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To:	General Secretariat of the Council
No. Cion doc.:	D067461/05
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 1,4-diaminobutane, 1-methylcyclopropene, ammonium acetate, bifenazate, chlorantraniliprole, chlormequat, cyprodinil, limestone, mandipropamid, pepper, pyridaben, repellants: blood meal, seaweed extracts and trimethylamine hydrochloride in or on certain products

Delegations will find attached document D067461/05.

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

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 1,4-diaminobutane, 1-methylcyclopropene, ammonium acetate, bifentazate, chlorantraniliprole, chloromequat, cyprodinil, limestone, mandipropamid, pepper, pyridaben, repellants: blood meal, seaweed extracts and trimethylamine hydrochloride in or on certain products

(Text with EEA relevance)

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 1,4-diaminobutane, 1-methylcyclopropene, ammonium acetate, bifenazate, chlorantraniliprole, chlormequat, cyprodinil, limestone, mandipropamid, pepper, pyridaben, repellants: blood meal, seaweed extracts and trimethylamine hydrochloride 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 1-methylcyclopropene, bifenazate, cyprodinil, mandipropamid and pyridaben, maximum residue levels ('MRLs') were set in Annex II to Regulation (EC) No 396/2005. For chlorantraniliprole and chlormequat, MRLs were set in Part A of Annex III to that Regulation. 1,4-diaminobutane, ammonium acetate, limestone, pepper, repellants: blood meal, seaweed extracts and trimethylamine hydrochloride are included in Annex IV to that Regulation.
- (2) In the context of a procedure for the authorisation of the use of a plant protection product containing the active substance 1-methylcyclopropene on apples and bananas, 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 bifenazate, such an application was submitted for elderberries. As regards chlormequat, such an application was submitted for barley. As regards cyprodinil, such an application was submitted for rhubarbs. As regards mandipropamid, such an application was submitted for kohlrabies and "herbs and edible flowers". As regards pyridaben, such an application was submitted for sweet peppers/bell peppers.
- (4) In accordance with Article 6(2) and (4) of Regulation (EC) No 396/2005 applications for import tolerances were submitted for chlorantraniliprole used in Malaysia on oil palms kernels and oil palms fruits, and pyridaben used in the United States on tree nuts. The applicants state that the authorised uses of those substances on such crops in those countries 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.

¹ OJ L 70, 16.3.2005, p. 1.

- (5) 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.
- (6) 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.
- (7) As regards 1-methylcyclopropene, the applicant 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 metabolism studies.
- (8) As regards chlormequat, the Authority recommended increasing the MRLs for certain products of animal origin following the use of the substance on barley.
- (9) 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.
- (10) 1,4-diaminobutane, ammonium acetate, limestone, pepper, repellants: blood meal, seaweed extracts and trimethylamine hydrochloride³ were temporarily included in Annex IV to Regulation (EC) No 396/2005 pending the finalisation of their evaluation under Directive 91/414/EEC⁴ or Regulation (EC) No 1107/2009. The Authority evaluated those substances and concluded that it is appropriate to retain limestone, pepper, repellants: blood meal, seaweed extracts and trimethylamine hydrochloride in

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 1-methylcyclopropene. EFSA Journal 2020;18(1):5963.

Reasoned opinion on the modification of the existing maximum residue level for bifenazate in elderberries. EFSA Journal 2019;17(11):5878.

Reasoned opinion on the setting of import tolerances for chlorantraniliprole in oil palms fruits and oil palms kernels. EFSA Journal 2019;17(11):5877.

Reasoned opinion on the modification of the existing maximum residue levels for chlormequat in barley and animal commodities. EFSA Journal 2020;18(1):5982.

Reasoned opinion on the modification of the existing maximum residue level for cyprodinil in rhubarbs. EFSA Journal 2019;17(9):5813.

Reasoned opinion on the modification of the existing maximum residue levels for mandipropamid in kohlrabies and herbs and edible flowers. EFSA Journal 2020;18(1):5958.

Reasoned opinion on the modification of the existing maximum residue level for pyridaben in sweet pepper/bell pepper and setting of an import tolerance in tree nuts. EFSA Journal 2020;18(2):6035.

³ Commission Regulation (EC) No 839/2008 of 31 July 2008 amending Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards Annexes II, III and IV on maximum residue levels of pesticides in or on certain products (OJ L 234, 30.8.2008, p. 1).

⁴ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p.1).

Annex IV to Regulation (EC) No 396/2005 permanently.⁵ ⁶ As regards 1,4-diaminobutane and ammonium acetate, it concluded that further consideration by risk managers was required. From a risk management perspective, it is appropriate to retain these substances in Annex IV to Regulation (EC) No 396/2005 permanently in view of their natural occurrence in the environment.

- (11) Based on the reasoned opinions, the statement and the conclusion 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.
- (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:

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
Ursula VON DER LEYEN

⁵ Statement on pesticide active substances that do not require a review of the existing maximum residue levels under Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2019;17(12):5954.

⁶ Conclusion on the peer review of the pesticide risk assessment of the active substance blood meal. EFSA Journal 2020;18(2):6006.