



2024/425

5.2.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/425

of 2 February 2024

concerning the non-approval of the active substance asulam-sodium, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council

(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) thereof,

Whereas:

- (1) On 19 December 2013, UPL Europe Limited submitted an application for the approval of the active substance asulam-sodium to the United Kingdom, the rapporteur Member State, pursuant to Article 7(1) of Regulation (EC) No 1107/2009.
- (2) In accordance with Article 9(3) of Regulation (EC) No 1107/2009, the rapporteur Member State notified the applicant, the other Member States, the Commission and the European Food Safety Authority ('the Authority') of the admissibility of the application on 30 June 2014.
- (3) The rapporteur Member State assessed the effects on human and animal health and the environment, in accordance with Article 11(2) Regulation (EC) No 1107/2009, for the use proposed by the applicant. The rapporteur Member State submitted a draft assessment report to the Commission and the Authority on 21 April 2016.
- (4) In accordance with Article 12(2) of Regulation (EC) No 1107/2009, the Authority circulated the draft assessment report received from the rapporteur Member State to the applicant and the other Member States and organised a public consultation on it.
- (5) Pursuant to Article 12(3) of Regulation (EC) No 1107/2009, the Authority requested that the applicant supply additional information to the Member States, the Commission and the Authority.
- (6) The assessment of the additional information by the rapporteur Member State was submitted to the Authority in the form of an updated draft assessment report.
- (7) The draft assessment report was reviewed by the Member States and the Authority. The Authority presented its conclusion ⁽²⁾ on the risk assessment of the active substance asulam-sodium to the Commission on 28 March 2018.
- (8) In its conclusion, the Authority found a high long-term risk to birds and mammals for all field crop representative uses for all species with exception of small insectivorous mammals.
- (9) During the peer review process, following the United Kingdom's notification of its intention to withdraw from the Union pursuant to Article 50 of the Treaty on European Union, France took over the responsibility for this active substance as the rapporteur Member State in June 2019.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ EFSA (European Food Safety Authority), 2018. Conclusion on the peer review of the pesticide risk assessment of the active substance asulam-sodium, *EFSA Journal* 2018;16(4):5251, 23 pp., <https://doi.org/10.2903/j.efsa.2018.5251>

- (10) As regards the new criteria to identify endocrine disrupting properties introduced by Commission Regulation (EU) 2018/605 ⁽³⁾, which became applicable on 10 November 2018, the conclusion of the Authority did not allow risk managers to conclude whether the active substance asulam-sodium is an endocrine disruptor, as the conclusion was completed before these new criteria entered into force. Therefore, in February 2019 the Commission requested the Authority to re-assess the information and update its conclusion on the potential endocrine disruption properties of asulam-sodium in accordance with the new criteria, as set out in point 3.6.5 of Annex II to Regulation (EC) No 1107/2009.
- (11) Following a consultation with Member States, the Authority consequently invited the applicant on 7 November 2019 to submit, within a period of 3 months, additional information for the purpose of the assessment of the fulfilment of the approval criteria laid down in point 3.6.5 and/or point 3.8.2 of Annex II to Regulation (EC) No 1107/2009 and/or documented evidence showing that the conditions for the application of the derogation under Article 4(7) of Regulation (EC) No 1107/2009 are met. On 6 February 2020, the applicant submitted information, which was evaluated as part of the peer review process.
- (12) On 13 October 2021, the Authority sent to the Commission its conclusion on the pesticide risk assessment of the active substance ⁽⁴⁾, which confirmed that asulam-sodium was considered to have endocrine disrupting properties that may cause adverse effects in humans, as set out in point 3.6.5 of Annex II to Regulation (EC) No 1107/2009.
- (13) Negligible exposure of humans to asulam-sodium cannot be demonstrated for asulam-sodium since residues above the default value set pursuant to Article 18(1), point (b), of Regulation (EC) No 396/2005 of the European Parliament and of the Council ⁽⁵⁾ are expected to occur. Therefore, the requirement set out in point 3.6.5 of Annex II to Regulation (EC) No 1107/2009 is not fulfilled.
- (14) In its evaluation of whether asulam-sodium is necessary to control a serious danger to plant health which cannot be contained by other available means including non-chemical methods in accordance with Article 4(7) of Regulation (EC) No 1107/2009, the Authority concluded that for some uses and in some Member States there may be an insufficient number of chemical alternatives available at the time of assessment. However, although they may not have the same efficacy as chemical methods and/or have economic or other feasibility limitations, some non-chemical methods are available (e.g. mechanical weeding). In addition, further chemical alternatives could be made available in the Member States concerned via mutual recognition of alternative products that are available in other Member States, as provided for in Article 40 of Regulation (EC) No 1107/2009. In addition, the Commission considers that no serious danger to plant health has been identified. Therefore, the Commission considers that the conditions for the application of the derogation in Article 4(7) of Regulation (EC) No 1107/2009 are not fulfilled.
- (15) The Commission presented a draft review report regarding asulam-sodium and a draft of this Regulation to the Standing Committee on Plants, Animals, Food and Feed on 25 May 2023 and 12 July 2023 respectively.
- (16) The Commission invited the applicant to submit its comments on the conclusion of the Authority and, in accordance with Article 13(1) of Regulation (EC) No 1107/2009, on the draft review report. The applicant submitted its comments, which have been carefully examined.
- (17) Despite the arguments put forward by the applicant, the concerns regarding the active substance could not be eliminated and that consequently it could not be concluded that the approval criteria are satisfied.

⁽³⁾ Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. (OJ L 101, 20.4.2018, p. 33).

⁽⁴⁾ EFSA (European Food Safety Authority), 2018. Updated peer review of the pesticide risk assessment of the active substance asulam-sodium, *EFSA Journal* 2021;19(11):6921, 31 pp., <https://doi.org/10.2903/j.efsa.2021.6921>

⁽⁵⁾ Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

- (18) By letter of 06 October 2023, the applicant withdrew its application for the approval of asulam-sodium. Therefore, asulam-sodium should not be approved.
- (19) This Regulation does not prevent the submission of a further application for the approval of asulam-sodium pursuant to Article 7 of Regulation (EC) No 1107/2009.
- (20) 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 of the active substance

The active substance asulam-sodium is not approved.

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, 2 February 2024.

For the Commission
The President
Ursula VON DER LEYEN