Council of the
European Union

Brussels, 19 December 2022
(OR. en)

16198/22

AGRILEG 203
PESTICIDE 59

COVER NOTE

From:	European Commission
date of receipt:	16 December 2022
To:	General Secretariat of the Council
No. Cion doc.:	D084205/04
Subject:	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 isoxaben, novaluron and tetraconazole in or on certain products

Delegations will find attached document D084205/04.

Encl.: D084205/04

EUROPEAN
COMMISSION

Brussels, XXX
SANTE/10108/2022
(POOL/E4/2022/10108/10108-EN.docx)
D084205/04
[…](2022) 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 isoxaben, novaluron and tetraconazole 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 isoxaben, novaluron and tetraconazole 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 isoxaben, novaluron and tetraconazole maximum residue levels ('MRLs') were set in Part A of Annex III to Regulation (EC) No 396/2005.

(2) For isoxaben, the European Food Safety Authority ('the Authority') 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 recommended lowering the existing MRLs for fruits and tree nuts, root and tuber vegetables, bulb vegetables, melons, pumpkins, witloof, chives, celery leaves, stem vegetables, sage, rosemary, thyme, basil, oilseeds and oil fruits, cereals, and chicory roots, in line with the principle of setting MRLs at levels as low as reasonably achievable and based on sufficient supporting data for the current good agricultural practices ('GAPs'). It recommended keeping the existing MRLs for courgettes and beans (fresh, without pods) based on sufficient supporting data for the current GAPs. As there is no risk for consumers with any of those MRLs, it is appropriate to set the MRLs for those products in Annex II to Regulation (EC) No 396/2005 at the level identified by the Authority.

(3) For isoxaben, the Authority further concluded that the MRLs for cotton seed, herbal infusions (dried, flowers), herbal infusions (dried, roots), and hops should be set at the current limits of determination ('LOD') specific to each product, in line with the principle of setting MRLs at levels as low as reasonably achievable and based on the current GAPs. However, as some information was not available, further consideration by risk managers was required. Therefore, while these MRLs are considered safe, they will 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

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

[2] European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for isoxaben according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2022;20(1):7062.

is appropriate to set the MRLs for those products at the LODs specific to each product in Annex II to Regulation (EC) No 396/2005.

(4) For isoxaben, an application pursuant to Article 6(1) of Regulation (EC) No 396/2005, requesting a modification of the existing MRL for peas (fresh, without pods) was submitted. As regards this application, a Member State made a request to use the fast-track procedure, foreseen in the Technical Guidelines on the MRL setting procedure[3], to set an MRL based on residue trials on beans (fresh, without pods). The Authority has recently assessed residue trials on beans (fresh, without pods) in the framework of the review of the existing MRLs for isoxaben and gave a reasoned opinion on the proposed MRL[4]. This opinion from the Authority relies on the current scientific and technical knowledge on the subject. As it is appropriate to extrapolate from the residue trials on beans (fresh, without pods) to peas (fresh, without pods), as confirmed by the existing Union guidelines on extrapolation of MRLs[5], it is unnecessary to request the Authority to provide a reasoned opinion on peas (fresh, without pods). It is therefore appropriate to set the MRL for peas (fresh, without pods) at the same level as the MRL for beans (fresh, without pods) on the basis of the residue trials performed on beans (fresh, without pods) in Annex II to Regulation (EC) No 396/2005.

(5) For novaluron, the Authority submitted a reasoned opinion on the review of the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005[6]. In view of various data gaps on toxicologically relevant issues, including uncertainties regarding possible endocrine disruptor properties of that active substance, the Authority could not rule out harmful effects on human health with the MRLs for novaluron in all products. It is therefore appropriate to set the MRLs for all products at the LODs specific to each product in Annex V to Regulation (EC) No 396/2005.

(6) For novaluron, the European Union reference laboratories for residues of pesticides proposed to change the residue definition to "Novaluron (sum of constituent isomers)" to clarify that residues can occur at any isomer ratio, as novaluron is a chiral compound. The Commission considers this new residue definition to be appropriate as it will ensure a high level of consumer protection and facilitate controls by enforcement authorities, and it does not affect the Authority's reasoned opinion. Therefore, in accordance with Article 14(2) (f) of Regulation (EC) No 396/2005, the residue definition for novaluron should be "Novaluron (sum of constituent isomers)".

(7) For tetraconazole, the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005[7]. It recommended keeping the existing MRL for kaki/Japanese persimmons based on sufficient

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3 Technical guidelines MRL setting procedure in accordance with Articles 6 to 11 of Regulation (EC) No 396/2005 and Article 8 of Regulation (EC) No 1107/2009 (SANTE/2015/10595 Rev. 6.1).

4 European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for isoxaben according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2022;20(1):7062.

5 Technical guidelines on data requirements for setting maximum residue levels, comparability of residue trials and extrapolation of residue data on products from plant and animal origin (SANTE/2019/12752 – 23 November 2020).

6 European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for novaluron according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2022;20(1):7041.

7 European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for tetraconazole according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2022;20(1):7111.

supporting data for the current GAPs. As there is no risk for consumers, it is appropriate to set the MRL for kaki/Japanese persimmons in Annex II to Regulation (EC) No 396/2005 at the level identified by the Authority.

(8) For tetraconazole, the Authority further concluded that the MRLs for loquats, apricots, peaches, table grapes, wine grapes, strawberries, cucumbers, gherkins, courgettes, rye, wheat, sugar beet root, products of animal origin except bovine liver and horse liver, and milks should be lowered in line with the principle of setting MRLs at levels as low as reasonably achievable and based on the current GAPs. It concluded that the MRLs for apples, pears, quinces, medlars, witloofs, globe artichokes, linseeds, rapeseeds, and birds' eggs should be maintained based on the current GAPs. It further concluded that the MRLs for tomatoes, aubergines, melons, pumpkins, watermelons, chicory roots, bovine liver and horse liver should be raised based on the current GAPs. However, as some information was not available, further consideration by risk managers was required. Therefore, while these MRLs are considered safe, they will 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.

(9) For tetraconazole, the Authority identified that no residue trials were available to derive MRL values for peppers, barley, buckwheat, maize, millet, oat, rice, and sorghum, so that further consideration by risk managers was required. In the absence of such trials, the Commission considers that it is appropriate to set the MRLs for those products at the LODs specific to each product in Annex II to Regulation (EC) No 396/2005.

(10) For tetraconazole, the European Union reference laboratories for residues of pesticides proposed to change the residue definition to "Tetraconazole (sum of constituent isomers)" to clarify that residues can occur at any isomer ratio, as tetraconazole is a chiral compound. The Commission considers this new residue definition to be appropriate as it will ensure a high level of consumer protection and facilitate controls by enforcement authorities, and it does not affect the Authority's reasoned opinion. Therefore, in accordance with Article 14(2) (f) of Regulation (EC) No 396/2005, the residue definition for tetraconazole should be "Tetraconazole (sum of constituent isomers)".

(11) The Authority assessed the existing Codex maximum residue levels ('CXLs') in its reasoned opinions. For setting the MRLs, the Commission has taken into account those CXLs that are considered safe for consumers in the Union.

(12) As regards products on which the use of plant protection products containing the active substances isoxaben, novaluron or tetraconazole is not authorised, and for which no import tolerances or CXLs exist, it is appropriate to set the MRLs at the specific LODs, or the default MRL should apply as provided for in Article 18(1), point (b), of Regulation (EC) No 396/2005.

(13) The Commission consulted the European Union reference laboratories for residues of pesticides on the need to adapt certain LODs. For all the active substances covered by this Regulation, those laboratories proposed product specific LODs.

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

(16) For isoxaben and tetraconazole, 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 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.

(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

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

Article 2

As regards the active substances isoxaben and tetraconazole in and on all products, 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 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 Publication: please insert date 6 months after entry into force*].

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