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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	24 July 2024
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	D091952/05
Subject:	COMMISSION REGULATION (EU) …/… of XXX 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 cyproconazole and spirodiclofen in or on certain products

Delegations will find attached document D091952/05.

Encl.: D091952/05

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COMMISSION REGULATION (EU) …/…

of XXX

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 cyproconazole and spirodiclofen in or on certain products

(Text with EEA relevance)

COMMISSION REGULATION (EU) …/…

of XXX

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 cyproconazole and spirodiclofen 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), and Article 49(2) thereof,

Whereas:

(1) For cyproconazole and spirodiclofen, maximum residue levels ('MRLs') were set in Part A of Annex III to Regulation (EC) No 396/2005.

(2) The approval of the active substance cyproconazole expired on 31 May 2021 and no application for a renewal of its approval has been submitted. All authorisations for plant protection products containing cyproconazole have been revoked. The European Food Safety Authority (the 'Authority') had submitted a reasoned opinion on the review of the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005[2]. The Authority proposed to change the residue definition to cyproconazole (sum of isomers). The Commission considers this new residue definition to be appropriate.

(3) The MRLs for cyproconazole in or on rapeseeds/canola seeds, soyabeans, liver and kidney of swine, bovine, sheep, goat and equine result from the implementation of Codex MRLs ('CXLs'), which the Authority had confirmed as safe for consumers. The MRLs for liver and kidney of swine, bovine, sheep, goat and equine for should therefore be set in Annex II to Regulation (EC) No 396/2005 at the existing levels in accordance with Article 14(2), point (e), of Regulation (EC) No 396/2005. As some information was not available for rapeseeds/canola seeds and soyabeans, further consideration by risk managers was required. While these MRLs based on CXLs are considered safe, they will therefore be reviewed. The review will take 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 those products in Annex II to Regulation (EC) No 396/2005 at the levels identified by the Authority.The MRLs for cyproconazole in or on peas (without pods), beans, peas, barley, buckwheat and other pseudocereals, maize/corn, common millet/proso millet, oat, rye, wheat,

[1] OJ L 70, 16.3.2005, p. 1, ELI: http://data.europa.eu/eli/reg/2005/396/oj.

[2] European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for cyproconazole according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2021;19(3):6483.

coffee beans and sugar beet roots, muscle, fat of swine, bovine, sheep, goat and equine and muscle, fat and liver of poultry, milk of cattle, sheep, goat and horse and birds' eggs were based on uses in the Union which are no longer authorised. There are CXLs for those products, which the Authority had confirmed as safe for consumers. However, as some information was not available, further consideration by risk managers was required. While the MRLs based on CXLs are considered safe, they will therefore be reviewed. The review will take 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 those products in Annex II to Regulation (EC) No 396/2005 at the levels identified by the Authority.

(4) For all other products, as the MRLs for cyproconazole were based on uses in the Union which are no longer authorised and there are no CXLs or import tolerances, it is appropriate to lower the MRLs to product-specific limits of determination ('LODs') and set them in Annex II 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.

(5) The approval of the active substance spirodiclofen expired on 31 July 2020 and no application for a renewal of its approval has been submitted. All authorisations for plant protection products containing spirodiclofen have been revoked. The Authority had submitted a reasoned opinion on the review of the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005[3]. It proposed to change the residue definition in food groups of animal origin to spirodiclofen-enol (M01), expressed as spirodiclofen. The Commission considers this new residue definition to be appropriate.

(6) The Authority concluded that the MRLs set for spirodiclofen in or on grapefruits, oranges, lemons, limes, mandarins, almonds, Brazil nuts, cashew nuts, chestnuts, macadamias, pecans, pistachios, walnuts, table grapes, avocados, mangoes and papayas were derived from import tolerances and were based on sufficient supporting data for the current GAPs and are considered safe for consumers. Based on the combined dataset of trials on grapefruits, oranges, and lemons, the MRL derived has been extrapolated to the whole group of citrus fruits. Based on the combined dataset of trials on almonds and pecans, the MRL derived has been extrapolated to the whole group of tree nuts (except coconuts and hazelnuts/cobnuts). However, a slightly different methodology to calculate MRLs has been used compared to the MRLs previously set for grapefruits, oranges, lemons, limes, mandarins, almonds, Brazil nuts, cashew nuts, chestnuts, macadamias, pecans, pistachios, walnuts, table grapes, avocados, mangoes and papayas. As a result, the MRLs for limes and mandarins should be maintained, the MRLs for grapefruits, oranges, lemons, almonds, avocados, mangoes and papayas should be lowered, the MRLs for Brazil nuts, cashew nuts, chestnuts, macadamias, pecans, pistachios, walnuts and table grapes should be raised and set in Annex II to Regulation (EC) No 396/2005.

(7) The MRLs for spirodiclofen in or on coconuts, hazelnuts/cobnuts, pine nut kernels, pome fruits, stone fruits, wine grapes, strawberries, blueberries, currants (black, red and white), tomatoes, sweet peppers/bell peppers, hops and muscle, fat, liver and kidney of swine, bovine, sheep, goat and equine, milk of cattle, sheep, goat and horse result from the implementation of CXLs, which the Authority had confirmed as safe

[3] European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for spirodiclofen according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2021;19(11):6908.

for consumers. Those MRLs should therefore be set in Annex II to Regulation (EC) No 396/2005 at the existing levels in accordance with Article 14(2), point (e), of Regulation (EC) No 396/2005.

(8) The MRLs for spirodiclofen in or on cucumbers and gherkins were based on uses in the Union which are no longer authorised. There are CXLs for those products, which the Authority had confirmed as safe for consumers. The MRLs for those products should therefore be set in Annex II to Regulation (EC) No 396/2005 at the levels of the CXLs in accordance with Article 14(2), point (e), of Regulation (EC) No 396/2005.

(9) For all other products, as the MRLs for spirodiclofen were based on uses in the Union which are no longer authorised and there are no CXL or import tolerances, it is appropriate to lower the MRLs to product-specific LODs in Annex II 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.

(10) The Commission consulted the European Union reference laboratories for residues of pesticides as regards the need to adapt certain LODs. For all the active substances covered by this Regulation, those laboratories proposed product-specific LODs that are analytically achievable.

(11) 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.

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

(13) To allow for the normal marketing, processing and consumption of products, this Regulation should not apply to products which have been placed on the market before the new MRLs become applicable and for which a high level of consumer protection is maintained.

(14) 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.

(15) 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 III 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 have been placed on the market in 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