

Brussels, XXX PLAN/2022/2637 v2 [...](2023) XXX draft

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 pyriproxyfen in or on certain products

(Text with EEA relevance)

EN EN

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 pyriproxyfen 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/EEC¹, and in particular Article 14(1), point (a), and Article 49(2) thereof,

Whereas:

- (1) Maximum residue levels ('MRLs') for pyriproxyfen were set in Part A of Annex III to Regulation (EC) No 396/2005.
- (2) The European Food Safety Authority ('the Authority') submitted a reasoned opinion on the review of the existing MRLs for pyriproxyfen in accordance with Article 12(1) of Regulation (EC) No 396/2005². The Authority recommended to lower the existing MRLs for pyriproxyfen on swine/bovine/goat/horse muscle, fat, liver and kidney, as well as cattle/horse milk to the limit of determination ('LOD') 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'). As there is no risk for consumers, it is appropriate to set the MRL for pyriproxyfen on these products in Annex II to Regulation (EC) No 396/2005 at the level identified by the Authority.
- (3) The Authority further concluded that the MRLs for pyriproxyfen on almonds, chestnuts, hazelnuts, pecans, pistachios, walnuts, pine nuts kernels, pome fruits, grapes, table olives, kaki/Japanese persimmons, pineapples, tomatoes, sweet peppers, aubergines, cucurbits with edible peel, and watermelons should be lowered in line with the principle of setting MRLs at levels as low as reasonably achievable and based on the current GAPs and Codex maximum residue limits ('CXLs'), which are confirmed as being safe for consumers³. It also concluded that the MRLs for pyriproxyfen on apricots, peaches, plums, strawberries, mangoes, papayas, melons, cotton seeds and tea should be maintained based on the current GAPs and CXLs, which are confirmed

-

OJ L 70, 16.3.2005, p. 1.

European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for pyriproxyfen according to Article 12 of Regulation (EC) No 396/2005; EFSA Journal 2022;20(11):7617.

European Food Safety Authority; Scientific support for preparing an EU position in the 51st Session of the Codex Committee on Pesticide Residues (CCPR); EFSA Journal 2019;17(7):5797.

as being safe for consumers^{3,4}. In addition, the Authority concluded that the MRLs for pyriproxyfen on citrus fruits, cherries and kumquats should be raised based on the current GAPs and CXLs, which are confirmed as being safe for consumers. As the Authority confirmed in an earlier reasoned opinion⁵ that the MRL for pyriproxyfen on banana is safe for consumers, that MRL can be maintained. However, as some information was not available, further consideration by risk managers was required. Therefore, while the MRLs for almonds, chestnuts, hazelnuts, pecans, pistachios, walnuts, pine nuts kernels, pome fruits, grapes, table olives, kaki/Japanese persimmons, pineapples, tomatoes, sweet peppers, aubergines, cucurbits with edible peel, watermelons, apricots, peaches, plums, strawberries, mangoes, papayas, melons, cotton seeds, tea, citrus fruits, cherries, kumquats and bananas 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 pyriproxyfen on those products in Annex II to Regulation (EC) No 396/2005 at the levels identified by the Authority.

- (4) As the Authority identified that no residue trials were available to derive MRL values for pyriproxyfen on macadamias, avocados, granate apples/pomegranates, cherimoyas, potatoes, sweet potatoes and yams, other root and tuber vegetables except sugar beets, bulb vegetables, okra/lady's fingers, pumpkins, brassica vegetables (excluding brassica roots and brassica baby leaf crops), lettuces and salad plants, spinaches and similar leaves, watercresses, witloofs/Belgian endives, herbs and edible flowers, legume vegetables, stem vegetables, beans (dry), and soyabeans, further consideration by risk managers was required. In the absence of such trials, which are necessary to derive a MRL value, the Commission considers that it is appropriate to set the MRLs for those products at the product specific LODs set out in Annex II to Regulation (EC) No 396/2005.
- (5) The Commission consulted the European Union reference laboratories for residues of pesticides as regards the need to adapt certain LODs. For pyriproxyfen, those laboratories proposed product specific LODs that are analytically achievable.
- (6) 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.
- (7) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (8) 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. This is the case for all products.
- (9) 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.
- (10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁴ European Food Safety Authority; Scientific support for preparing an EU position in the 52nd Session of the Codex Committee on Pesticide Residues (CCPR); EFSA Journal 2021;19(8):6766.

European Food Safety Authority; Reasoned Opinion on the modification of the existing maximum residue levels for pyriproxyfen in bananas; EFSA Journal 2016;14(2):438.

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 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