# Commission Regulation (EU) No 61/2014 of 24 January 2014 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 cyromazine, fenpropidin, formetanate, oxamyl and tebuconazole in or on certain products (Text with EEA relevance)

## COMMISSION REGULATION (EU) No 61/2014

## of 24 January 2014

## 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 cyromazine, fenpropidin, formetanate, oxamyl and tebuconazole 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 cyromazine and oxamyl, maximum residue levels (MRLs) were set in Annex II and Part B of Annex III to Regulation (EC) No 396/2005. For fenpropidin, formetanate and tebuconazole, MRLs were set in Part A of Annex III to that Regulation.

(2) For cyromazine, the European Food Safety Authority, hereinafter 'the Authority', submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005[(2)]. The Authority recommended lowering the MRLs for tomatoes and aubergines. For other products it recommended raising the MRLs.

(3) The Authority concluded that concerning the MRLs for cyromazine in lamb's lettuce, lettuce, rocket, rucola, beans (fresh with pods), peas (fresh with pods) and celery some information was not available and that further consideration by risk managers was required. As there is no risk for consumers, MRLs for those products should be set in Annex II to Regulation (EC) No 396/2005 at the existing level or the level identified by the Authority. Those MRLs will be reviewed; the review will take into account the information available within two years from the publication of this Regulation.

(4) The Authority concluded that concerning the MRLs for cyromazine in fresh herbs no information was available and that further consideration by risk managers was required. Taking into account additional information on the good agricultural practices provided by the Netherlands and as there is no risk for consumers, MRLs for those products should be set in Annex II to Regulation (EC) No 396/2005 at the existing level. Those

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MRLs will be reviewed; the review will take into account the information available within two years from the publication of this Regulation.

(5) The Authority indicated that the evaluated use for cyromazine in escarole may raise concerns of consumer protection. The MRL for that product should be set 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.

(6) Cyromazine is a pharmacologically active substance in veterinary medicine. As regards ovine products, MRLs for those products should be set at the same level as provided for in Commission Regulation (EU) No 37/2010[(3)] because exposure from use in veterinary medicinal products is expected to be higher than from use in plant protection products.

(7) For fenpropidin, the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005[(4)]. It proposed to change the residue definition. It recommended lowering the MRLs for bananas, oats, rye, wheat and sugar beet root. For other products it recommended raising or keeping the existing MRLs.

(8) For formetanate, the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(2) of Regulation (EC) No 396/2005 in conjunction with Article 12(1) thereof[(5)]. It recommended keeping the existing MRL for tomatoes.

(9) The Authority concluded that concerning the MRLs for formetanate in melons and watermelons some information was not available and that further consideration by risk managers was required. As there is no risk for consumers, MRLs for those products should be set in Annex II to Regulation (EC) No 396/2005 at the existing level or the level identified by the Authority.

(10) The Authority concluded that concerning the MRLs for formetanate in table and wine grapes, strawberries, peppers, cucumbers, beans with pods, leek and courgettes no information was available and that further consideration by risk managers was required. MRLs for those products should be set 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.

(11) The Authority indicated that the existing MRL for formetanate in courgettes may raise concerns of consumer protection.

(12) In the context of a procedure for the authorisation of the use of a plant protection product containing the active substance formetanate on apricots, peaches/nectarines, table and wine grapes, strawberries, peppers, cucumbers, melons, pumpkins, watermelons, lettuce and escarole, an application was made in accordance with Article 6(1) of Regulation (EC) No 396/2005 for the modification of the existing MRLs.

(13) 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.

(14) The Authority assessed the application and the evaluation report, examining in particular the risks to the consumer and, where relevant, to animals and gave a reasoned

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opinion on the proposed MRLs[(6)]. It forwarded this opinion to the Commission and the Member States and made it available to the public.

(15) The Authority concluded in its reasoned opinion that, as regards the use of formetanate on apricots, the submitted data are not sufficient to set a new MRL. It indicated that the proposed MRLs for strawberries, peppers, cucumbers and courgettes may raise concerns of consumer protection. MRLs for those products should be set 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.

(16) As regards all other uses, the Authority concluded that all requirements with respect to data were met and that the modifications to the MRLs requested by the applicants were acceptable with regard to consumer safety on the basis of a consumer exposure assessment for 27 specific European consumer groups. It took into account the most recent information on the toxicological properties of formetanate. Neither the lifetime exposure to this substance via consumption of all food products that may contain it, nor the short-term exposure due to high consumption of the relevant crops and products showed that there is a risk that the acceptable daily intake (ADI) or the acute reference dose (ARfD) is exceeded.

(17) For oxamyl, the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(2) of Regulation (EC) No 396/2005 in conjunction with Article 12(1) thereof[(7)]. It recommended keeping the existing MRLs for certain products.

(18) The Authority concluded that concerning the MRLs for oxamyl in oranges, mandarins, bananas, tomatoes, aubergines, cucumbers, gherkins and courgettes some information was not available and that further consideration by risk managers was required. As there is no risk for consumers, MRLs for those products should be set in Annex II to Regulation (EC) No 396/2005 at the existing level or the level identified by the Authority. Those MRLs will be reviewed; the review will take into account the information available within two years from the publication of this Regulation. Concerning the MRLs for oranges, mandarins and potatoes, the Authority concluded that further consideration of the risk assessment values by risk managers was required, taking into account the specific limit of determination in the residue trials.

(19) The Authority indicated that the evaluated new uses for oxamyl in peppers, melons and watermelons as well as the existing MRL for peppers may raise concerns of consumer protection. MRLs for those products should be set 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.

(20) For tebuconazole, the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005[(8)]. It proposed to change the residue definition. It recommended lowering the MRLs for apples, pears, apricots, peaches, table grapes, strawberries, blackberries, raspberries, blueberries, cranberries, currants, gooseberries, elderberries, carrots, parsnips, parsley roots, garlic, tomatoes, cucumber, pumpkins, watermelons, broccoli, cauliflower, head cabbage, asparagus, leek, soya bean, rye grain, wheat grain and ruminant milk. For other products it recommended raising or keeping the existing MRLs.

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(21) The Authority concluded that concerning the MRLs for tebuconazole in cherries, wine grapes, dewberries, salsify, aubergines, melons, celery, peanuts, rice grain, hops, spices (seeds) and caraway some information was not available and that further consideration by risk managers was required. As there is no risk for consumers, MRLs for those products should be set in Annex II to Regulation (EC) No 396/2005 at the existing level or the level identified by the Authority. Those MRLs will be reviewed; the review will take into account the information available within two years from the publication of this Regulation. As regards caraway, it is appropriate to take into account additional information on the good agricultural practice provided by Austria and to set the MRL for that product at the same level as for the group of spices — seeds.

(22) The Authority concluded that concerning the MRLs for tebuconazole in kohlrabi, beans (fresh, with and without pods), peas (fresh, with pods), sunflower seed and sugar beet root no information was available and that further consideration by risk managers was required. MRLs for kohlrabi, sunflower seed and sugar beet root should be set 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. Taking into account comments by trading partners of the Union and as there is no risk for consumers, MRLs for beans (fresh, with and without pods) and peas (fresh, with pods) should be set in Annex II to Regulation (EC) No 396/2005 at the existing level. The MRLs for beans (fresh, with and without pods) and peas (fresh, with pods) will be reviewed; the review will take into account the information available within two years from the publication of this Regulation.

(23) The Authority indicated that the evaluated use for tebuconazole in Chinese cabbage as well as the existing MRLs for apples, pears, cherries, peaches, table and wine grapes, and Chinese cabbage may raise concerns of consumer protection. The MRL for Chinese cabbage should be set 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.

(24) As regards tebuconazole in citrus fruit except oranges, lettuce and other salad plants, chives, parsley and dry pulses, the Authority submitted opinions concerning MRLs for those products[9][10]. As those opinions contain additional information previously not available to the Authority, it is appropriate to take them into account.

(25) As regards tebuconazole in plums, garlic, onions, sweet corn, globe artichokes, dry beans, peanuts, soya bean, cotton seed, hops and mammalian edible offal, the Codex Alimentarius Commission (CAC)[11] adopted Codex MRLs (CXLs) for tebuconazole. As these CXLs are supported by an updated assessment of the Authority, it is appropriate to take them into account, with the exception of those CXLs which are not safe for consumers in the Union and for which the Union presented a reservation to the CAC[12].

(26) As regards products for which neither relevant authorisations or import tolerances were reported at Union level nor Codex MRLs were available, the Authority concluded that further consideration by risk managers was required. Taking into account the current scientific and technical knowledge, MRLs for those products should be set 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.

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(27) 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.

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

(29) 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.

(30) 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 lawfully produced before the modification of the MRLs and for which information shows that a high level of consumer protection is maintained.

(31) 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.

(32) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

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*

As regards the active substances in and on products, as set out in the following list, Regulation (EC) No 396/2005 as it stood before being amended by this Regulation shall continue to apply to products which were lawfully produced before 14 August 2014:

(1) cyromazine and fenpropidin: all products;

(2) formetanate: all products except table and wine grapes, tomatoes, aubergines, courgettes, melons, pumpkins and watermelons;

(3) oxamyl: all products except peppers;

(4) tebuconazole: wine and all other products except apples, pears, cherries, peaches, table and wine grapes, and Chinese cabbage.

*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*.

However, it shall apply from 14 August 2014 except for formetanate in table and wine grapes, tomatoes, aubergines, melons, pumpkins and watermelons, for which it shall apply from the date of entry into force.

This Regulation shall be binding in its entirety and directly applicable in all Member States.