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Subject:	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 myclobutanil, napropamide and sintofen in or on certain products

Delegations will find attached document D063987/04.

Encl.: D063987/04

EUROPEAN
COMMISSION

Brussels, XXX
SANTE/11371/2018
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[…](2020) 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 myclobutanil, napropamide and sintofen in or on certain products

(Text with EEA relevance)

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 myclobutanil, napropamide and sintofen 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 myclobutanil maximum residue levels (MRLs) were set in Annex II and Part B of Annex III to Regulation (EC) No 396/2005. For napropamide MRLs were set in Part A of Annex III to Regulation (EC) No 396/2005. For sintofen no MRLs were 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 Regulation (EC) No 396/2005 applies.

(2) For myclobutanil the European Food Safety Authority ("the Authority"), submitted a reasoned opinion on the review of the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005[2]. It proposed to change the residue definition. It recommended raising or keeping the existing MRLs for apples, pears, quinces, medlars, loquats/Japanese medlars, apricots, cherries (sweet), peaches, plums, table grapes and wines grapes. The Authority concluded that concerning the MRLs for strawberries, blackberries, gooseberries (green, red and yellow), bananas, tomatoes, aubergines/eggplants, melons, pumpkins, watermelons, lamb's lettuces/corn salads, beans (with pods), globe artichokes, hops, sugar beet roots, 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), poultry (muscle, fat, liver), milk (cattle, sheep, goat, 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 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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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 myclobutanil according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2018;16(8):5392.

(3) For napropamide the Authority submitted a reasoned opinion on the review of the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005[3]. It proposed to change the residue definition. It recommended lowering the MRLs for almonds, chestnuts, hazelnuts/cobnuts, pecans, pine nut kernels, pistachios, walnuts, apples, pears, quinces, medlars, loquats/Japanese medlars, apricots, cherries (sweet), peaches, plums, potatoes, celeriacs/turnip rooted celeries, horseradishes, radishes, swedes/rutabagas, turnips, tomatoes, aubergines/eggplants, broccoli, cauliflowers, Brussels sprouts, head cabbages, lamb's lettuces/corn salads, Roman rocket/rucola, beans (with pods), linseeds, poppy seeds, sesame seeds, sunflower seeds, rapeseeds/canola seeds, soyabeans, mustard seeds, cotton seeds, pumpkin seeds, safflower seeds, borage seeds, gold of pleasure seeds, hemp seeds and castor beans. The Authority concluded that concerning the MRLs for grapefruits, oranges, lemons, limes, mandarins, strawberries, blackberries, dewberries, raspberries (red and yellow), blueberries, cranberries, currants (black, red and white), gooseberries (green, red and yellow), rose hips, elderberries, herbs and edible flowers, herbal infusions (from flowers, leaves and herbs, roots and any other part of the plant) and fruit spices 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 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 sintofen the European Food Safety Authority ("the Authority"), submitted a reasoned opinion on the review of the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005[4]. It concluded that concerning the MRL for wheat some information was not available and that further consideration by risk managers was required. No other authorisations exist for this substance. As there is no risk for consumers, this MRL should be set in Annex II to Regulation (EC) No 396/2005 at the level identified by the Authority. This MRL will be reviewed; the review will take into account the information available within two years from the publication of this Regulation.

(5) 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 (LOD) or the default MRL should apply, as provided for in Article 18(1)(b) of Regulation (EC) No 396/2005.

(6) 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.

(7) 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.

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[3] European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for napropamide according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2018;16(8):5394.

[4] European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for sintofen according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2018;16(8):5406.

(8) 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.

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

(10) 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.

(11) 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.

(12) 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

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