EUROPEAN
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 1-methyl-3-(trifluoromethyl)-1H-pyrazole-4-carboxamide, cycloxydim, cyflumetofen, cyfluthrin, metobromuron and penthiopyrad in or on certain products

(Text with EEA relevance)

COMMISSION REGULATION (EU) …/…

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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 1-methyl-3-(trifluoromethyl)-1H-pyrazole-4-carboxamide, cycloxydim, cyflumetofen, cyfluthrin, metobromuron and penthiopyrad 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) and Article 49(2) thereof,

Whereas:

(1) For cycloxydim, cyflumetofen and penthiopyrad, maximum residue levels ('MRLs') are set in Part A of Annex III to Regulation (EC) No 396/2005. For cyfluthrin MRLs are set in Annexes II and III to that Regulation. For 1-methyl-3-(trifluoromethyl)-1H-pyrazole-4-carboxamide (PAM) and metobromuron, no specific MRLs are set in Regulation (EC) No 396/2005, and as these active substances are not included in Annex IV to that Regulation, the default value of 0.01 mg/kg laid down in Article 18(1), point (b), of that Regulation applies.

(2) The European Food Safety Authority ('the Authority') submitted a reasoned opinion on the existing MRLs for beta-cyfluthrin and cyfluthrin in accordance with Article 12(1) of Regulation (EC) No 396/2005[2]. In its reasoned opinion the Authority confirmed the residue definition as "cyfluthrin, including other mixtures of constituent isomers (sum of isomers)". As beta-cyfluthrin is such an isomer of cyfluthrin, MRLs established for cyfluthrin also cover beta-cyfluthrin. Both substances are no longer approved as active substances used in plant protection products in the EU. Therefore, the Authority assessed the MRLs based on non-EU uses of plant protection products, such as those currently established by the Codex Alimentarius Commission (Codex Maximum Residue Limits (CXLs) and the import tolerances reported by Member States. The Authority also took into account the authorised use of cyfluthrin in veterinary medicinal products for bovine and ovine and the MRLs set in Regulation (EU) No 470/2009[3] The Authority recommended lowering the MRLs for apples,

[1] OJ L 070, 16.3.2005, p. 1.

[2] European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for beta-cyfluthrin and cyfluthrin according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2021;19(9):6837.

[3] Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and

pears, potatoes, sweet peppers/bell peppers, head cabbages, "fruit spices", "root and rhizome spices", swine (muscle, liver, kidney), bovine (muscle liver, kidney), sheep (muscle, liver, kidney), goat (muscle, liver, kidney) equine (muscle, liver, kidney), poultry (muscle, fat, liver), horse milk and birds' eggs. The Authority also recommended lowering the MRLs for grapefruit, oranges, lemons, limes, mandarins, tomatoes, aubergines/eggplants, rapeseeds/canola seeds, cotton seeds. Further, the Authority recommended keeping the existing MRLs for soyabean, fat (bovine, sheep, goat, equine), milk (cattle, sheep and goat) for which sufficient supporting data on good agricultural practices were submitted and assessed by the Authority. As there is no risk for consumers, it is appropriate to set the MRLs for all products above in Annex II to Regulation (EC) No 396/2005 at the existing level or at the level identified by the Authority.

(3) For the use of beta-cyfluthrin and cyfluthrin on cauliflower, the Authority identified a possible acute risk for consumers if the CXL for cauliflower was set. Therefore the MRL will be lowered to the default value of 0.01mg/kg.

(4) The Authority further concluded that concerning the MRLs for barley and wheat some information was not available and that further consideration by risk managers was required. 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 cyfluthrin, for barley and wheat in Annex II to Regulation (EC) No 396/2005 at the level identified by the Authority.

(5) For cycloxydim, the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005[4]. The Authority recommended lowering the MRLs for apples, pears, apricots, peaches, table and wine grapes, celeriacs/turnip rooted celeries, peas (fresh, with pods), Florence fennels, globe artichokes, rapeseeds/canola seeds, sugar beet roots and poultry (muscle, fat, liver). It recommended raising MRLs for strawberries, potatoes, sweet potatoes, beetroots, horseradishes, parsnips, parsley roots/Hamburg roots parsley, radishes, salsifies, swedes/rutabagas, turnips, garlic, shallots, broccoli, cauliflowers, Brussels sprouts, head cabbage, kohlrabies, Roman rocket/rucola, red mustards, Baby leaf crops (including brassica species), spinaches, purslanes, chards/beet leaves, "herbs and edible flowers", beans (without pods), peas (with pods), lentils, lupins/lupini beans, poppy seeds, mustard seeds, cotton seeds, borage seeds, bovine (muscle, fat, kidney), sheep (muscle, fat, kidney), goat (muscle, fat, kidney), equine(muscle, fat, kidney), milk (cattle, sheep, goat, horse) and bird's eggs. It recommended keeping those existing MRLs for other products for which sufficient supporting data on good agricultural practices were submitted and assessed by the Authority. As there is no risk for consumers, it is appropriate to set the MRLs for all products above in Annex II to Regulation (EC) No 396/2005 at the existing level or the level identified by the Authority.

(6) The Authority further concluded that concerning the MRLs for spring onions/green onions and Welsh onions, lamb's lettuces/corn salads, escaroles/broad-leaved endives,

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amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council. OJ L 152, 16.06.2009, p. 11.

[4] European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for cycloxydim according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2020; 18(1): 5962.

cresses and other sprouts and shoots, land cresses, maize/corn and herbal infusions from roots, some information was not available and that further consideration by risk managers was required. 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 cycloxydim, for all products above in Annex II to Regulation (EC) No 396/2005 at the level identified by the Authority.

(7) For cyflumetofen, the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005[5]. It recommended keeping the existing MRLs for strawberries, azaroles/Mediterranean medlars, kaki/Japanese persimmons, tomatoes, aubergines/eggplants, cucumbers and hops for which sufficient supporting data on good agricultural practices were submitted and assessed by the Authority. 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 level identified by the Authority.

(8) The Authority further concluded that concerning the MRLs for swine (muscle, fat, liver kidney), bovine (muscle, fat, liver kidney), sheep (muscle, fat, liver kidney), goat (muscle, fat, liver kidney), equine (muscle, fat, liver kidney), and milk (cattle, sheep, goat, horse) some information was not available and that further consideration by risk managers was required. 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 cyflumetofen for all products above in Annex II to Regulation (EC) No 396/2005 at the level identified by the Authority.

(9) For metobromuron, the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005[6]. It proposed to change the residue definition to the sum of metobromuron and 4-bromophenylurea, expressed as metobromuron.

(10) The Authority concluded that concerning the MRLs for strawberries, potatoes, carrots, parsnips, lamb's lettuces/corn salads, spinaches, watercresses, celery leaves, parsley, sage, thyme, basil and edible flowers, beans (with pods), beans (without pods), asparagus, Florence fennels, beans, peas, sunflower seeds, soyabeans, swine (muscle, fat, liver kidney), bovine (muscle, fat, liver kidney), sheep (muscle, fat, liver kidney), goat (muscle, fat, liver kidney), equine (muscle, fat, liver kidney), and milk (cattle, sheep, goat, horse) some information was not available and that further consideration by risk managers was required. While these MRLs are considered safe for consumers, 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 metobromuron, for all products above in Annex II to Regulation (EC) No 396/2005 at the level identified by the Authority.

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5 European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for cyflumetofen according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2021;19(8):6812.

6 European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for metobromuron according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2021;19(9):6841.

(11) For penthiopyrad, the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005[7]. For products of animal origin, it proposed two separate residue definitions, 'penthiopyrad' and '1-methyl-3-(trifluoromethyl)-1H-pyrazole-4-carboxamide (PAM)', in order to cover the presence of the metabolite 1-methyl-3-(trifluoromethyl)-1H-pyrazole-4-carboxamide (PAM) from the use of penthiopyrad in products of animal origin. The Authority recommended lowering the MRLs for apricots, peaches and oats. It recommended raising MRLs for rye and wheat. It recommended keeping the existing MRLs for other products for which sufficient supporting data on good agricultural practices were submitted and assessed by the Authority. 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 existing level or the level identified by the Authority.

(12) The Authority further concluded that concerning the MRLs for spring onions/green onions and Welsh onions, lamb's lettuces/corn salads, lettuces, cresses and other sprouts and shoots, land cresses, Roman rocket/rucola, red mustards, spinaches, purslanes, chards/beet leaves, chervil, chives, cardoons, celeries, Florence fennels, leeks, rhubarbs, cotton seeds, barley and sorghum some information was not available and that further consideration by risk managers was required. 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 penthiopyrad, for all products above in Annex II to Regulation (EC) No 396/2005 at the level identified by the Authority.

(13) As regards 1-methyl-3-(trifluoromethyl)-1H-pyrazole-4-carboxamide (PAM), which is a main metabolite of penthiopyrad, the Authority recommended, based on the metabolism studies of penthiopyrad in livestock, setting MRLs at the limit of determination ('LOD') in products of animal origin. With regard to products of plant origin, the Authority did not propose any MRLs because this metabolite is not relevant for products of plant origin. Furthermore, in products of plant origin 1-methyl-3-(trifluoromethyl)-1H-pyrazole-4-carboxamide (PAM) may occur naturally and setting an MRL at the default value of 0.01 mg/kg is not appropriate. It is therefore appropriate to clarify in Annex II that the default value of 0.01 mg/kg for 1-methyl-3-(trifluoromethyl)-1H-pyrazole-4-carboxamide (PAM) does not apply to products of plant origin. As there is no risk for consumers, it is appropriate to set the MRLs in Annex II to Regulation (EC) No 396/2005 at the level identified by the Authority. The Authority assessed the existing 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.

(14) As regards products on which the use of the plant protection product concerned is not authorised in the Union, and for which no import tolerances or CXLs exist, MRLs should be set at the LOD or for the default value of 0.01mg/kg to apply, as provided for in Article 18(1), point (b), of Regulation (EC) No 396/2005.

(15) The Commission consulted the European Union reference laboratories for residues of pesticides as regards the need to adapt certain LOD. For all the active substances

[7] European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for penthiopyrad according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2021; 19(9):6810.

covered by this Regulation those laboratories proposed product specific LODs that are analytically achievable.

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

(17) For 1-methyl-3-(trifluoromethyl)-1H-pyrazole-4-carboxamide, cycloxydim, cyflumetofen, cyfluthrin, metobromuron and penthiopyrad, 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 modified MRLs become applicable and for which information shows that a high level of consumer protection is maintained.

(18) 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 adapt themselves to meet the requirements which result from the modification of the MRLs.

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

Article 2

As regards 1-methyl-3-(trifluoromethyl)-1H-pyrazole-4-carboxamide, cycloxydim, cyflumetofen, cyfluthrin, metobromuron and penthiopyrad 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 Publication: please insert date 6 months after entry into force]*.

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