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Delegations will find attached document D055857/02.

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[...](2018) **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
lambda-cyhalothrin 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 lambda-cyhalothrin 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 49(2) thereof,

Whereas:

- (1) For lambda-cyhalothrin maximum residue levels (MRLs) were set in Part B of Annex III to Regulation (EC) No 396/2005.
- (2) For lambda-cyhalothrin the European Food Safety Authority, (the Authority), submitted a reasoned opinion on the review of the existing MRLs in accordance with Article 12 of Regulation (EC) No 396/2005 in conjunction with Article 12(1) thereof². The Authority subsequently submitted a conclusion on the peer review of lambda-cyhalothrin³, in which the analytical endpoints of the substance were updated. In accordance with Article 43 of Regulation (EC) No 396/2005 the Commission requested the Authority to revise the assessment of lambda-cyhalothrin taking into account the new endpoints. On 2 December 2015, the Authority submitted a reasoned opinion on the revision of the review of the existing MRLs for lambda-cyhalothrin⁴. The residue definition of lambda-cyhalothrin covers also the substance gamma-cyhalothrin. The Commission asked the Authority, in accordance with Article 43 of Regulation (EC) No 396/2005, to review the MRLs for lambda-cyhalothrin, taking into account also the possible uses of gamma-cyhalothrin. On 26 July 2017 the Authority submitted a reasoned opinion on the focused review on the existing MRLs for lambda-cyhalothrin in light of the unspecific residue definition⁵.

¹ OJ L 070, 16.3.2005, p. 1.

² European Food Safety Authority, 2014. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for lambda-cyhalothrin according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2014;12(1):3546.

³ European Food Safety Authority, 2014. Conclusion on the peer review of the pesticide risk assessment of the active substance lambda-cyhalothrin. EFSA Journal 2014;12(5):3677.

⁴ EFSA (European Food Safety Authority), 2015. Reasoned opinion on the revision of the review of the existing maximum residue levels for lambda-cyhalothrin. EFSA Journal 2015;13(12):4324.

⁵ EFSA (European Food Safety Authority), 2017. Reasoned opinion on the focused review of the existing maximum residue levels for lambda-cyhalothrin in light of the unspecific residue definition and the

- (3) The Authority proposed to change the residue definition for all products. It identified a risk for consumers concerning the MRLs for kale and rice grain. It is therefore appropriate to lower these MRLs. The Authority concluded that concerning the MRLs of all products some information was not available and that further consideration by risk managers was required. As there is no risk for consumers, the MRLs for those products should be set in Annex II to Regulation (EC) No 396/2005 at the existing level or the level identified by the Authority. The Authority also concluded that concerning the MRLs for sunflower seeds, soya beans and tea no information was available and that further consideration by risk managers was required. The MRLs for these products should be set at the specific limit of determination or at the default MRL as set out in Article 18(1)(b) of Regulation (EC) No 396/2005.
- (4) As regards products on which the use of the plant protection product concerned is not authorised, and for which no import tolerances or Codex maximum residue limits (CXLs) exist, MRLs should be set at the specific limit of determination or the default MRL should apply, as provided for in Article 18(1)(b) of Regulation (EC) No 396/2005.
- (5) The Commission consulted the European Union reference laboratories for residues of pesticides as regards the need to adapt certain limits of determination. As regards several substances, those laboratories concluded that for certain commodities technical development requires the setting of specific limits of determination.
- (6) 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.
- (7) 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.
- (8) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (9) In order to allow for the normal marketing, processing and consumption of products, this Regulation should provide for a transitional arrangement for products which have been produced before the modification of the MRLs and for which information shows that a high level of consumer protection is maintained.
- (10) 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.
- (11) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

existing good agricultural practices for the substance gamma-cyhalothrin. EFSA journal 2017;15(7):4930.

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

As regards the active substance lambda-cyhalothrin in and on all products, except kale and rice grain, Regulation (EC) No 396/2005 as it stood before being amended by this Regulation shall continue to apply to products which were produced in the EU or imported into the EU before [*Office of Publications please insert date of application of this Regulation*].

Article 3

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 6 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
Jean-Claude JUNCKER