EUROPEAN
COMMISSION

Brussels, XXX
PLAN/2023/946 v1
[…](2023) XXX draft

COMMISSION REGULATION (EU) …/…

of XXX

amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for desmedipham, etridiazole, flurtamone, profoxydim, difenacoum and potassium permanganate in or on certain products

(Text with EEA relevance)

COMMISSION REGULATION (EU) …/…

of XXX

amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for desmedipham, etridiazole, flurtamone, profoxydim, difenacoum and potassium permanganate 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/EEC[1], and in particular Article 14(1), point (a), Article 18(1), point (b), and Article 49(2) thereof,

Whereas:

(1) For the active substances desmedipham, flurtamone and profoxydim, maximum residue levels ('MRLs') were set in Annex II to Regulation (EC) No 396/2005. For the active substance etridiazole, MRLs were set in Part A of Annex III to Regulation (EC) No 396/2005. For the active substances difenacoum and potassium permandanate, no specific MRLs were set in Regulation (EC) No 396/2005, and as these active substances are not included in Annex IV to that Regulation, the default value of 0,01 mg/kg laid down in Article 18(1), point (b), of that Regulation applies.

(2) The approval of the active substance desmedipham expired on 1 July 2019 and was non-renewed[2]. All authorisations for plant protection products containing that active substance have been revoked. No Codex maximum residue limits ('CXLs') or import tolerances exist for that substance. The MRLs for desmedipham on all products are set at the limit of determination ('LOD'). In line with technical progress, lower levels of LODs are now achievable. It is therefore appropriate to lower the MRLs set out for desmedipham in Annex II to Regulation (EC) No 396/2005 to the current product specific LODs in accordance with Article 17 of Regulation (EC) No 396/2005 in conjunction with Article 14(1), point (a), thereof, and move them to Annex V to Regulation (EC) No 396/2005 in accordance with Article 18(1), point (b), of that Regulation. Additionally, as the MRLs on all products are set at the product specific LODs, there is no longer a need for confirmatory data. Therefore, all footnotes containing requests for confirmatory data should be deleted.

---

1 OJ L 70, 16.3.2005, p. 1.

2 Commission Implementing Regulation (EU) 2019/1100 of 27 June 2019 concerning the non-renewal of approval of the active substance desmedipham, 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 175, 28.6.2019, p. 17).

(3) The approval of the active substance etridiazole expired on 31 May 2021 and no application for renewal of its approval had been submitted. All authorisations for plant protection products containing that active substance have been revoked. No CXLs or import tolerances exist for that substance. It is therefore appropriate to delete the MRLs set for this substance in Part A to Annex III to Regulation (EC) No 396/2005 in accordance with Article 17 of Regulation (EC) No 396/2005 in conjunction with Article 14(1), point (a), thereof. MRLs for etridiazole on all products should be set at the product specific LODs in Annex V to Regulation (EC) No 396/2005 in accordance with Article 18(1), point (b), of that Regulation.

(4) The approval of the active substance flurtamone expired on 27 December 2018 and was non-renewed[3]. All authorisations for plant protection products containing that active substance have been revoked. No CXLs or import tolerances exist for that substance. The MRLs for flurtamone on all products are set at the product specific LODs. It is therefore appropriate to move the MRLs set for flurtamone in Annex II to Regulation (EC) No 396/2005 to Annex V to Regulation (EC) No 396/2005 in accordance with Article 18(1), point (b), of that Regulation.

(5) The approval of the active substance profoxydim expired on 31 July 2021 and no application for renewal of its approval had been submitted. All authorisations for plant protection products containing that active substance have been revoked. No CXLs or import tolerances exist for that substance. The MRLs for profoxydim on all products are set at the product specific LODs. It is therefore appropriate to move the MRLs set for profoxydim in Annex II to Regulation (EC) No 396/2005 to Annex V to Regulation (EC) No 396/2005 in accordance with Article 18(1), point (b), of that Regulation.

(6) The approval of the active substance difenacoum expired on 30 December 2019 and no application for renewal of its approval had been submitted. All authorisations for plant protection products containing that active substance have been revoked. No CXLs or import tolerances exist for that substance. It is therefore appropriate to set the MRLs for difenacoum on all products at the product specific LODs in Annex V to Regulation (EC) No 396/2005 in accordance with Article 18(1), point (b), of that Regulation.

(7) The active substance potassium permanganate is not approved[4]. No CXLs or import tolerances exist for that substance. It is therefore appropriate to set the MRLs for potassium permanganate on all products at the product specific LODs in Annex V to Regulation (EC) No 396/2005 in accordance with Article 18(1), point (b), of that Regulation.

(8) The Commission consulted the European Union reference laboratories for residues of pesticides as regards the need to adapt certain LODs. Those laboratories proposed product specific LODs that are analytically achievable.

---

[3] Commission Implementing Regulation (EU) 2018/1917 of 6 December 2018 concerning the non-renewal of approval of the active substance flurtamone, 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 Commission Implementing Regulation (EU) No 540/2011 (OJ L 311, 7.12.2018, p. 27).

[4] Commission Decision of 30 September 2008 concerning the non-inclusion of Beauveria brongniartii and potassium permanganate in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing these substances (OJ L 263, 2.10.2008, p. 12).

(9) 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.

(10) Annexes II, III and V to Regulation (EC) No 396/2005 should therefore be amended accordingly.

(11) To allow for the normal marketing, processing and consumption of products, this Regulation should not apply to products, which have been produced in the Union or imported into the Union before the new MRLs become applicable and for which a high level of consumer protection is maintained.

(12) 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 modification of the MRLs.

(13) 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, III and V to Regulation (EC) No 396/2005 are amended in accordance with the Annex to this Regulation.

Article 2

Regulation (EC) No 396/2005 as it stood before being amended by this Regulation shall continue to apply to products which were produced in the Union or imported into the Union before … [*Office of publications: please insert date 6 months after the date of entry into force of this Regulation*].

Article 3

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 … [*Office of publications: please insert date 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