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To:	General Secretariat of the Council
No. Cion doc.:	D042689/16
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 cyazofamid, cycloxydim, difluoroacetic acid, fenoxycarb, flumetralin, fluopicolide, flupyradifurone, fluxapyroxad, kresoxim-methyl, mandestrobin, mepanipyrim, metalaxyl-M, pendimethalin and tefluthrin in or on certain products

Delegations will find attached document D042689/16.

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EUROPEAN
COMMISSION

Brussels, XXX
SANTE/12095/2015
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D042689/02
[…](2015) 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 cyazofamid, cycloxydim, difluoroacetic acid, fenoxycarb, flumetralin, fluopicolide, flupyradifurone, fluxapyroxad, kresoxim-methyl, mandestrobin, mepanipyrim, metalaxyl-M, pendimethalin and tefluthrin 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 cyazofamid, cycloxydim, difluoroacetic acid, fenoxycarb, flumetralin, fluopicolide, flupyradifurone, fluxapyroxad, kresoxim-methyl, mandestrobin, mepanipyrim, metalaxyl-M, pendimethalin and tefluthrin 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 16(1)(a) thereof,

Whereas:

(1) For cyazofamid, kresoxim-methyl, mepanipyrim and pendimethalin, maximum residue levels (MRLs) were set in Annex II to Regulation (EC) No 396/2005. For metalaxyl-M, MRLs were set in Annex II and Part B of Annex III to that Regulation. For cycloxydim, fenoxycarb, fluopicolide, fluxapyroxad and tefluthrin, MRLs were set in Part A of Annex III to that Regulation. For difluoroacetic acid, flumetralin, flupyradifurone and mandestrobin, no specific MRLs were set nor were those substances included in Annex IV to that Regulation, so the default value of 0.01 mg/kg laid down in Article 18(1)(b) thereof applies.

(2) In the context of a procedure for the authorisation of the use of a plant protection product containing the active substance cyazofamid on spring onions, globe artichokes, leeks and hops, an application was submitted in accordance with Article 6(1) of Regulation (EC) No 396/2005 for modification of the existing MRLs.

(3) As regards cycloxydim, such an application was submitted for raspberries, currants, beetroots, celeriacs, horseradishes, Jerusalem artichokes, parsnips, salsifies, swedes, aubergines, Brussels sprouts, head cabbages, Chinese cabbages, kales, escaroles, cress, land cress, rucola, red mustards, leaves/sprouts Brassica, spinaches, purslanes, beet leaves, lentils, linseed, poppy seed, rapeseeds, herbal infusions from roots and dry

[1] OJ L 70, 16.3.2005, p. 1.

horseradish.

As regards fenoxycarb, such an application was submitted for peaches, table olives and olives for oil production. As regards fluopicolide, such an application was submitted for valerian. As regards fluxapyroxad, such an application was submitted for grapes and potatoes. As regards kresoxim-methyl, such an application was submitted for leeks. As regards mepanipyrim, such an application was submitted for blackberries, raspberries and peppers. As regards metalaxyl-M, such an application was submitted for gooseberries. As regards pendimethalin, such an application was submitted for lettuce. As regards tefluthrin, such an application was submitted for beetroots, celeriacs, radishes, swedes, turnips, garlic, onions, shallots, herbal infusions from roots, root and rhizome spices, sugar beet and chicory roots.

(4) In accordance with Article 8 of Regulation (EC) No 396/2005, those applications were evaluated by the Member States concerned and the evaluation reports were forwarded to the Commission.

(5) The European Food Safety Authority, hereinafter 'the Authority', assessed the applications and the evaluation reports, examining in particular the risks to the consumer and, where relevant, to animals and gave reasoned opinions on the proposed MRLs[2]. It forwarded those opinions to the Commission and the Member States and made them available to the public.

(6) The Authority concluded in its reasoned opinions that, as regards the use of cyazofamid on spring onions, globe artichokes and leeks, a risk to the consumer cannot be excluded. As regards the use of cycloxydim on cress, land cress, rucola, red mustards, leaves/sprouts Brassica, lentils, linseed, poppy seed, the submitted data were not sufficient to set new MRLs. The existing MRLs should therefore be kept.

[2] EFSA scientific reports available online: http://www.efsa.europa.eu:
Reasoned opinion on the modification of maximum residue levels for cyazofamid in hops, globe artichokes, leeks and spring/green onions and Welsh onions. EFSA Journal 2015;13(8):4204.
Reasoned opinion on the modification of the existing MRLs for cycloxydim in various crops. EFSA Journal 2015;13(9):4219 [30 pp.].
Reasoned opinion on the modification of the existing maximum residue levels for fenoxycarb in peaches and olives. EFSA Journal 2015;13(7):4202 [21 pp.].
Reasoned opinion on the modification of the existing maximum residue level for fluopicolide in valerian. EFSA Journal 2015;13(9):4217 [24 pp.].
Reasoned opinion on the modification of the existing maximum residue levels for fluxapyroxad in grapes and potatoes. EFSA Journal 2015;13(9):4223 [25 pp.].
Reasoned opinion on the modification of the existing maximum residue level for kresoxim-methyl in leeks. EFSA Journal 2015;13(8):4215 [18 pp.].
Reasoned opinion on the modification of the existing maximum residue levels for mepanipyrim in blackberries, raspberries and peppers. EFSA Journal 2015;13(9):4218 [19 pp.].
Reasoned opinion on the modification of the existing maximum residue level for metalaxyl-M in gooseberries. EFSA Journal 2015;13(7):4179 [18 pp.].
Reasoned opinion on the modification of the existing maximum residue level for pendimethalin in lettuce. EFSA Journal 2015;13(9):4249 [18 pp.].
Reasoned opinion on the setting of maximum residue levels for tefluthrin in various crops. EFSA Journal 2015;13(7):4196 [24 pp.].

(7) As regards all other applications, 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.

(8) It took into account the most recent information on the toxicological properties of the substances. Neither the lifetime exposure to these substances via consumption of all food products that may contain them, 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 or the acute reference dose is exceeded.

(9) For flumetralin, flupyradifurone and mandestrobin, the Authority submitted conclusions on the peer review of the pesticide risk assessment of those active substances[3]. In that framework, it recommended to set MRLs covering the representative uses according to good agricultural practices in the Union.

(10) As regards flupyradifurone, the Authority recommends setting temporary MRLs for several products due to the persistence of the active substance in soil. It concluded that the relevant component of the residues identified in rotational crops and products of animal origin was the metabolite difluoroacetic acid (DFA). MRLs therefore need to be set for both DFA and its parent coumpound flupyradifurone. For rotational crops and products of animal origin, the Authority requested additional rotational crop field studies. Those MRLs will be reviewed; the review will take into account the information available within two years from the publication of this Regulation. The Commission consulted the European Union reference laboratories on the appropriate limits of determination.

(11) 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.

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

(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:

[3] Conclusion on the peer review of the pesticide risk assessment of the active substance flumetralin. EFSA Journal 2014;12(12):3912 [62 pp.].
Conclusion on the peer review of the pesticide risk assessment of the active substance flupyradifurone. EFSA Journal 2015;13(2):4020 [101 pp.].
Conclusion on the peer review of the pesticide risk assessment of the active substance mandestrobin. EFSA Journal 2015;13(5):4100 [72 pp.].

Article 1

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

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union.*

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