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Delegations will find attached document D089878/3.

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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 haloxyfop in or on certain products

(Text with EEA relevance)

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

Whereas:

(1) For the active substance haloxyfop, maximum residue levels ('MRLs') were set in Annex II to Regulation (EC) No 396/2005.

(2) In accordance with Article 6(2) and (4) of Regulation (EC) No 396/2005, an application for import tolerance was submitted for haloxyfop used in Australia on linseeds and rapeseeds/canola seeds. The applicant claims that the authorised uses of that substance on such crop in Australia leads to residues exceeding the MRL contained in Regulation (EC) No 396/2005 for linseeds, and that a higher MRL is necessary to avoid trade barriers for the importation of linseeds and rapeseeds.

(3) In accordance with Article 8 of Regulation (EC) No 396/2005, the application was evaluated by the Member State concerned and in accordance with Article 9 of that Regulation, the evaluation report was forwarded to the Commission.

(4) The European Food Safety Authority ('the Authority') assessed the application and the evaluation report, examining in particular the risks to consumers and, where relevant, to animals and gave a reasoned opinion on the proposed MRL[2]. It forwarded that opinion to the applicant, the Commission and the Member States, and made it available to the public.

(5) The Authority concluded that all requirements with respect to data were met and that the modification to the MRL requested by the applicant was acceptable with regard to consumer safety on the basis of a consumer exposure assessment for 27 specific

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

[2] European Food Safety Authority reasoned opinion on the setting of import tolerances for haloxyfop-P in linseed and rapeseed. EFSA Journal 2018;16(11):5470.

European consumer groups. It took into account the consumption data and the information on the toxicological properties of the substance valid at that time. The Authority concluded that neither the lifetime exposure to the substance via consumption of all food products that may contain it, nor the short-term exposure due to high consumption of those products showed that there is any risk that the acceptable daily intake or the acute reference dose is exceeded.

(6) A MRL for soya beans based on an application for an import tolerance was previuosly implemented in Commission Regulation (EU) 2017/171[3] since the Authority concluded that the proposed MRL was safe for consumers[4].

(7) In 2020, according to Commission Implementing Regulation (EU) 2020/1643[5], the approval of the active substance haloxyfop was not renewed due to the decision, of the applicant for renewal, to no longer support that application for renewal of approval.

(8) All authorisations for plant protection products containing haloxyfop have been revoked. It is therefore appropriate to delete the existing MRLs set for that active substance in Annex II of Regulation (EC) No 396/2005 in accordance with Article 17 of that Regulation in conjunction with Article 14(1)(a) thereof.

(9) In accordance with Article 43 of Regulation (EC) No 396/2005, the Commission requested the Authority to provide a reasoned opinion, assessing the risks that the current MRLs based on import tolerances and CXLs for haloxyfop may pose to consumers considering the most recent consumption data available and the presence or absence of submission of the required confirmatory information to address the data gaps identified during the MRL review in accordance to the Article 12 of Regulation (EC) No 396/2005[6].

(10) The Authority concluded that the existing MRLs for haloxyfop in soya beans, as well as the proposed import tolerances for that active substance in linseed and rapeseed/canola seeds and the existing CXLs for onions and sunflowers seeds are not expected to pose a risk to consumers. However, considering the most recent consumption data and data requirements, for soya beans and sunflower seeds some information was not available and further consideration by risk managers was therefore required[7].

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3 Commission Regulation (EU) 2017/171 of 30 January 2017 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for aminopyralid, azoxystrobin, cyantraniliprole, cyflufenamid, cyproconazole, diethofencarb, dithiocarbamates, fluazifop-P, fluopyram, haloxyfop, isofetamid, metalaxyl, prohexadione, propaquizafop, pyrimethanil, Trichoderma atroviride strain SC1 and zoxamide in or on certain products (OJ L 30, 3.2.2017, p. 45).

4 European Food Safety Authority reasoned opinion on the setting of import tolerance for haloxyfop-P in soya beans. EFSA Journal 2016;14(7):4551.

5 Commission Implementing Regulation (EU) 2020/1643 of 5 November 2020 amending Implementing Regulation (EU) No 540/2011 as regards the approval periods of the active substances calcium phosphide, denathonium benzoate, haloxyfop-P, imidacloprid, pencycuron and zeta-cypermethrin (OJ L 370, 6.11.2020, p. 18).

6 Commission Regulation (EU) 2015/2075 of 18 November 2015 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for abamectin, desmedipham, dichlorprop-P, haloxyfop-P, oryzalin and phenmedipham in or on certain products (OJ L 302, 19.11.2015, p. 15).

7 European Food Safety Authority reasoned opinion on the targeted review of maximum residues levels (MRLs) for haloxyfop-P. EFSA Journal 2022;20(11):7658.

(11) Since the MRL for haloxyfop in soya beans and the CXL for sunflower seeds are considered safe for consumers and the missing information was identified during the risk assessment performed by the Authority only in 2022, it is appropriate to provide the applicant time to submit the requested data. Those MRLs will therefore be reviewed taking into account the information available within two years from the publication of this Regulation. As there is no risk for consumers, it is appropriate to set the MRLs for onions, soya beans, linseed, rapeseed/canola seeds and sunflower seeds in Annex II to Regulation (EC) No 396/2005 at the levels identified by the Authority.

(12) Additionally, the Authority identified that the product specific LOD for milk of 0,01* mg/kg is the major contributor to chronic exposure, so that the LOD for this product should be set at 0,002mg/kg. For all other products, it is appropriate to lower the respective MRLs set out for haloxyfop in Annex II to Regulation (EC) No 396/2005 to the product specific LOD in accordance with Article 14(1)(a) of Regulation (EC) No 396/2005, in conjunction with Article 17 of that Regulation.

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

(14) 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.

(15) Annex II to Regulation (EC) No 396/2005 should therefore be amended accordingly.

(16) 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.

(17) 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 prepare themselves to meet the new requirements which will result from the modification of the MRLs.

(18) 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 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