COMMISSION IMPLEMENTING REGULATION (EU) 2016/138

of 2 February 2016

concerning the non-approval of the active substance 3-decen-2-one, 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) In accordance with Article 7(1) of Regulation (EC) No 1107/2009, on 14 September 2011, the Netherlands received an application from AMVAC CV (now AMVAC Netherlands BV) for the approval of the active substance 3-decen-2-one.

(2) In accordance with Article 9(3) of that Regulation, the rapporteur Member State notified the applicant, the other Member States, the Commission and the European Food Safety Authority (hereinafter 'the Authority') of the admissibility of the application on 13 April 2012.

(3) For that active substance, the effects on human and animal health and the environment have been assessed, in accordance with Article 11(2) and (3) of that Regulation, for the use proposed by the applicant. The rapporteur Member State submitted a draft assessment report to the Commission and the Authority on 26 November 2013.

(4) The Authority complied with Article 12(1) of Regulation (EC) No 1107/2009. In accordance with Article 12(3) of that Regulation, it requested that the applicant supply additional information to the Member States, the Commission and the Authority. The assessment of the additional information by the rapporteur Member State was submitted to the Authority in the format of an updated draft assessment report.

(5) The draft assessment report was reviewed by the Member States and the Authority. The Authority presented to the Commission its conclusion on the risk assessment of the active substance 3-decen-2-one [2] on 3 December 2014. The Authority concluded that the presence of positive genotoxicity results and the limited toxicological data package prevented final toxicological reference values from being established and therefore the risk assessment for operators, workers, bystanders, residents and consumers could not be completed. It further concluded that the evaluation of the MRL application with the request to exempt 3-decen-2-one from MRL setting could not be finalised, since the available information is insufficient to conclude on whether use of 3-decen-2-one as an active substance in plant protection products will have no immediate or delayed harmful effects on human health, including that of vulnerable groups, through dietary intakes.

(6) 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.

(7) However, despite the arguments put forward by the applicant, the concerns referred to in recital 5 could not be eliminated.

(8) Consequently, it has not been demonstrated that it may be expected that, with respect to one or more representative uses of at least one plant protection product containing 3-decen-2-one, the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. The active substance 3-decen-2-one should therefore not be approved pursuant to Article 13(2) of Regulation (EC) No 1107/2009.

[1] OJ L 309, 24.11.2009, p. 1.
[2] *EFSA Journal* 2015;13(1):3932 Available online: www.efsa.europa.eu/efsajournal

(9) This Regulation does not prejudice the submission of a further application for 3-decen-2-one pursuant to Article 7 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

Non-approval of active substance

The active substance 3-decen-2-one 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 2016.

For the Commission
The President
Jean-Claude JUNCKER