Brussels, XXX
SANTE/10776/2021 Rev. 1
[…](2021) 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 1,4-dimethylnaphthalene, 8-hydroxyquinoline, pinoxaden and valifenalate 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 1,4-dimethylnaphthalene, 8-hydroxyquinoline, pinoxaden and valifenalate 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/EEC[1], and in particular Article 14(1)(a) and Article 49(2) thereof,

Whereas:

(1) For 1,4-dimethylnaphthalene, 8-hydroxyquinoline, pinoxaden and valifenalate, maximum residue levels (MRLs) were set in Part A of Annex III to Regulation (EC) No 396/2005.

(2) For 1,4-dimethylnaphthalene the European Food Safety Authority ("the Authority"), submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005[2]. The Authority noted that, as 1,4-dimethylnaphthalene could naturally occur in some plant compounds, setting MRLs for commodities of plant origin at the Limit of Determination (LOD) may be inappropriate. Based on currently available monitoring data temporary MRLs for commodities of plant origin (with the exception of potatoes) are proposed, pending the submission of further monitoring data to confirm them. The Authority proposed to change the residue definition for commodities of animal origin. It concluded that concerning the MRLs for potatoes and products of animal origin, some information was not available and that further consideration by risk managers was required. All above mentioned MRLs will be reviewed; the review will take into account the information available within two years from the publication of this Regulation. As there is no risk for consumers, MRLs should be set in Annex II to Regulation (EC) No 396/2005 at the existing level or the level identified by the Authority.

(3) For 8-hydroxyquinoline the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005[3]. The

[1] OJ L 070, 16.3.2005, p. 1.

[2] European Food Safety Authority; Reasoned Opinion on the review of the existing maximum residue levels for 1,4-dimethylnaphthalene according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2021;19(5):6597.

[3] European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for 8-hydroxyquinoline according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2021;19(4):6566.

Authority concluded that due to missing data the consumer risk assessment performed is indicative and therefore proposed maintaining all MRLs to the LOD. Concerning the MRL for strawberries, the Authority concluded that some information was not available and that further consideration by risk managers was required. This MRL will be reviewed; the review will take into account the information available within two years from the publication of this Regulation. As there is no risk for consumers, MRLs should be set in Annex II to Regulation (EC) No 396/2005 at the existing level or the level identified by the Authority.

(4) For pinoxaden the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005[4]. It proposed to change the residue definition. It recommended lowering the MRLs for barley, rye, and wheat. The Authority concluded that concerning the MRLs for products of animal origin, some information was not available and that further consideration by risk managers was required. The MRLs for products of animal origin will be reviewed; the review will take into account the information available within two years from the publication of this Regulation. As there is no risk for consumers, MRLs should be set in Annex II to Regulation (EC) No 396/2005 at the existing level or the level identified by the Authority.

(5) For valifenalate the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005[5]. It proposed to change the residue definition for commodities of animal origin. It recommended lowering MRLs for onions, shallots, and aubergines/eggplants. For other products, it recommended raising or keeping the existing MRLs. Concerning the MRL for tomatoes, the Authority concluded that some information was not available and that further consideration by risk managers was required. This MRL will be reviewed; the review will take into account the information available within two years from the publication of this Regulation. As there is no risk for consumers, this MRL should be set in Annex II to Regulation (EC) No 396/2005 at the existing level or the level identified by the Authority.

(6) 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 LOD or the default MRL should apply, as provided for in Article 18(1)(b) of Regulation (EC) No 396/2005.

(7) 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.

(8) 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.

(9) 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.

(10) Regulation (EC) No 396/2005 should therefore be amended accordingly.

---

[4] European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for pinoxaden according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2021;19(3):6503.

[5] European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for valifenalate according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2021;19(5):6591.

(11) 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.

(12) 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.

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

Article 2

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 Union or imported into the Union before [*Office of Publication: please insert date 6 months after entry into force*].

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
Ursula VON DER LEYEN