COMMISSION IMPLEMENTING REGULATION (EU) 2022/1443

of 31 August 2022

concerning the non-approval of calcium propionate 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 7 April 2020, the Commission received an application from Niacet B.V. ('the applicant') for the approval of calcium propionate as a basic substance to be used in plant protection as a fungicide in amenity grassland and on flower bulb and flower tuber crops. On 17 September 2021, the Commission received a revised application, which was accompanied by the information required under Article 23(3), second subparagraph, of Regulation (EC) No 1107/2009.

(2) One relevant evaluation of calcium propionate, carried out in accordance with other Union legislation as referred to in Article 23(2) of Regulation (EC) No 1107/2009 was available, namely, an evaluation from the ANS Panel of the European Food Safety Authority ('the Authority') ([2]). The outcome of this evaluation has been taken into account by the Authority as well as by the Commission.

(3) The Commission asked the Authority for scientific assistance. The Authority provided the Commission with a technical report on calcium propionate on 24 August 2021 ([3]). The Authority concluded that, even though no Union harmonised classification is available in the classification & labelling inventory ([4]) on the European Chemicals Agency (ECHA) website, the published information indicates that calcium propionate has eye-damaging effects. In addition, the Authority considers that further toxicological assessment of the toxicity of calcium propionate by inhalation is necessary if, as foreseen in the application, the substance is intended to be used in a spray application after dilution with water.

(4) Additionally, the assessment of dermal toxicity, endocrine disrupting properties and immunotoxicity has not been provided.] by the applicant. No robust and exhaustive justifications were mentioned in the application.

(5) The Authority also noted that an assessment of operator, worker, bystander and resident exposure is needed for each of the uses included in the application, but this was not provided, nor was a risk assessment of the impurities present in the basic substance.

(6) Moreover, the Authority indicated that the potential for a build-up of the impurities lead, mercury and arsenic in the environment remains an open issue for the proposed use pattern, which requires a high application frequency.

([1]) OJ L 309, 24.11.2009, p. 1.

([2]) EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources Added to Food), 2014. Scientific Opinion on the re-evaluation of propionic acid (E 280), sodium propionate (E 281), calcium propionate (E 282) and potassium propionate (E 283) as food additives. EFSA Journal 2014; 12(7):3779, 45 pp. doi:10.2903/j.efsa.2014.3779.

([3]) 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 calcium propionate to be used in plant protection as a fungicide in amenity grassland and on flower bulb and flower tuber crops. EFSA supporting publication 2021:EN-6834. 87pp. doi:10.2903/sp.efsa.2021.EN-6834.

([4]) C&L Inventory (europa.eu).

(7) Finally, the Authority concluded that the intended uses and doses raise a concern regarding possible adverse effects of calcium propionate on non-target organisms, including bees and non-target arthropods, earthworms and other soil macro-organisms, soil micro-organisms, and organisms involved in biological methods of sewage treatment.

(8) The Commission presented the review report, concluding that the approval criteria for basic substances are not fulfilled in the case of calcium propionate and that it is therefore appropriate not to approve it as a basic substance, as well as a draft of this Implementing Regulation to the Standing Committee on Plants, Animals, Food and Feed on 27 January 2022 and 18 May 2022, respectively.

(9) The Commission invited the applicant to submit its comments on the technical report of the Authority and on the draft review report of the Commission. The applicant submitted its comments, which have been carefully examined.

(10) However, despite the arguments put forward by the applicant, the concerns related to the substance 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 not to approve calcium propionate as a basic substance.

(12) This Regulation does not prevent the submission of a further application for the approval of calcium propionate 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 calcium propionate 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, 31 August 2022.

For the Commission
The President
Ursula VON DER LEYEN