Commission Regulation (EU) 2019/50 of 11 January 2019 amending Annexes II, III, IV and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for chlorantraniliprole, clomazone, cyclaniliprole, fenazaquin, fenpicoxamid, fluoxastrobin, lambda-cyhalothrin, mepiquat, onion oil, thiacloprid and valifenalate in or on certain products (Text with EEA relevance)

COMMISSION REGULATION (EU) 2019/50

of 11 January 2019

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(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 5(1), Article 14(1)(a) and Article 18(1)(b) thereof,

Whereas:

(1) For clomazone, fluoxastrobin, lambda-cyhalothrin, mepiquat and thiacloprid, maximum residue levels (MRLs) were set in Annex II to Regulation (EC) No 396/2005. For chlorantraniliprole, fenazaquin and valifenalate, MRLs were set in Part A of Annex III to that Regulation. For cyclaniliprole, fenpicoxamid and onion oil, 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) On 4 July 2009, Codex Alimentarius Commission adopted a Codex maximum residue limit (CXL) for lambda-cyhalothrin in rye[(2)].

(3) In accordance with Article 5(3) of Regulation (EC) No 178/2002 of the European Parliament and of the Council[(3)], where international standards exist or their completion is imminent, they are to be taken into consideration in the development or adaptation of food law, except where such standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives of food law or where there is a scientific justification, or where they would result in a different level of protection from the one determined as appropriate in the Union. Moreover, in accordance with point (e) of Article 13 of that Regulation, the Union is to promote

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consistency between international technical standards and food law while ensuring that the high level of protection adopted in the Union is not reduced.

(4) The CXL for lambda-cyhalothrin in rye is safe for consumers in the Union[4] and should therefore be included in Regulation (EC) No 396/2005 as MRL.

(5) In the context of a procedure for the authorisation of the use of a plant protection product containing the active substance clomazone on chamomile and plantains, an application was submitted in accordance with Article 6(1) of Regulation (EC) No 396/2005 for modification of the existing MRLs.

(6) As regards fluoxastrobin, such an application was submitted for garlic, rapeseed, linseeds, poppy seeds, mustard seeds and gold of pleasure seeds. As regards mepiquat, such an application was submitted for rapeseed, linseeds, poppy seeds, mustard seeds, gold of pleasure seeds, sunflower seeds, liver (from swine, sheep and goat), kidney (from swine), milks and eggs. As regards thiacloprid, such an application was submitted for borage seeds and radishes. As regards valifenalate, such an application was submitted for tomatoes, aubergines, lettuces, onions, shallots and garlic.

(7) In accordance with Article 6(2) and (4) of Regulation (EC) No 396/2005 applications were submitted for chlorantraniliprole and fenazaquin used in the United States on hops and almonds, respectively. The applicants claim that the authorised uses of those substances on such crops in the United States 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.

(8) 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.

(9) The European Food Safety Authority, hereinafter '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 MRLs[5]. It forwarded those opinions to the applicants, the Commission and the Member States and made them available to the public.

(10) As regards fluoxastrobin in garlic, the Authority assessed an application with a view of setting an MRL for onions and gave a reasoned opinion on the proposed MRL[6]. In accordance with the existing Union guidelines on extrapolation of MRLs, it is appropriate to set the MRL for onions also for garlic.

(11) 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.

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(12) For mepiquat temporary MRLs were set by Commission Regulation (EU) 2016/1003[(7)] for cultivated fungi until 31 December 2018 to address a cross-contamination that affected untreated cultivated fungi with straw lawfully treated with mepiquat. Member States and the Authority have submitted recent monitoring data showing that residues of mepiquat still occur at levels above the relevant limit of determination. It is therefore appropriate to extend the validity of the current MRL set at 0,09 mg/kg. The MRL will be reviewed; the review will take into account the information available within four years from the publication of this Regulation.

(13) As regards lambda-cyhalothrin, several MRLs were modified by Commission Regulation (EU) 2018/960[(8)]. That Regulation lowers the MRL for rye to the limit of determination, omitting the existing CXL for rye, as of 26 January 2019. In the interest of legal certainty, it is appropriate for the MRL provided for by this Regulation, to apply from the same date.

(14) In the context of the approval of the active substance fenpicoxamid, 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 Council[(9)]. Such 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 recommended setting MRLs covering the representative uses on rye and wheat according to Good Agricultural Practices (GAPs) in the Union and an import tolerance request for bananas from Panama[(10)].

(15) Onion oil is approved as basic substance by Commission Implementing Regulation (EU) 2018/1295[(11)]. The conditions of use of that substance 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 that substance in Annex IV to Regulation (EC) No 396/2005.

(16) The active substance cyclaniliprole was not approved by Commission Implementing Regulation (EU) 2017/357[(12)]. As no MRLs were set in Regulation (EC) No 396/2005, it is appropriate to include the substance in Annex V to that Regulation.

(17) Based on the reasoned opinions and the conclusion 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.

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

(19) 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:

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Article 1

Annexes II, III, IV 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 day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 January 2019. However, it shall apply from 26 January 2019 for the MRL for lambda-cyhalothrin in rye.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 11 January 2019.

For the Commission

The President

Jean-Claude JUNCKER

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ANNEX

Annexes II, III, IV and V to Regulation (EC) No 396/2005 are amended as follows:

(1) Annex II is amended as follows:

(a) the columns for clomazone, fluoxastrobin, lambda-cyhalothrin, mepiquat and thiacloprid are replaced by the following:

PESTICIDE RESIDUES AND
MAXIMUM RESIDUE LEVELS (MG/KG)

Code number	**Groups and examples of individual products to which the MRLs apply[b]**	**Clomazone**	**Fluoxastrobin (sum of fluoxastrobin and its Z-isomer) (R)**	**lambda-Cyhalothrin (F) (R)**	**Mepiquat (sum of mepiquat and its salts, expressed as mepiquat chloride)**	**Thiacloprid**
(1)	(2)	(3)	(4)	(5)	(6)	(7)
0100000	**FRUITS, FRESH or FROZEN; TREE NUTS**		0,01[a]			
0110000	**Citrus fruits**	0,01[a]		0,2 (+)	0,02[a]	0,01[a]
0110010	Grapefruits					
0110020	Oranges					
0110030	Lemons					
0110040	Limes					
0110050	Mandarins					
0110990	Others (2)					
0120000	**Tree nuts**	0,02[a]		0,01[a] (+)	0,05[a]	0,02[a]
0120010	Almonds					
0120020	Brazil nuts					
0120030	Cashew nuts					