EUROPEAN
COMMISSION

Brussels, XXX
PLAN/2022/2563 Rev.5
[…](2023) XXX draft

COMMISSION REGULATION (EU) …/…

of XXX

amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 2,4-DB, iodosulfuron-methyl, mesotrione and pyraflufen-ethyl in or on certain products

(Text with EEA relevance)

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(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)(a) and Article 49(2) thereof,

Whereas:

(1) For 2,4-DB, iodosulfuron-methyl, mesotrione and pyraflufen-ethyl, maximum residue levels ('MRLs') were set in Annex II to Regulation (EC) No 396/2005.

(2) During the review of those MRLs pursuant to Article 12 of Regulation (EC) No 396/2005, the European Food Safety Authority ('the Authority') identified some information as unavailable for certain products. The available information was sufficient for the Authority to propose MRLs that are safe for consumers. Data gaps were indicated in Annex II to that Regulation specifying the date by which the missing information was to be submitted to the Authority by the applicant in support of the proposed MRLs.

(3) For 2,4-DB, the missing information concerning its metabolism and analytical methods for barley, oats, rye and wheat was submitted by the applicant and the Authority concluded that the data gap indicated in Annex II to Regulation (EC) No 396/2005 was sufficiently addressed[2]. Therefore, for these products, the existing MRLs in Annex II to Regulation (EC) No 396/2005 should be maintained, and the footnote requiring the submission of additional information should be deleted from that Annex. For swine (muscle, fat, liver, kidney), bovine (muscle, fat, liver, kidney, edible offals), sheep (muscle, fat, liver, kidney, edible offals), goat (muscle, fat, liver, kidney, edible offals), equine (muscle, fat, liver, kidney, edible offals), other farmed terrestrial animals (muscle, fat, liver, kidney, edible offals) and milk (cattle, sheep, goat, horse), although information on analytical methods was submitted by the applicant, a feeding study for ruminants is still missing. The Authority concluded that this information was not sufficient to address the data gap previously identified and recommended that risk managers consider lowering the MRLs for those products to the limit of determination ('LOD')[2]. Therefore, it is appropriate to set the MRLs for

[1] OJ L 70, 16.3.2005, p. 1.

[2] European Food Safety Authority; 'Lack of confirmatory data following Article 12 MRL reviews for 2,4-DB, iodosulfuron-methyl, mesotrione, methoxyfenozide and pyraflufen-ethyl', EFSA Journal, 2023;21(5):8013.

those products in Annex II to Regulation (EC) No 396/2005 at the product-specific LOD, and to delete the footnote indicating a request for a submission additional information from that Annex.

(4) For iodosulfuron-methyl, the missing information concerning storage stability, crop metabolism and residue trials for linseeds and residue trials for maize/corn was not submitted by the applicant. The Authority therefore concluded that the data gap previously identified was not addressed[3], and recommended that risk managers consider lowering those MRLs to the LOD. Therefore, for these products, it is appropriate to set the MRLs in Annex II to Regulation (EC) No 396/2005 at the product-specific LOD, and to delete the [footnote indicating a] request for the submission of additional information from that Annex.

(5) For mesotrione, the missing information on residue trials investigating residue levels of that substance and its metabolite AMBA (free and conjugate) for sugar canes was not submitted by the applicant. The Authority therefore concluded that the data gap previously identified was not addressed[4], and recommended that risk managers consider lowering that MRL to the LOD. Therefore, for sugar canes, it is appropriate to set the MRL in Annex II to Regulation (EC) No 396/2005 at the product-specific LOD, and to delete the requirement to submit additional information from that Annex.

(6) For pyraflufen-ethyl, the missing information concerning analytical methods for hops was not submitted by the applicant. The Authority therefore concluded that the data gap previously identified was not addressed[5], and recommended that risk managers consider lowering that MRL to the LOD. Therefore, for hops, it is appropriate to set the MRL in Annex II to Regulation (EC) No 396/2005 at the product-specific LOD, and to delete the requirement to submit additional information from that Annex.

(7) The Commission consulted the European Union reference laboratories as regards the need to adapt certain LODs. Those laboratories concluded that for certain products technical developments permit the setting of lower LODs.

(8) 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.

(9) Regulation (EC) No 396/2005 should therefore be amended accordingly.

(10) In order to allow for the normal marketing, processing and consumption of products, this Regulation should provide for a transitional measure for products which have been produced before the modification of the MRLs and for which it has been shown that a high level of consumer protection is maintained.

(11) A reasonable period should be allowed to elapse before the modified 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.

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3 European Food Safety Authority; 'Lack of confirmatory data following Article 12 MRL reviews for 2,4-DB, iodosulfuron-methyl, mesotrione, methoxyfenozide and pyraflufen-ethyl', EFSA Journal, 2023;21(5):8013.

4 European Food Safety Authority; 'Lack of confirmatory data following Article 12 MRL reviews for 2,4-DB, iodosulfuron-methyl, mesotrione, methoxyfenozide and pyraflufen-ethyl', EFSA Journal, 2023;21(5):8013.

5 European Food Safety Authority; 'Lack of confirmatory data following Article 12 MRL reviews for 2,4-DB, iodosulfuron-methyl, mesotrione, methoxyfenozide and pyraflufen-ethyl', EFSA Journal, 2023;21(5):8013.

(12) 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

Annex II to Regulation (EC) No 396/2005 is 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 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 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