COMMISSION IMPLEMENTING REGULATION (EU) 2019/1881

of 8 November 2019

amending Regulation (EU) No 37/2010 to classify the substance diflubenzuron as regards its maximum residue limit

(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 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and the Council ([1]), and in particular Article 14 in conjunction with Article 17 thereof,

Having regard to the opinion of the European Medicines Agency formulated by the Committee for Medicinal Products for Veterinary Use,

Whereas:

(1) Article 17 of Regulation (EC) No 470/2009 requires that the maximum residue limit ('MRL') for pharmacologically active substances intended for use in the Union in veterinary medicinal products for food-producing animals or in biocidal products used in animal husbandry is established in a Regulation.

(2) Table 1 of the Annex to Commission Regulation (EU) No 37/2010 ([2]) sets out the pharmacologically active substances and their classification regarding MRLs in foodstuffs of animal origin.

(3) Diflubenzuron is already included in that table as an allowed substance for salmonidae species, applicable to muscle and skin.

(4) On 7 May 2014, the Commission requested the European Medicines Agency ('EMA') to issue a new opinion on diflubenzuron in accordance with Article 11 of Regulation (EC) No 470/2009, taking into account the genotoxic potential of diflubenzuron's metabolite 4-chloroaniline as well as the results of the more recent evaluations of diflubenzuron as a pesticide, undertaken by the European Food Safety Authority EFSA) ([3]), and as a biocide, coordinated by the Joint Research Centre of the Commission ([4]).

(5) In its opinion of 7 May 2015, the Committee for Medicinal Products for Veterinary Use ('CVMP') concluded that the genotoxic metabolite has not been confirmed to be present in fish muscle and adopted an opinion noting that further data on 4-chloroaniline formation and depletion in fish muscle was required in order to fully characterise the risk, if any, to the consumer from exposure to diflubenzuron. Publicly available reports about pharmacology of diflubenzuron indicated that in sheep, swine and chicken, 4-chloroaniline has been found as a minor metabolite. Based on that opinion, EMA recommended to amend the existing entry for diflubenzuron in salmonidae species in table 1 of the Annex to Commission Regulation (EU) No 37/2010 and to establish a provisional MRL, pending provision of additional residue data.

([1]) OJ L 152, 16.6.2009, p. 11.
([2]) Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (OJ L 15, 20.1.2010, p. 1).
([3]) EFSA Journal 2012;10(9):2870. Conclusion on the peer review of the pesticide risk assessment of confirmatory data submitted for the active substance Diflubenzuron
([4]) Diflubenzuron assessment report, available at http://dissemination.echa.europa.eu/Biocides/ActiveSubstances/0062-18/0062-18_Assessment_Report.pdf

(6) Having considered the recommendation from EMA, the Commission clarified in March 2017 that Regulation (EC) No 470/2009 only allows the establishment of a provisional MRL in cases where scientific data are incomplete and where there are no grounds for supposing that residues of the substance at the level proposed constitute a hazard to human health. In the case of diflubenzuron there is a possibility that the genotoxic metabolite 4-chloroaniline is present in treated fish at levels that could be hazardous to human health, and consequently the establishment of a provisional MRL was not considered appropriate, according to the Commission. The Commission also highlighted the EFSA 2015 conclusion ([5]) relating to the use of diflubenzuron in plant protection products, indicating that the available data were not sufficient to demonstrate that the representative uses were safe for consumers. For those reasons, the Commission invited the CVMP to revise its opinion of 7 May 2015.

(7) On 15 March 2018, CVMP adopted its revised opinion on the establishment of maximum residue limits for diflubenzuron ([6]). Based on that opinion, EMA has recommended that the existing entry for diflubenzuron in salmonidae species in table 1 of the Annex to Commission Regulation (EU) No 37/2010 be amended so that the MRL is reduced. The MRL value is set at 10 µg/kg in order to ensure that consumer exposure to 4-chloroaniline remains at an acceptable level.

(8) According to Article 5 of Regulation (EC) No 470/2009, EMA is to consider using MRLs established for a pharmacologically active substance in a particular foodstuff for another foodstuff derived from the same species, or MRLs established for a pharmacologically active substance in one or more species for other species.

(9) EMA has considered that the extrapolation of the entry for diflubenzuron to fin fish is not appropriate at this time due to a lack of evidence that the metabolite 4-chloroaniline is not formed in any relevant amount in every species concerned.

(10) Pursuant to the CVMP opinions and the EMA recommendation, it appears necessary for the protection of human health to reduce the MRL for diflubenzuron from 1 000 µg/kg to 10 µg/kg.

(11) Regulation (EU) No 37/2010 should therefore be amended accordingly.

(12) It is appropriate to grant the stakeholders concerned a reasonable period of time to take measures that may be required to comply with the new MRL for diflubenzuron.

(13) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Veterinary Medicinal Products,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EU) No 37/2010 is amended as set out in the Annex to this Regulation.

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*.

([5]) EFSA Journal 2015;13(12):4222.Peer review on the review of the approval of the active substance diflubenzuron regarding the metabolite PCA

([6]) EMA/CVMP/153976/2018 MRL summary opinion Diflubenzuron 16 March 2018.

It shall apply from 10 January 2020.

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

Done at Brussels, 8 November 2019.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

In Table 1 of the Annex to Regulation (EU) No 37/2010, the entry for the substance 'diflubenzuron' is replaced by the following:

Pharmacologically active Substance	Marker residue	Animal Species	MRLs	Target Tissues	Other Provisions (according to Article 14(7) of Regulation (EC) No 470/2009)	Therapeutic Classification
'Diflubenzuron	Diflubenzuron	*Salmonidae*	10 µg/kg	Muscle and skin in natural proportions	NO ENTRY	Antiparasitic agents/ Agents against ectoparasites'