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Delegations will find attached document D057206/03.

Encl.: D057206/03

EUROPEAN
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Brussels, XXX
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[…](2018) 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 bromadiolone, etofenprox, paclobutrazol and penconazole 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 bromadiolone, etofenprox, paclobutrazol and penconazole 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), Article 18(1)(b) and Article 49(2) thereof,

Whereas:

(1) For etofenprox and paclobutrazol maximum residue levels (MRLs) were set in Part A of Annex III to Regulation (EC) No 396/2005. For penconazole, MRLs were set in Annex II and Part B of Annex III to Regulation (EC) No 396/2005. For bromadiolone no MRLs are set in Regulation (EC) No 396/2005, and as this active substance is not included in Annex IV to that Regulation, the default value of 0,01 mg/kg laid down in Article 18(1)(b) of that Regulation applies.

(2) For bromadiolone, the European Food Safety Authority ("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[2]. All existing authorisations for plant protection products containing bromadiolone are restricted to the use as rodenticide only and are not intended for direct application on edible crops. It is therefore appropriate to set the MRLs at the default limit of determination. These default values should be set in Annex V to Regulation (EC) No 396/2005 in accordance with Article 18(1)(b) of that Regulation.

(3) For etofenprox, 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[3]. The Authority recommended lowering the MRLs for chestnuts, hazelnuts/cobnuts, apples, pears, apricots, cherries (sweet), plums, grapes, strawberries, blackberries, raspberries (red and yellow), blueberries, currants (black, red and white), gooseberries (green, red and yellow), figs, kaki/Japanese persimmons, granate apples/pomegranates, potatoes, garlic, onions, tomatoes, sweet peppers/bell peppers, aubergines/eggplants, Brussel sprouts, head cabbages, beans (with pods), beans (without pods), lupins/lupine beans (dry), cereals, sugar beet roots, swine

1 OJ L 70, 16.3.2005, p. 1.

2 European Food Safety Authority; Review of the existing maximum residue levels for bromadiolone according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2017;15(5):4835.

3 European Food Safety Authority; Review of the existing maximum residue levels for etofenprox according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2017;15(8):4964.

(muscle, liver and kidney), bovine (muscle, liver and kidney), sheep (muscle, liver and kidney), goat (muscle, liver and kidney), equine (muscle, liver and kidney), other farmed terrestrial animals (muscle, liver and kidney) and milk (sheep and goat). For other products, it recommended raising or keeping the existing MRLs. It concluded that concerning the MRLs for grapefruits, oranges, lemons, limes, mandarins, peaches, kiwi fruits (green, red, yellow), melons, pumpkins, watermelons, lamb's lettuces/corn salads, lettuces, escaroles/broad-leaved endives, cresses and other sprouts and shoots, Roman rocket/rucola, spinaches, chards/beet leaves, chervil, chives, celery leaves, parsley, sage, rosemary, thyme, basil and edible flowers, laurel/bay leave, tarragon, lentils (fresh), beans (dry), rapeseeds/canola seeds, fat tissue of swine, bovine, sheep goat and equine, poultry (muscle, fat tissue and liver), milk (cattle, sheep, goat and horse) and birds eggs, some information was not available and that further consideration by risk managers was required. As there is no risk for consumers, the 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. These MRLs will be reviewed; the review will take into account the information available within two years from the publication of this Regulation.

(4) For paclobutrazol, 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[4]. The Authority proposed to change the residue definition to paclobutrazol (sum of constituent isomers). It recommended lowering the MRLs for apples, pears, quinces, medlars, loquats/Japanese medlars, apricots, peaches, plums, grapes, table olives, linseeds, sesame seeds, rapeseeds/canola seeds, mustard seeds, borage seeds, gold of pleasure seeds, hemp seeds, olives for oil production, bovine (muscle, fat tissue, liver and kidney) and equine (muscle, fat tissue, liver and kidney). The 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.

(5) For penconazole, 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]. The Authority proposed to change the residue definition to penconazole (sum of constituent isomers). It recommended lowering the MRLs for almonds, hazelnuts/cobnuts, walnuts, apples, pears, quinces, medlars, loquats, apricots, strawberries, currants (black, red and white), cucumbers, gherkins, courgettes, peas (with and without pods), globe artichokes, hops, bovine (muscle, fat tissue, liver and kidney), equine (muscle, fat tissue, liver and kidney), poultry (muscle, fat tissue, liver and kidney), milk and bird eggs. For other products, it recommended raising or keeping the existing MRLs. It concluded that concerning the MRLs for cherries (sweet), peaches, plums, grapes, blackberries, raspberries (red and yellow), gooseberries (green, red and yellow), sweet peppers/bell peppers, aubergines/eggplants, melons, pumpkins, watermelons some information was not available and that further consideration by risk managers was required. As there is no risk for consumers, the 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. These MRLs will be reviewed; the review will take into account the information available within two years from the publication of this Regulation.

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4 European Food Safety Authority; Review of the existing maximum residue levels for paclobutrazol according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2017;15(8):4974.

5 European Food Safety Authority; Review of the existing maximum residue levels for penconazole according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2017;15(6):4853.

(6) As regards products on which the use of the plant protection product concerned is not authorised, and for which no import tolerances or Codex maximum residue limits (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.

(7) The Commission consulted the European Union reference laboratories for residues of pesticides as regards the need to adapt certain limits of determination. As regards several substances, those laboratories concluded that for certain commodities technical development requires the setting of specific limits of determination.

(8) 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.

(9) 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.

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

(11) 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.

(12) 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.

(13) 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 etofenprox, paclobutrazol and penconazole 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*
*Jean-Claude JUNCKER*