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To:	General Secretariat of the Council
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Subject:	COMMISSION REGULATION (EU) .../... of XXX amending Annexes II and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for aclonifen, boscalid, cow milk, etofenprox, ferric pyrophosphate, L-cysteine, lambda-cyhalothrin, maleic hydrazide, mefentrifluconazole, sodium 5-nitroguaiacolate, sodium o-nitrophenolate, sodium p-nitrophenolate and triclopyr in or on certain products

Delegations will find attached document D068961/04.

Encl.: D068961/04



Brussels, **XXX**
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[...](2020) **XXX** draft

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

of **XXX**

amending Annexes II and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for aconifen, boscalid, cow milk, etofenprox, ferric pyrophosphate, L-cysteine, lambda-cyhalothrin, maleic hydrazide, mefentrifluconazole, sodium 5-nitroguaiacolate, sodium o-nitrophenolate, sodium p-nitrophenolate and triclopyr in or on certain products

(Text with EEA relevance)

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

of **XXX**

amending Annexes II and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for aclonifen, boscalid, cow milk, etofenprox, ferric pyrophosphate, L-cysteine, lambda-cyhalothrin, maleic hydrazide, mefentrifluconazole, sodium 5-nitroguaiacolate, sodium o-nitrophenolate, sodium p-nitrophenolate and triclopyr 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 aclonifen, boscalid, etofenprox, lambda-cyhalothrin, maleic hydrazide, mefentrifluconazole, sodium 5-nitroguaiacolate, sodium o-nitrophenolate, sodium p-nitrophenolate and triclopyr, maximum residue levels ('MRLs') were set in Annex II to Regulation (EC) No 396/2005. For ferric pyrophosphate, L-cysteine and cow milk, 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 aclonifen on sweet peppers/bell peppers, herbal infusions and spices, 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 boscalid, such an application was submitted for pomegranates, honey and other apiculture products following the use on rapeseed. As regards etofenprox, such an application was submitted for plums. As regards lambda-cyhalothrin, such an application was submitted for seed and fruit spices. As regards maleic hydrazide, such an application was submitted for chicory roots. As regards mefentrifluconazole, such an application was submitted for pome fruits, apricots, cherries, peaches, plums, grapes, potatoes, sweet corn, maize, sunflower seeds, rapeseeds/canola seeds and sugar beet roots. As regards sodium 5-nitroguaiacolate, sodium o-nitrophenolate, sodium p-nitrophenolate, such an application was submitted for grapes, strawberries, raspberries, currants, maize/corn, rice, wheat and hops. As regards triclopyr, such an application was submitted for kiwi fruits.

¹ OJ L 70, 16.3.2005, p. 1.

- (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 ('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 MRLs². It forwarded those opinions to the applicants, the Commission and the Member States and made them available to the public.
- (6) As regards all 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.
- (7) As regards aclonifen, the applicant also submitted information previously unavailable during the review conducted in accordance with Article 12 of Regulation (EC) No 396/2005. That information concerns residue trials and analytical methods.
- (8) As regards sodium 5-nitroguaiacolate, sodium o-nitrophenolate, sodium p-nitrophenolate, the applicant also submitted such an information on analytical methods.
- (9) As regards boscalid, the applicant made the reference standard for 2-chloro-N-(4'-chloro-5-hydroxybiphenyl-2-yl)nicotinamide commercially available.
- (10) As regards maleic hydrazide, the Authority assessed an application with a view of setting an MRL for carrots in the framework of the conclusion on the peer review of the pesticide risk assessment of the active substance³. In accordance with the existing

² EFSA scientific reports available online: <http://www.efsa.europa.eu>:

Reasoned opinion on the evaluation of confirmatory data following the Article 12 MRL review for aclonifen. EFSA Journal 2020;18(5):6102.

Reasoned opinion on the modification of the existing maximum residue level for boscalid in honey. EFSA Journal 2019;17(11):5897.

Reasoned opinion on the modification of the existing maximum residue level for boscalid in pomegranates. EFSA Journal 2020;18(9):6236.

Reasoned opinion on the modification of the existing maximum residue level for etofenprox in plums. EFSA Journal 2020;18(7):6192.

Reasoned opinion on the modification of the existing maximum residue levels for lambda- cyhalothrin in seed and fruit spices. EFSA Journal 2020;18(6):6110.

Reasoned opinion on the modification of the existing maximum residue levels for mefenfluoconazole in various crops. EFSA Journal 2020;18(7):6193.

Reasoned opinion on the evaluation of confirmatory data following the Article 12 MRL review for sodium 5- nitroguaiacolate, sodium o- nitrophenolate and sodium p- nitrophenolate (sodium nitrocompounds). EFSA Journal 2020;18(3):6060.

Reasoned opinion on the modification of the existing maximum residue level for triclopyr in kiwi. EFSA Journal 2020;18(7):6191.

³ Conclusion on the peer review of the pesticide risk assessment of the active substance maleic hydrazide. EFSA Journal 2016;14(6):4492.

Union guidelines on extrapolation of MRLs, it is appropriate to apply the MRL for carrots also to chicory roots.

- (11) As regards mefentrifluconazole, the Authority recommended increasing the MRLs for swine liver, bovine kidney and milk from cattle, sheep and goat, following the use of the substance on feed items.
- (12) In the context of the approval of the active substance ferric pyrophosphate, an MRL application was included in the summary dossier in accordance with Article 8(1)(g) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council⁴. That application was evaluated by the Member State concerned in accordance with Article 11(2) of that Regulation. The Authority assessed the application and delivered a conclusion on the peer review of the pesticide risk assessment of the active substance, where it concluded that the inclusion of ferric pyrophosphate in Annex IV to Regulation (EC) No 396/2005 is appropriate⁵.
- (13) L-cysteine and cow milk have been approved as basic substances by Commission Implementing Regulation (EU) 2020/642⁶ and Commission Implementing Regulation (EU) 2020/1004⁷, respectively. The conditions of use of those substances are not expected to lead to the presence of residues in food or feed commodities that may pose a risk to the consumer. It is therefore appropriate to include those substances in Annex IV to Regulation (EC) No 396/2005.
- (14) Based on the reasoned opinions and the conclusions of the Authority and taking into account the factors relevant to the matter under consideration, the respective modifications to the MRLs fulfil the requirements of Article 14(2) of Regulation (EC) No 396/2005.
- (15) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (16) 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 IV to Regulation (EC) No 396/2005 are amended in accordance with the Annex to this Regulation.

⁴ 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).

⁵ Conclusion on the peer review of the pesticide risk assessment of the active substance ferric pyrophosphate. EFSA Journal 2020;18(1):5986.

⁶ Commission Implementing Regulation (EU) 2020/642 of 12 May 2020 approving the basic substance L-cysteine 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 150, 13.5.2020, p. 134).

⁷ Commission Implementing Regulation (EU) 2020/1004 of 9 July 2020 approving the basic substance cow milk 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 221, 10.7.2020, p. 133).

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
Ursula VON DER LEYEN