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To:	General Secretariat of the Council
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Subject:	COMMISSION REGULATION (EU) .../... of XXX amending Annexes II and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for chlorpyrifos and chlorpyrifos-methyl in or on certain products

Delegations will find attached document D064960/03.

Encl.: D064960/03



Brussels, **XXX**
SANTE/12380/2019
(POOL/E4/2019/12380/12380-EN.docx)
D064960/03
[...](2020) **XXX** draft

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

of **XXX**

amending Annexes II and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for chlorpyrifos and chlorpyrifos-methyl in or on certain products

(Text with EEA relevance)

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

of **XXX**

amending Annexes II and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for chlorpyrifos and chlorpyrifos-methyl 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 14(1)(a) and Article 18(1)(b) thereof,

Whereas:

- (1) For chlorpyrifos and chlorpyrifos-methyl, maximum residue levels (MRLs) were set in Annex II to Regulation (EC) No 396/2005.
- (2) The approvals of the active substances chlorpyrifos and chlorpyrifos-methyl were not renewed by Commission Implementing Regulation (EU) 2020/18² and Commission Implementing Regulation (EU) 2020/17³, respectively.
- (3) All existing authorisations for plant protection products containing chlorpyrifos and chlorpyrifos-methyl have been revoked. It is therefore appropriate to delete the MRLs set out for these substances in Annex II to Regulation (EC) No 396/2005 in accordance with Article 17 of Regulation (EC) No 396/2005 in conjunction with Article 14(1)(a) thereof.
- (4) The Commission consulted the European Union reference laboratories as regards the need to adapt certain limits of determination (LODs) for the two substances. Those laboratories concluded that technical development permits the setting of LODs at 0.01 mg/kg for chlorpyrifos and chlorpyrifos-methyl in all products. Those default values should be listed in Annex V in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005.

¹ OJ L 70, 16.3.2005, p. 1.

² Commission Implementing Regulation (EU) 2020/18 of 10 January 2020 concerning the non-renewal of approval of the active substance chlorpyrifos, 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 Commission Implementing Regulation (EU) No 540/2011 (OJ L 7, 13.1.2020, p. 14).

³ Commission Implementing Regulation (EU) 2020/17 of 10 January 2020 concerning the non-renewal of approval of the active substance chlorpyrifos-methyl, 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 Commission Implementing Regulation (EU) No 540/2011 (OJ L 7, 13.1.2020, p. 11).

- (5) In the context of the non-renewal of the approval of chlorpyrifos and chlorpyrifos-methyl, the European Food Safety Authority ('the Authority') published statements on the human health assessment for those active substances⁴ ⁵. In those statements the Authority confirmed developmental neurotoxicity of both active substances in children and could not exclude a genotoxic potential due to the exposure to residues of the two substances in food.
- (6) 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.
- (7) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (8) 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.
- (9) 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 V 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*.

It shall apply from [*Office of Publication: please insert date 3 months after entry into force*].

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

⁴ Statement on the available outcomes of the human health assessment in the context of the pesticides peer review of the active substance chlorpyrifos. EFSA Journal 2019;17(5):5809.

⁵ Updated statement on the available outcomes of the human health assessment in the context of the pesticides peer review of the active substance chlorpyrifos-methyl. EFSA Journal 2019;17(11):5908.