

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2021/464

of 17 March 2021

concerning the non-approval of *Capsicum annuum* L. var. *annuum*, longum group, cayenne extract 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 14 March 2018, the Commission received an application from the company Bio Natural Protect for the approval of *Capsicum annuum* L. var. *annuum*, longum group, cayenne extract as a basic substance for use as a repellent to seed-eating mammals and birds. A revised application, received on 23 May 2019, was accompanied by the information required under the second subparagraph of Article 23(3) of Regulation (EC) No 1107/2009.
- (2) The Commission asked the European Food Safety Authority ('the Authority') for scientific assistance. The Authority provided the Commission with a technical report on the *Capsicum annuum* L. var. *annuum*, longum group, cayenne extract on 31 March 2020 ⁽²⁾. The Authority concluded that the specifications of the proposed *Capsicum annuum* L. var. *annuum*, longum group, cayenne extract, including its main active component capsaicin, were not well defined. Furthermore, according to the Authority, the fate and behaviour properties in the environment provided for some of the possible extract components, including capsaicin, were uncertain and additional studies on toxicity to all non-target species were required. The Authority noted that there was also evidence provided by companies to the European Chemicals Agency that components of the *Capsicum annuum* L. var. *annuum*, longum group, cayenne extract may have to be classified as causing serious eye damage, harmful if swallowed and also as cause of skin irritation.
- (3) Additionally, the Scientific Committee on Food has identified genotoxic potential of capsaicin ⁽³⁾.
- (4) No relevant evaluation, carried out in accordance with other Union legislation as referred to in Article 23(2) of Regulation (EC) No 1107/2009, was available.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ EFSA (European Food Safety Authority), 2020. Technical report on the outcome of the consultation with Member States and EFSA on the basic substance application for approval of *Capsicum annuum* L. var. *annuum*, longum group, cayenne extract to be used in plant protection as repellent to seed-eating mammals and birds. EFSA supporting publication 2020:EN-1838. 77pp. doi:10.2903/sp.efsa.2020.EN-1838.

⁽³⁾ Opinion of the Scientific Committee on Food on Capsaicin (adopted on 26 February 2002); https://ec.europa.eu/food/sites/food/files/safety/docs/fs_food-improvement-agents_flavourings-out120.pdf

- (5) The Commission presented the review report ⁽⁴⁾ and the draft of this Regulation on the non-approval of *Capsicum annuum* L. var. *annuum*, longum group, cayenne extract to the Standing Committee on Plants, Animals, Food and Feed on 17 July 2020.
- (6) The Commission invited the applicant to submit its comments on the technical report of the Authority and on the Commission's draft review report. The applicant submitted its comments, which have been carefully examined.
- (7) However, despite the arguments put forward by the applicant, the concerns related to the substance cannot be eliminated.
- (8) Consequently, as laid down in the Commission's review report, it has not been established that the requirements laid down in Article 23 of Regulation (EC) No 1107/2009 are satisfied. It is therefore appropriate not to approve *Capsicum annuum* L. var. *annuum*, longum group, cayenne extract as a basic substance.
- (9) This Regulation does not prejudice the submission of a further application for the approval of *Capsicum annuum* L. var. *annuum*, longum group, cayenne extract as a basic substance in accordance with Article 23(3) of Regulation (EC) No 1107/2009.
- (10) 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 *Capsicum annuum* L. var. *annuum*, longum group, cayenne extract 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*.

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

Done at Brussels, 17 March 2021.

For the Commission
The President
Ursula VON DER LEYEN

⁽⁴⁾ https://ec.europa.eu/food/plant/pesticides/eu-pesticides-db_en