

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1281**of 14 September 2020****concerning the non-approval of the active substance ethametsulfuron-methyl, 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) thereof,

Whereas:

- (1) According to Article 80(1)(a) of Regulation (EC) No 1107/2009, Council Directive 91/414/EEC ⁽²⁾ is to apply, with respect to the procedure and the conditions for approval, to active substances for which a decision has been adopted in accordance with Article 6(3) of that Directive before 14 June 2011. For ethametsulfuron-methyl Commission Decision 2011/124/EU ⁽³⁾ has been adopted in accordance with Article 6(3) of that Directive on 23 February 2011.
- (2) On 29 June 2010, DuPont de Nemours GmbH submitted an application for the inclusion of the active substance ethametsulfuron-methyl in Annex I to Directive 91/414/EEC to the United Kingdom in accordance with Article 6(2) of Directive 91/414/EEC. Decision 2011/124/EU confirmed that the dossier was 'complete' in the sense that it could be considered as satisfying, in principle, the data and information requirements of Annexes II and III to Directive 91/414/EEC.
- (3) Subsequently, FMC Agricultural Solutions A/S acquired all rights concerning ethametsulfuron-methyl from DuPont de Nemours GmbH.
- (4) The assessment of the effects of ethametsulfuron-methyl on human and animal health and the environment for the uses proposed by the applicant has been carried out in accordance with the procedure provided in Article 6(2) and (4) of Directive 91/414/EEC. The United Kingdom submitted a draft assessment report to the Commission and the European Food Safety Authority ('the Authority') on 17 September 2012.
- (5) The draft assessment report was reviewed by the Member States and the Authority. The Authority presented to the Commission its conclusion ⁽⁴⁾ on the pesticide risk assessment of the active substance ethametsulfuron-methyl on 11 December 2013. In April 2014, the European Commission mandated the Authority to organise and perform a peer review as regards new data on one metabolite of ethametsulfuron-methyl. The Authority presented to the Commission its updated conclusion ⁽⁵⁾ on 14 July 2014.
- (6) By letter of 7 May 2020, FMC Agricultural Solutions A/S withdrew the application for the approval of ethametsulfuron-methyl.
- (7) Due to the withdrawal of the application, ethametsulfuron-methyl should not be approved.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

⁽³⁾ Commission Decision 2011/124/EU of 23 February 2011 recognising in principle the completeness of the dossier submitted for detailed examination in view of the possible inclusion of ethametsulfuron in Annex I to Council Directive 91/414/EEC (OJ L 49, 24.2.2011, p. 42).

⁽⁴⁾ EFSA (European Food Safety Authority), 2014. Conclusion on the peer review of the pesticide risk assessment of the active substance ethametsulfuron (evaluated variant ethametsulfuron-methyl). *EFSA Journal* 2014;12(1):3508, 94 pp. doi:10.2903/j.efsa.2014.3508

⁽⁵⁾ EFSA (European Food Safety Authority), 2014. Conclusion on the peer review of the pesticide risk assessment of the active substance ethametsulfuron (evaluated variant ethametsulfuron-methyl). *EFSA Journal* 2014;12(7):3787, 96 pp. doi:10.2903/j.efsa.2014.3787

- (8) This Regulation does not prevent the submission of a further application for the active substance ethametsulfuron-methyl pursuant to Article 7 of Regulation (EC) No 1107/2009.
- (9) 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 active substance

The active substance ethametsulfuron-methyl 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, 14 September 2020.

For the Commission
The President
Ursula VON DER LEYEN
