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COMMISSION REGULATION (EU) .../...

of **XXX**

amending Annexes II and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bifenthrin in or on certain products

(Text with EEA relevance)

COMMISSION REGULATION (EU) .../...

of **XXX**

amending Annexes II and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bifenazate in or on certain products

(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 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/EEC¹, and in particular Article 14(1), point (a), and Article 18(1), point (b), thereof,

Whereas:

- (1) For bifenazate, maximum residue levels ('MRLs') were set in Annex II to Regulation (EC) No 396/2005.
- (2) The approval of the active substance bifenazate was renewed by Commission Implementing Regulation (EU) 2022/698². The consumer risk assessment for edible crops could not be finalised, as relevant information needed to ensure consumer safety was not provided and the toxicity of a relevant metabolite could not be determined, therefore Regulation (EU) 2022/698 restricted the use of the active substance bifenazate to non-edible crops kept in permanent greenhouses. This was due to data gaps³ that could have an impact on the assessment of residue levels in the different crops and due to missing toxicological reference values for metabolite D3598 (bifenazate-diazene) included in the residue definition.
- (3) According to Article 46 of Regulation (EC) No 1107/2009⁴, Member States can decide on the duration of the grace periods for sale and distribution, the disposal, storage, and use of existing stocks of the plant protection product concerned. Maximum grace period granted by Member States for bifenazate will expire on or before 1 January 2024.

¹ OJ L 70, 16.3.2005, p. 1.

² Commission Implementing Regulation (EU) 2022/698 of 3 May 2022 renewing the approval of the active substance bifenazate 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, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 130, 4.5.2022, p. 3).

³ European Food Safety Authority's conclusion on the updated peer review of the pesticide risk assessment of the active substance bifenazate. EFSA Journal 2021;19(8):6818.

⁴ 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 (OJ L 309 24.11.2009, p. 1).

- (4) As bifenazate based plant protection products are only approved to be used in non-edible crops, it is appropriate to lower the MRLs set out for this substance in Annex II to Regulation (EC) No 396/2005 and list them in Annex V to by establishing them at the limit of determination ('LOD') of that Regulation once the grace periods will have expired.
- (5) The Commission consulted the European Union Reference laboratories for residues of pesticides as regards the appropriate LODs. Those laboratories proposed product specific LODs that are analytically achievable for those products for which MRLs are established at the LOD.
- (6) Through the World Trade Organisation, the trading partners of the Union were consulted on the new MRLs and their comments have been taken into account.
- (7) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (8) A reasonable period should be allowed to elapse before the new MRLs become applicable in order to permit Member States, third countries and food business operators to adapt themselves to the requirements which result from the amendments.
- (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

Annexes II and V to Regulation (EC) No 396/2005 are amended in accordance with 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*.

It shall apply from ... [6 months after the date of entry into force of this Regulation].

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

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN