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Subject:	COMMISSION REGULATION (EU) .../... of XXX amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for benzovindiflupyr, chlorantraniliprole, deltamethrin, ethofumesate, haloxyfop, Mild Pepino Mosaic Virus isolate VC1, Mild Pepino Mosaic Virus isolate VX1, oxathiapiprolin, penthiopyrad, pyraclostrobin, spirotetramat, sunflower oil, tolclofos-methyl and trinexapac in or on certain products
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Delegations will find attached document D049578/02.

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Brussels, **XXX**
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D049578/02
[...] (2017) **XXX** draft

COMMISSION REGULATION (EU) .../...

of **XXX**

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(Text with EEA relevance)

COMMISSION REGULATION (EU) .../...

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amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for benzovindiflupyr, chlorantraniliprole, deltamethrin, ethofumesate, haloxyfop, Mild Pepino Mosaic Virus isolate VC1, Mild Pepino Mosaic Virus isolate VX1, oxathiapiprolin, penthiopyrad, pyraclostrobin, spirotetramat, sunflower oil, tolclofos-methyl and trinexapac 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/EEC¹, and in particular Article 5(1) and Article 14(1)(a) thereof,

Whereas:

- (1) For benzovindiflupyr, deltamethrin, ethofumesate, haloxyfop, pyraclostrobin, tolclofos-methyl and trinexapac, maximum residue levels (MRLs) were set in Annex II to Regulation (EC) No 396/2005. For chlorantraniliprole, penthiopyrad and spirotetramat, MRLs were set in Part A of Annex III to that Regulation. For Mild Pepino Mosaic Virus isolate VC1, Mild Pepino Mosaic Virus isolate VX1, oxathiapiprolin and sunflower oil, 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 deltamethrin on celeries, Florence fennels and rhubarbs, 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 haloxyfop, such an application was submitted for parsley roots and leeks. As regards penthiopyrad, such an application was submitted for apricots, peaches, barley and oat. As regards pyraclostrobin, such an application was submitted for celeriacs, spinaches, chards/beet leaves, witloofs, beans and peas with pods, peas without pods, celeries and Florence fennels. As regards spirotetramat, such an application was submitted for pomegranates, "other root and tuber vegetables" and

¹ OJ L 70, 16.3.2005, p. 1.

chicory roots. As regards tolclofos-methyl, such an application was submitted for potatoes.

- (4) In accordance with Article 6(2) and (4) of Regulation (EC) No 396/2005 an application was submitted for benzovindiflupyr used on pome fruits, wine grapes, potatoes, "tropical root and tuber vegetables", Jerusalem artichokes, solanacea, cucurbits, pulses, linseeds, poppy seeds, rapeseeds, mustard seeds, cotton seeds, gold of pleasure seeds, barley, maize, oat, rye, wheat, ginger, turmeric and occurring in liver of ruminants and trinexapac used on poppy seed. The applicants claim that the authorised uses of those substances on such crops in North America and Australia 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.
- (5) In accordance with Article 53 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council², on 27 June 2016 the United Kingdom informed the Commission that it has authorised the placing on the market of a plant protection product containing the active substance chlorantraniliprole to be used on hops, due to an unexpected outbreak of Lepidoptera species. Such authorisation appeared a necessary measure, because the outbreak of Lepidoptera species could not be contained by any other reasonable means. The United Kingdom has also notified the authorisation to the other Member States, the Commission and the Authority in accordance with Article 18(4) of Regulation (EC) No 396/2005 with a view to setting a temporary MRL for hops.
- (6) 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.
- (7) 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 MRLs³. It forwarded those opinions to the applicants, the Commission and the Member States and made them available to the public.

² Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

³ EFSA scientific reports available online: <http://www.efsa.europa.eu>:
Reasoned opinion on the setting of import tolerances for benzovindiflupyr in various plant and animal origin commodities. EFSA Journal 2016;14(12):4644 [30 pp.].
Reasoned opinion on the setting of a temporary maximum residue level for chlorantraniliprole in hops. EFSA Journal 2016;14(11):4638 [16 pp.].
Reasoned opinion on the modification of the existing maximum residue levels for deltamethrin in celery, Florence fennel and rhubarb. EFSA Journal 2017;15(1):4683 [24 pp.].
Reasoned opinion on the modification of MRLs for haloxyfop-P in parsley root and leek. EFSA Journal 2016;14(10):4608 [13 pp.].
Reasoned opinion on the modification of the existing maximum residue levels for penthiopyrad in stone fruits and cereals. EFSA Journal 2016;14(12):4648 [19 pp.].
Reasoned opinion on the modification of the existing maximum residue levels for pyraclostrobin in various crops. EFSA Journal 2017;15(1):4686 [22 pp.].
Reasoned opinion on the modification of the existing maximum residue level for tolclofos-methyl in potatoes. EFSA Journal 2017;15(2):4730 [25 pp.].
Reasoned opinion on the setting of import tolerance for trinexapac in poppy seed. EFSA Journal 2016;14(11):4636 [15 pp.].

- (8) The Authority concluded in its reasoned opinion on benzovindiflupyr that, as regards its use on cucurbits with inedible peel, the submitted data were not sufficient to set new MRLs. The existing MRLs should therefore be kept.
- (9) As regards the use of chlorantraniliprole on hops, the Authority proposed three different MRLs for that product, to be considered by the risk managers. As there is no risk to consumers, the MRL for that product should be set in Annex III to Regulation (EC) No 396/2005 at 10 mg/kg, which is derived by scaling down the residue trials by a factor of 3, considering that they were overdosed in terms of number of applications and application rate. This MRL should be set as temporary valid until 31 December 2020.
- (10) 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. 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 products showed that there is a risk that the acceptable daily intake or the acute reference dose is exceeded.
- (11) For ethofumesate, Mild Pepino Mosaic Virus isolate VC1, Mild Pepino Mosaic Virus isolate VX1 and oxathiapiprolin, the Authority submitted conclusions on the peer review of the pesticide risk assessment of those active substances⁴.
- (12) For ethofumesate, the Authority recommended setting MRLs for beetroots, sugar beet roots and chards. For Mild Pepino Mosaic Virus isolate VC1 and Mild Pepino Mosaic Virus isolate VX1, it recommended including those substances in Annex IV to Regulation (EC) No 396/2005. For oxathiapiprolin, it recommended setting MRLs for table grapes, potatoes, tomatoes, aubergines, cucurbits with edible peel, melons, lettuces and grape vine leaves. In accordance with the existing Union guidelines on extrapolation of MRLs, it is appropriate to set the MRL for table grapes also for wine grapes.
- (13) The Commission consulted the European Union reference laboratories on the appropriate limits of determination. As regards oxathiapiprolin, those laboratories concluded that for certain commodities technical development requires the setting of specific limits of determination.

Reasoned opinion on the setting of maximum residue levels for spirotetramat in pomegranates and various vegetables. EFSA Journal 2017;15(1):4684. [22 pp.].

⁴ Conclusion on the peer review of the pesticide risk assessment of the active substance ethofumesate. EFSA Journal 2016;14(1):4374 [141 pp.].

Conclusion on the peer review of the pesticide risk assessment of the active substance Mild Pepino mosaic virus isolate VC1. EFSA Journal 2016;14(12):4651 [23 pp.].

Conclusion on the peer review of the pesticide risk assessment of the active substance Mild Pepino mosaic virus isolate VX1. EFSA Journal 2016;14(12):4650 [22 pp.].

Conclusion on the peer review of the pesticide risk assessment of the active substance oxathiapiprolin. EFSA Journal 2016;14(7):4504 [89 pp.].

- (14) Sunflower oil is approved as a basic substance by Commission Implementing Regulation (EU) 2016/1978⁵. The Commission considers that the inclusion of that substance in Annex IV to Regulation (EC) No 396/2005 is appropriate.
- (15) Based on the reasoned opinions and the conclusions 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.
- (16) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (17) 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 IV 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

⁵ Commission Implementing Regulation (EU) 2016/1978 of 11 November 2016 approving the basic substance sunflower oil in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 305, 12.11.2016, p. 23).