Commission Regulation (EU) 2019/1791 of 17 October 2019 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-decanol, 2,4-D, ABE-IT 56, cyprodinil, dimethenamid, fatty alcohols, florpyrauxifen-benzyl, fludioxonil, fluopyram, mepiquat, pendimethalin, picolinafen, pyraflufen-ethyl, pyridaben, S-abscisic acid and trifloxystrobin in or on certain products (Text with EEA relevance)

COMMISSION REGULATION (EU) 2019/1791

of 17 October 2019

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-decanol, 2,4-D, ABE-IT 56, cyprodinil, dimethenamid, fatty alcohols, florpyrauxifen-benzyl, fludioxonil, fluopyram, mepiquat, pendimethalin, picolinafen, pyraflufen-ethyl, pyridaben, S-abscisic acid and trifloxystrobin 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 5(1), Article 14(1)(a) and Article 16(1)(a) thereof,

Whereas:

(1) For 2,4-D, cyprodinil, dimethenamid, fludioxonil, mepiquat, pendimethalin, picolinafen, pyraflufen-ethyl, pyridaben and trifloxystrobin, maximum residue levels (‘MRLs’) were set in Annex II to Regulation (EC) No 396/2005. For fluopyram, MRLs were set in Part A of Annex III to that Regulation. 1-decanol, fatty alcohols and S-abscisic acid were included in Annex IV to that Regulation. For ABE-IT 56 and florpyrauxifen-benzyl, 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) In the context of a procedure for the authorisation of the use of a plant protection product containing the active substance cyprodinil on Florence fennels, 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 dimethenamid-P, such an application was submitted for spring onions, lettuces, escarole and ‘herbs and edible flowers’. As regards fludioxonil, such an application was submitted for Florence fennels. As regards fluopyram, such an application was submitted for broccoli. As regards mepiquat, such an application was submitted for cultivated fungi. As regards pendimethalin, such an application

Changes to legislation: *There are outstanding changes not yet made to Commission Regulation (EU) 2019/1791. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

was submitted for strawberries, garlic, onions, shallots, tomatoes, peppers, aubergines, cucumbers, gherkins, courgettes, melons, pumpkins, watermelons, globe artichoke, leek and rape seed. As regards picolinafen, such an application was submitted for barley, oats, rye and wheat. As regards pyraflufen-ethyl, such an application was submitted for citrus fruits, tree nuts, pome fruits, stone fruits, grapes, currants, gooseberries, elderberries, table olives, potatoes, rapeseeds, cotton seeds, olives for oil production, barley, oat, rye and wheat. As regards pyridaben, such an application was submitted for tomatoes and aubergines. As regards trifloxystrobin, such an application was submitted for broccoli.

(4) In accordance with Article 6(2) and (4) of Regulation (EC) No 396/2005 an application for import tolerance was submitted for 2,4-D used in Canada and the United States on soyabeans. The applicant claims that the authorised uses of that substance on such crops in those countries lead to residues exceeding the MRL contained in Regulation (EC) No 396/2005 and that a higher MRL is necessary to avoid trade barriers for the importation of those crops.

(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 MRLs[(2)]. It forwarded those opinions to the applicants, the Commission and the Member States and made them available to the public.

(7) As regards 2,4-D, the applicant submitted information previously unavailable during the review conducted in accordance with Article 12 of Regulation (EC) No 396/2005. That information concerns a validated analytical method for high oil content matrices.

(8) As regards dimethenamid, the applicant submitted such an information on plant metabolism.

(9) As regards pendimethalin, the applicant submitted the missing residue trials.

(10) As regards picolinafen, the applicant submitted a validated analytical method for cereals and products of animal origin and the missing feeding study for ruminants.

(11) As regards pyraflufen-ethyl, the applicant submitted validated analytical methods for high water, dry, acid and fat matrices, the missing storage stability study for cereals and made the reference standard for pyraflufen commercially available.

(12) As regards all 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

***Changes to legislation:** There are outstanding changes not yet made to Commission Regulation (EU) 2019/1791. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

showed that there is a risk that the acceptable daily intake or the acute reference dose is exceeded.

(13) As regards mepiquat, mushroom growers submitted recent monitoring data specifically on oyster mushrooms showing that residues occur in those products at higher levels than the current temporary MRL set for cultivated fungi. Those residues result from a cross-contamination of cultivated fungi with straw lawfully treated with mepiquat. In the light of the Authority's conclusions on risk to consumers, the MRL for oyster mushrooms should be set at the level corresponding to the 95th percentile of all the sample results while maintaining the existing MRL for other cultivated fungi. That MRL will be reviewed; the review will take into account the information available by 31 December 2022.

(14) In the context of the approval of the active substance florpyrauxifen-benzyl, 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[(3)]. That 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 an MRL covering the representative use on rice according to Good Agricultural Practices (GAPs) in the Union[(4)].

(15) In the context of the approval of the active substance ABE-IT 56, the Authority concluded that the inclusion of that substance in Annex IV to Regulation (EC) No 396/2005 is appropriate[(5)].

(16) 1-decanol, fatty alcohols[(6)] and S-abscisic acid[(7)] were temporarily included in Annex IV to Regulation (EC) No 396/2005 pending the finalisation of their evaluation under Directive 91/414/EEC[(8)] or Regulation (EC) No 1107/2009. The Authority re-evaluated those substances and concluded that it is appropriate to retain them in Annex IV to Regulation (EC) No 396/2005 permanently[(9)].

(17) As regards pyridaben, several MRLs were modified by Commission Regulation (EU) 2019/90[(10)]. That Regulation lowers the MRLs for several products, including tomatoes and aubergines, to the limit of determination as of 13 August 2019. In the interest of legal certainty, it is appropriate for the MRLs for pyridaben, provided for by this Regulation, to apply from the same date.

(18) Based on the reasoned opinions and the conclusions 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.

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

(20) 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:

Changes to legislation: *There are outstanding changes not yet made to Commission Regulation (EU) 2019/1791. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

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*.

It shall however apply from 13 August 2019 for the MRLs for pyridaben.

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

Done at Brussels, 17 October 2019.

For the Commission

The President

Jean-Claude JUNCKER

***Changes to legislation:** There are outstanding changes not yet made to Commission Regulation (EU) 2019/1791. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

ANNEX

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

(1) Annex II is amended as follows:

(a) the columns for 2,4-D, cyprodinil, dimethenamid, fludioxonil, pendimethalin, picolinafen, pyraflufen-ethyl, pyridaben and trifloxystrobin 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 (a)**	**2,4-D (sum of 2,4-D, its salts, its esters and its conjugates, expressed as 2,4-D)**	**Cyprodinil (F) (R)**	**Dimethenamid including other mixtures of constituent isomers including dimethenamid-P (sum of isomers)**	**Fludioxonil (F) (R)**	**Pendimethalin (F)**	**Picolinafen**	**Pyraflufen-ethyl (Sum of pyraflufen-ethyl and pyraflufen, expressed as pyraflufen-ethyl)**	**Pyridaben (F) (R)**	**Trifloxystrobin (F) (R)**
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
0100000	**FRUITS, FRESH or FROZEN; TREE NUTS**			0,01[a]		0,05[a]	0,01[a]	0,02[a]		
0110000	1 **Citrus fruits**		0,02[a]		10				0,3	0,5
0110010	Grapefruits									
0110020	Oranges									
0110030	Lemons									
0110040	Limes									
0110050	Mandarins									
0110990	Others (2)									
0120000	0,2 **Tree nuts**								0,01[a]	0,02