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Subject:	COMMISSION REGULATION (EU) .../... of XXX amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for deltamethrin, metalaxyl, thiabendazole and trifloxystrobin in or on certain products.

Delegations will find attached document D089877/4 .

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COMMISSION REGULATION (EU) …/…

of XXX

amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for deltamethrin, metalaxyl, thiabendazole and trifloxystrobin in or on certain products

(Text with EEA relevance)

COMMISSION REGULATION (EU) …/…

of XXX

amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for deltamethrin, metalaxyl, thiabendazole and trifloxystrobin 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 deltamethrin, metalaxyl, thiabendazole and trifloxystrobin, maximum residue levels ('MRLs') were set in Annex II to Regulation (EC) No 396/2005.

(2) During the assessment of those MRLs in accordance with Article 12 of Regulation (EC) No 396/2005[2], the European Food Safety Authority ('the Authority') identified some information as unavailable for certain products. The available information was sufficient for the Authority to propose MRLs that are safe for consumers and the data gaps were indicated in Annex II of that Regulation specifying the date by which the missing information was to be submitted to the Authority in support of the proposed MRLs.

(3) For deltamethrin, such information concerning the method of enforcement and residue trials was provided to confirm the existing MRLs for 'tree nuts', melons, watermelons, other cucurbits with inedible peel, Chinese cabbages, rice and wheat. The Authority concluded that the data provided was sufficient to address the data gap identified. Therefore, for these products, the existing MRLs in Annex II to Regulation (EC) No 396/2005 should be maintained.

(4) The information provided on residue trials analysing simultaneously the residue definitions for enforcement and risk assessment was not sufficient to confirm the existing MRLs of deltamethrin for quinces, medlars, loquats, apricots, cherries, peaches, 'other small fruits and berries', beetroots, celeriac, horseradishes, Jerusalem artichokes, parsley roots, radishes, salsifies, swedes, turnips, 'other root and tuber vegetables', 'bulb vegetables', aubergines, kales, kohlrabies, leeks, olives for oil production, 'herbal infusions from roots' and chicory roots. However, the Authority was able to conclude that the current MRLs are safe for consumers by using a

[1] OJ L 70, 16.3.2005, p. 1, ELI: http://data.europa.eu/eli/reg/2005/396/oj.

[2] Reasoned opinion on the Evaluation of confirmatory data following the Article 12 MRL review and modification of the existing maximum residue levels for deltamethrin in tomatoes and okra/lady's fingers. EFSA Journal 2022;20(3):7107.

conversion factor for recalculating the results of the residue trials obtained according to the residue definition for enforcement to the residue definition for risk assessment. Therefore, for these products, the existing MRLs in Annex II to Regulation (EC) No 396/2005 should be kept.

(5) The current MRLs for apples, table olives, carrots, pumpkins, 'flowering brassica', 'legume vegetables', 'cereals (except rice and wheat)', root and rhizome spices, grapes, strawberries, 'cucurbits with edible peel', lamb's lettuce, cresses, land cresses, Roman rocket, red mustards, baby leaf crops, grape leaves, watercresses, chervil, cultivated fungi, lentils, peas, lupins, tea and 'products of animal origin, including milk and eggs' are based on Codex maximum residue limits (CXLs), which were included in Annex II to Commission Regulation (EC) No 396/2005[3]. Despite a discrepancy between the Union and the Codex residue definitions, the Authority concluded that the current MRLs are safe for consumers. Therefore, for these products the existing MRLs in Annex II to Regulation (EC) No 396/2005 should be kept.

(6) For 'citrus fruits', kiwis, escaroles, spinaches and similar leaves, globe artichokes, beans, oilseeds, fruit spices, bud spices and flower pistil spices, the Authority concluded that the data gap previously identified was not addressed and that risk managers may consider replacing those MRLs either with alternative MRLs, available for 'citrus fruits', or with the product specific Limit of Determination ('LOD'). Lower MRL was available for 'citrus fruits' based on (alternative) GAPs and with a view to setting MRLs at the lowest reasonable level, it is appropriate to set new lower MRLs for them in Annex II to Regulation (EC) No 396/2005. Since for the other products listed no fall-back GAPs were available, it is appropriate to set the levels at the product specific LOD.

(7) Additional information provided on residue trials was combined with the existing data, enabling the Authority to derive lower MRLs for 'cane fruits', 'herbs and edible flowers (except chervil)', 'herbal infusions from flowers', 'herbal infusions from leaves and herbs', sweet peppers/bell peppers and head cabbages and higher MRL for plums. The Authority concluded that the new MRLs are safe for consumers. Therefore, for these products, new MRLs should be included in Annex II to Regulation (EC) No 396/2005.

(8) The Authority identified a risk for consumers concerning the existing MRLs for pears, potatoes and lettuces and concluded that risk managers may consider replacing those MRLs either with alternative lower MRLs, available for pears and lettuces, or replacing those MRLs with the product specific LOD. As a fall-back GAP leading to a lower MRL was available for pears and lettuces, but not for potatoes, it is appropriate to set a new, lower MRLs only for pears and lettuces, but lower the MRL to the product-specific LOD for potatoes. For the sake of clarity, the footnotes indicating a lack of information concerning those products should be deleted from Annex II to Regulation (EC) No 396/2005.

(9) The Authority received several applications pursuant to Article 6 of Regulation (EC) No 396/2005 to modify the existing MRLs for deltamethrin in tomatoes and

[3] Commission Regulation (EU) 2018/832 of 5 June 2018 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 cyantraniliprole, cymoxanil, deltamethrin, difenoconazole, fenamidone, flubendiamide, fluopicolide, folpet, fosetyl, mandestrobin, mepiquat, metazachlor, propamocarb, propargite, pyrimethanil, sulfoxaflor and trifloxystrobin in or on certain products (OJ L 140, 6.6.2018, p. 38, ELI: http://data.europa.eu/eli/reg/2018/832/oj).

okra/lady's fingers[2], carobs/Saint John's breads[4] and maize[5]. Regarding tomatoes and okra/lady's fingers the Authority recommended raising the MRLs for those products[2]. Therefore, the MRLs for tomatoes and okra/lady's fingers should be set at the level identified by the Authority. For carobs/Saint John's breads, the Authority, after having initially identified a long-term consumer intake concern for the proposed MRL[4], in the subsequent confirmatory data assessment, concluded that the proposed value was safe for consumers[2]. It is therefore appropriate to set this MRL at the proposed level. Regarding maize, the Authority concluded that the data provided was sufficient to derive a new MRL but that this level was lower than the existing one that is based on a CXL, which is safe for consumers[5]. The existing MRL should therefore be maintained.

(10) In accordance with Article 6(2) and (4) of Regulation (EC) No 396/2005 an application was submitted for deltamethrin on mangos and papayas. The applicant claimed that the authorised uses of deltamethrin on such crops in Brazil lead to residues exceeding the MRLs contained in Regulation (EC) No 396/2005 and that higher MRLs are necessary to avoid trade barriers for the importation of those crops. The Authority assessed the application and concluded that the submitted data were sufficient to set new (higher) MRLs that were considered safe for consumers[6]. As there is no risk for consumers, it is appropriate to set the MRLs for mangoes and papayas in Annex II to Regulation (EC) No 396/2005 at the level identified by the Authority.

(11) For metalaxyl, the European Union reference laboratories recommended to change the residue definition for monitoring products of animal origin to 'sum of metalaxyl (sum of enantiomers) and metabolites (free + conjugated) M3 (N- (2,6-dimethylphenyl)-N-(hydroxyacetyl)alanine methyl ester) and M8 (N-(2-hydroxymethyl-6- methylphenyl)-N-(methoxyacetyl)alanine methyl ester (sum of enantiomers), expressed as metalaxyl'. The Commission considers this new residue definition to be appropriate.

(12) To address the data gaps identified during by the Authority in the framework of the MRL review for metalaxyl under Article 12 of Regulation (EC) No 396/2005, the applicant provided new data regarding analytical methods and residue trials. For cocoa beans and hops, the Authority concluded[7] that the data provided was sufficient to address the gap identified and that the additional residue trials for cocoa beans lead to a new (lower) MRL as safe for consumers. The Authority concluded that the new MRL is safe for consumers. Therefore, for hops the existing MRL should be maintained and for cocoa beans the new (lower) MRL should be included in Annex II to Regulation (EC) No 396/2005. For lemons, limes, mandarins, apples, pears, grapes, onions, sweet peppers/bell peppers, melons, watermelons, globe artichokes, soyabeans and 'products of animal origin' the Authority concluded that the data gap previously identified was not addressed and that risk managers may consider replacing those MRLs either with alternative MRLs, when available, or replacing those MRLs with the product specific LOD. As a fall-back GAP leading to a lower MRL was available for limes, mandarins, onions, sweet peppers/bell peppers, melons, watermelons and globe artichokes, it is appropriate to set new lower MRLs. For "herbs and edible

4 Reasoned opinion on the modification of the existing maximum residue level for deltamethrin in carobs/Saint John's breads. EFSA Journal 2020;18(10):6271.

5 Reasoned opinion on the modification of the existing maximum residue level for deltamethrin in maize/corn. EFSA Journal 2022;20(7):7446.

6 Reasoned opinion on the setting of import tolerances for deltamethrin in mangoes and papayas. EFSA Journal 2022;20(3):7198.

7 Reasoned opinion on the evaluation of confirmatory data following the Article 12 MRL review for metalaxyl-M. EFSA Journal 2021;19(12):6996.

flowers" it was possible to extrapolate indoor data from open-leaf varieties of lettuce and it is appropriate to maintain its MRLs. Since for lemons, apples, pears, and soyabeans no fall-back GAP was available, it is appropriate to lower these MRLs to the product specific LOD. For 'products of animal origin' the Authority reviewed the existing MRLs based on updated dietary burden calculations and proposed new (lower) MRLs for kidney and edible offals from swine, sheep and goats and higher MRLs for liver, kidney and edible offals from bovine and equine. As there is no risk for consumers, it is appropriate to set the MRLs for 'products of animal origin' in Annex II to Regulation (EC) No 396/2005 at the level identified by the Authority. For the sake of clarity, the respective footnotes indicating a lack of information concerning those products should be deleted from Annex II to Regulation (EC) No 396/2005.

(13) In accordance with Article 6(2) and (4) of Regulation (EC) No 396/2005 an application was submitted for metalaxyl-M used in oil palms fruits and peppercorn (black, green and white). The applicant claimed that the authorised uses of metalaxyl-M in oil palms in Colombia and in peppercorn in Vietnam lead to residues exceeding the MRLs contained in Regulation (EC) No 396/2005 and that higher MRLs are necessary to avoid trade barriers for the importation of those crops. The Authority assessed the application and concluded that the submitted data were sufficient to set new MRLs that were safe for consumers[8]. As there is no risk for consumers, it is appropriate to set the MRLs for oil palms fruits and peppercorn in Annex II to Regulation (EC) No 396/2005 at the level identified by the Authority.

(14) On 13 December 2022, the Codex Alimentarius Commission adopted new CXLs for metalaxyl[9]. In accordance with Article 5(3) of Regulation (EC) No 178/2002 of the European Parliament and of the Council[10], where international standards exist or their completion is imminent, they are to be taken into consideration in the development or adaptation of food law, except where such standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives of food law or where there is a scientific justification, or where they would result in a different level of protection from the one determined as appropriate in the Union. Moreover, in accordance with Article 13, point (e), of that Regulation, the Union is to promote consistency between international technical standards and food law while ensuring that the high level of protection adopted in the Union is not reduced. The Authority assessed the risks to consumers and produced a scientific report[11]. In cases where the Authority had identified a potential consumer health risk, the Union presented reservations[12,13] to the Codex Committee on Pesticides Residues on the

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8 Reasoned opinion on the setting of import tolerances for metalaxyl-M in oil palms fruits and peppercorn. EFSA Journal 2023;21(5):8008.

9 Joint FAO/WHO Food Standards Programme Codex Alimentarius Commission. Appendix III. Forty-fifth Session. Virtual, 21-25 November, 12-13 and 19 December 2022 and 6 February 2023. https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-701-45%252FFinal%252520Report%252520CAC45%252FCompiled%2BREP22_CAC.pdf.

10 Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1, ELI: http://data.europa.eu/eli/reg/2002/178/oj).

11 Scientific support for preparing an EU position for the 53rd Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal 2022;20(9):7521.

12 European Union comments on Codex CX/PR 22/53/5: https://www.fao.org/fao-who-codexalimentarius/sh-

CXLs proposed. This was the case for metalaxyl in apples, pears and head cabbages. Those CXLs, for which the Union did not present a reservation to the Codex Committee on Pesticides Residues since the Authority did not identify risks for consumers in the Union, can therefore be considered safe. This is the case for the CXLs for metalaxyl in grapes, onions, potatoes and peppercorn. Those CXLs should therefore be included in Annex II to Regulation (EC) No 396/2005.

(15) For thiabendazole, information concerning the potential consumer exposure to the metabolite benzimidazole, residue trials and storage stability were provided to confirm the existing MRLs for apples, avocados and potatoes. The Authority concluded[14] that the data provided was sufficient to address the gap identified and derived a new (lower) MRL based on additional residue trials that were submitted for avocado. The Authority concluded that the new MRL is safe for consumers. Therefore, for apples and potatoes the existing MRLs should be maintained and for avocados the new MRL should be included in Annex II to Regulation (EC) No 396/2005. The Authority identified a potential short-term consumer intake concern for the existing MRL for papayas. Therefore, for papayas the existing MRL should be lowered to the product specific LOD. For the sake of clarity, the respective footnotes indicating a lack of information concerning those products should be deleted from Annex II to Regulation (EC) No 396/2005.

(16) For trifloxystrobin, the European Union reference laboratories recommended to change the residue definition for monitoring products of animal origin to "Sum of trifloxystrobin and [(E,E)-methoxyimino-{2-[1-(3-trifluoromethylphenyl)ethylideneamino-oxymethyl]phenyl}acetic acid] (CGA 321113), expressed as trifloxystrobin (F)". The Commission considers this new residue definition to be appropriate.

(17) Some of the data gaps identified during by the Authority in the framework of the MRL review for trifloxystrobin under Article 12 of Regulation (EC) No 396/2005 were addressed in Commission Regulation (EU) 2018/832[3], regarding analytical methods and the commercial availability of the metabolite CGA321113. To address the remaining data gaps identified by the Authority, the applicant provided new data regarding residue trials for 'herbs and edible flowers', beans with pods and oats. The Authority concluded[15] that the data provided was sufficient to address the data gap identified and that the additional residue trials derived new MRLs which are safe for consumers. Therefore, those new MRLs should be included in Annex II to Regulation (EC) No 396/2005. For passion fruits/maracujas, cucumbers, gherkins and Chinese cabbages/pe-tsai the Authority concluded that the data gap previously identified was not addressed and that risk managers may consider maintaining those MRLs with the existing CXLs, available for cucumbers and gherkins or replacing those MRLs with the product specific LOD. As a fall-back GAP leading to an MRL safe for the

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13 Report of the 53rd session of the Codex Committee on Pesticide Residues REP22/PR53: https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-718-53%252FREPORT%252FFINAL%2BREPORT%252FREP22_PR53e.pdf.

14 Reasoned opinion on the evaluation of confirmatory data following the Article 12 MRL review for thiabendazole. EFSA Journal 2022;20(8):7539.

15 Reasoned opinion on the modification of existing maximum residue levels in various crops and evaluation of confirmatory data following the Article 12 MRL review for trifloxystrobin. EFSA Journal 2022;20(1):7048.

consumers was available at the same level for cucumbers and gherkins it is appropriate to maintain those MRLs, while since for passion fruits/maracujas and Chinese cabbages/pe-tsai no fall-back GAP was available, then it is appropriate to lower these MRLs to the product specific LOD. For the sake of clarity, the respective footnotes indicating a lack of information concerning those products should be deleted from Annex II to Regulation (EC) No 396/2005.

(18) Together with the confirmatory data, the applicant also submitted several applications to modify the existing MRLs for trifloxystrobin in various crops under Article 6 of Regulation (EC) No 396/2005. The Authority assessed the applications and concluded that the submitted data were sufficient to set new MRLs for sweet peppers/bell peppers, kales, chicory roots and honey that were safe for consumers[15, 16]. 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. When assessing the data submitted on escaroles, the Authority identified a risk for consumers concerning the proposed (higher) MRL, while it confirmed that the current MRL is safe for consumers. It is therefore appropriate to maintain its MRL at the existing level. Regarding witloofs/Belgian endives, the Authority concluded that the data provided was insufficient to derive a new MRL. It is therefore appropriate to maintain its MRL at the existing level which is the product specific LOD.

(19) The Commission consulted the European Union reference laboratories as regards the need to adapt certain LODs. Those laboratories proposed product specific LOD that are analytically achievable for all products.

(20) 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.

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

(22) In order to allow for the normal marketing, processing and consumption of products, this Regulation should provide for a transitional measure for products which have been placed on the market in the Union before the modification of the MRLs and for which information shows that a high level of consumer protection is maintained.

(23) 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.

(24) 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

Annex II to Regulation (EC) No 396/2005 is amended in accordance with the Annex to this Regulation.

[16] Modification of the existing maximum residue level for trifloxystrobin in honey. EFSA Journal 2023;21(8):8189

Article 2

Regulation (EC) No 396/2005 as it stood before being amended by this Regulation shall continue to apply to products which were placed on the market in the Union before *[Office of Publications: please insert* date *6 months after date of entry into force of this Regulation*], except for the MRLs for deltamethrin on pears, potatoes and lettuces and for thiabendazole in papayas.

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 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