contaminants in the Food Chain (CONTAM); EFSA Panel on Food Additives and Flavourings (FAF); EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA). EFSA supporting publication 2023:EN-8434. 20 pp. doi:10.2903/sp.efsa.2023.EN-8434.

⁽³⁾ EFSA (European Food Safety Authority), 2023. Overall conclusions on the application for approval of eggshell powder as a basic substance to be used in plant protection as a fungifuge on grapevines. EFSA supporting publication 2023:EN-8434. 20 pp. doi:10.2903/sp.efsa.2023.EN-8434.

⁽⁴⁾ OJ L 313, 6.9.2021, p. 15.

- (6) With regard to human health, the Authority concluded that, considering the content of lead in the eggshell powder according to the specification provided by the applicant, a possible concern for neurodevelopmental effects based on dietary exposure estimates for consumers (for high consumers of table grapes (children) and wine grapes (adults)). The Authority therefore declared that the intended use of eggshell powder with the proposed specification level for lead cannot be concluded as safe. Additionally, according to the Authority, residues of eggshell powder are very likely to be present on the berries due to the intended last application of eggshell powder at the time when the berries are ripe for harvest. The Authority also noted that eggs and products derived thereof require allergen labelling under the EU food law ⁽⁵⁾. This would lead to an obligatory labelling of the final foodstuffs.
- (7) As regards the effect of eggshell powder on the environment, the Authority noted that scarce data are available in the dossier for exposure and hazard assessment for non-target organisms. Furthermore, neither a quantitative risk assessment nor a risk assessment based on a sound weight of evidence approach were available for any group of non-target organisms.
- (8) The Commission presented the review report ⁽⁶⁾ and a draft of this Implementing Regulation to the Standing Committee on Plants, Animals, Food and Feed on 22 May 2024 and 10 July 2024, respectively.
- (9) The Commission invited the applicant to submit its comments on the technical report of the Authority and on the Commission's review report. The applicant submitted its comments, which were taken into due consideration.
- (10) 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 the environment could not be eliminated.
- (11) 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 to establish that eggshell powder is not approved as a basic substance.
- (12) This Regulation does not prevent the submission of a further application for the approval of eggshell powder as a basic substance in accordance with Article 23(3) of Regulation (EC) No 1107/2009.
- (13) 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

The substance eggshell powder is not approved as a basic substance.

Article 2

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

⁽⁵⁾ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. (OJ L 31, 1.2.2002, p. 1. ELI: <http://data.europa.eu/eli/reg/2002/178/oj>).

⁽⁶⁾ Final Review report for the basic substance eggshell powder finalised by the Standing Committee on Plants, Animals, Food and Feed on 11 July 2024 in view of the non-approval of eggshell powder as basic substance in accordance with Regulation (EC) No 1107/2009.

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

Done at Brussels, 4 September 2024.

For the Commission
The President
Ursula VON DER LEYEN
