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COMMISSION

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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 imazalil in or on certain products

(Text with EEA relevance)

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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 imazalil 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) Maximum residue levels (MRLs) for imazalil were set in Annex II and Part B of Annex III to Regulation (EC) No 396/2005.

(2) The European Food Safety Authority ("the Authority") submitted a reasoned opinion on the existing MRLs for imazalil in accordance with Article 12(1) of Regulation (EC) No 396/2005[2]. It recommended lowering the MRLs for potatoes, tomatoes, barley grains, oat grains, rye grains and wheat grains. For certain other products it recommended raising the existing MRLs.

(3) The Authority concluded that concerning certain MRLs, some information was not available and that further consideration by risk managers was required. From a risk management perspective, it is appropriate to set MRLs in Annex II to Regulation (EC) No 396/2005 at the existing level or the level identified by the Authority for citrus fruits, strawberries, blackberries, raspberries, courgettes, melons, and muscle, fat tissue, liver and kidney of swine, bovine and equine, as well as cattle milk and horse milk, as for those products limited information was available and the Authority derived MRLs that do not raise concerns of consumer protection. Those MRLs will be reviewed; the review will take into account the information available within two years from the publication of this Regulation. From a risk management perspective, it is appropriate to set MRLs in Annex II to Regulation (EC) No 396/2005 at the specific limit of determination or at the default MRL as set out in Article 18(1)(b) of Regulation (EC) No 396/2005 for pome fruits, persimmon, bananas and sweet peppers/bell peppers, as for those products no information was available from which the Authority could derive MRLs that do not raise concerns of consumer protection.

(4) The Authority indicated that the derived MRLs for imazalil in grapefruits, oranges, apples, pears, bananas, potatoes and bovine liver, as well as the Codex maximum

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

[2] European Food Safety Authority; Review of the existing maximum residue levels for imazalil according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2017;15(9):4977.

residue limit (CXL) underlying the EU-MRL for medlar, may raise concerns of consumer protection. Taking into account additional information available for grapefruits, oranges and potatoes, it derived alternative MRLs for grapefruits, oranges, potatoes and bovine liver that do not raise such concerns. As regards the MRLs for apples, pears, medlar and bananas, the Authority indicated that risk managers may consider setting them at the specific limit of determination or at the default MRL as set out in Article 18(1)(b) of Regulation (EC) No 396/2005.

(5) The Authority proposed revised residue definitions. It is appropriate to change the residue definitions accordingly.

(6) Independently from the MRL review performed in accordance with Article 12(1) of Regulation (EC) No 396/2005, an application was submitted in accordance with Article 6 of that Regulation to modify the existing MRLs for imazalil in citrus fruits, apples, pears, bananas and potatoes and in products of animal origin.

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

(8) In accordance with Article 10 of Regulation (EC) No 396/2005, the Authority assessed the application and the evaluation report, examining in particular the risks to the consumer and, where relevant, to animals and gave its reasoned opinion[3] on the proposed MRLs. It forwarded that opinion to the applicants, the Commission and the Member States and made it available to the public.

(9) The Authority concluded in its reasoned opinion in accordance with Article 10 of Regulation (EC) No 396/2005 that the MRLs for the intended uses could not be amended until the risk assessment for the plant metabolites R014821, FK-772 and FK-284 was completed with regard to genotoxicity and general toxicity. It further concluded that certain information identified as not available in the MRL review performed in accordance with Article 12(1) of that Regulation was submitted with the application in accordance with Article 6 of that Regulation.

(10) Due to the adoption of the reasoned opinion under Article 10 of Regulation (EC) No 396/2005 after the adoption of the reasoned opinion under Article 12(1) of that Regulation and the horizontal nature of the toxicity concerns identified for the imazalil metabolites R014821, FK-772 and FK-284, the Commission requested the Authority to update its reasoned opinion on the existing MRLs for imazalil in accordance with Article 43 of Regulation (EC) No 396/2005.

(11) The Authority submitted a reasoned opinion[4] updating the review of the existing MRLs for imazalil based on the new toxicological information.

(12) In that reasoned opinion, the Authority derived the same MRLs as in its reasoned opinion in accordance with Article 12 of Regulation (EC) No 396/2005, except for citrus fruits, melons and commodities of animal origin. For these commodities, it did not propose MRLs, because it could not finalise the assessment of the toxicological properties of metabolite R014821.

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[3] European Food Safety Authority; Modification of the existing maximum residue levels for imazalil in various commodities. EFSA Journal 2018;16(6):5329.

[4] European Food Safety Authority; Reasoned Opinion on the updated review of the existing maximum residue levels for imazalil according to Article 12 of Regulation (EC) No 396/2005 following new toxicological information. EFSA Journal 2018;16(10):5453.

(13) Commission Implementing Regulation (EU) No 705/2011[5] renewed the approval of imazalil in accordance with Article 13(2) of Regulation (EC) No 1107/2009[6]. While in the risk assessment preceding the adoption of that Regulation the Authority had identified uncertainties regarding the toxicological properties of metabolite R014821[7], the approval conditions were not restricted in this regard at the risk management stage. Additional information on the toxicological properties of metabolite R014821 submitted with the application in accordance with Article 6 of Regulation (EC) No 396/2005 did not entirely address those uncertainties but did not lead to an increased level of concern, either. From a risk management perspective, it is consistent and appropriate to set MRLs for those products for which the Authority in its reasoned opinion in accordance with Article 12 of Regulation (EC) No 396/2005 derived MRLs that do not raise concerns of consumer protection in Annex II to Regulation (EC) No 396/2005 at the existing level or the level identified by the Authority.

(14) Existing CXLs were taken into account in the reasoned opinions of the Authority. CXLs which are safe for consumers in the Union were considered for MRL setting.

(15) As regards products on which the use of the plant protection product concerned is not authorised, and for which no import tolerances or CXLs exist, MRLs should be set at the specific limit of determination or the default MRL should apply, as provided for in Article 18(1)(b) of Regulation (EC) No 396/2005.

(16) The Commission consulted the European Union reference laboratories for residues of pesticides as regards the need to adapt certain limits of determination. Those laboratories concluded that for certain commodities technical development requires the setting of specific limits of determination.

(17) Based on the reasoned opinions of the Authority and taking into account the factors relevant to the matter under consideration, the appropriate modifications to the MRLs fulfil the requirements of Article 14(2) of Regulation (EC) No 396/2005.

(18) 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.

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

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

(21) 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.

(22) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

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5 OJ L 190, 21.7.2011, p. 43.

6 OJ L 309, 24.11.2009, p. 1.

7 European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance imazalil. EFSA Journal 2010, 8(3):1526.

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 were produced in the Union or imported into the Union before [*Office of Publication: please insert date 6 months after entry into force of this Regulation*], except for grapefruit, oranges, apples, pears, medlar, bananas, potatoes and bovine liver.

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 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
Jean-Claude JUNCKER