

COMMISSION REGULATION (EU) 2021/1842**of 20 October 2021****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 flupyradifurone and difluoroacetic acid 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 flupyradifurone and difluoroacetic acid, maximum residue levels ('MRLs') were set in Part A of Annex III to Regulation (EC) No 396/2005.
- (2) In the context of a procedure for the authorisation of the use of a plant protection product containing the active substance flupyradifurone on strawberries, table olives, okra/lady's fingers, cauliflowers, broccoli, Brussels sprouts, head cabbages, kales, kohlrabies, 'lettuces and salad plants', 'spinaches and similar (leaves)', 'herbs and edible flowers', beans, peas, rapeseeds/canola seeds, mustard seeds and olives for oil production, an application was submitted in accordance with Article 6(1) of Regulation (EC) No 396/2005 for modification of the existing MRLs for flupyradifurone and its main metabolite difluoroacetic acid.
- (3) In accordance with Article 6(2) and (4) of Regulation (EC) No 396/2005 an application for import tolerances was submitted for flupyradifurone used in the United States on citrus fruits, prickly pears/cactus fruits, cotton seeds, sweet corn, barley, maize/corn, sorghum and wheat, in the United States and Canada on tree nuts, pome fruits, grapes, blueberries, 'root and tuber vegetables', tomatoes, sweet peppers/bell peppers, aubergines/eggplants, melons, celeries, pulses, peanuts, soyabeans and hops, in Brazil on coffee beans, and in Ghana and Ivory Coast on cocoa beans. The applicants state that the authorised uses of that substance on such crops in those countries lead to residues exceeding the MRLs contained in Regulation (EC) No 396/2005 for flupyradifurone and difluoroacetic acid and that higher MRLs are necessary to avoid trade barriers for the import of those crops.
- (4) In the context of these applications, the applicant submitted to the Rapporteur Member State, the Netherlands, the additional rotational crop field studies and livestock feeding studies within the deadline set under Commission Regulation (EU) 2016/486 ⁽²⁾.
- (5) In accordance with Article 8 of Regulation (EC) No 396/2005, those applications were evaluated by the Netherlands, and the evaluation reports were forwarded to the Commission.

⁽¹⁾ OJ L 70, 16.3.2005, p. 1.

⁽²⁾ Commission Regulation (EU) 2016/486 of 29 March 2016 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 cyazofamid, cycloxydim, difluoroacetic acid, fenoxycarb, flumetralin, fluopicolide, flupyradifurone, fluxapyroxad, kresoxim-methyl, mandestrobin, mepanipyrim, metalaxyl-M, pendimethalin and tefluthrin in or on certain products (OJ L 90, 6.4.2016, p. 1).

- (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 ⁽³⁾. It forwarded those opinions to the applicants, the Commission and the Member States and made them available to the public.
- (7) As regards flupyradifurone in prickly pear/cactus fruit, melons, tomatoes and hops, the Authority concluded that the submitted data was insufficient to set new MRLs. As regards flupyradifurone in celeries, an acute intake concern could not be excluded. 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.
- (8) Following the assessment of the additional rotational crop field studies and livestock feeding studies, the Authority recommended raising, lowering or keeping the existing MRLs for flupyradifurone and difluoroacetic acid in rotational crops and products of animal origin. In particular, the Authority suggested lowering the MRLs for flupyradifurone in grape leaves and difluoroacetic acid in maize, cocoa beans and swine liver. These MRLs should be set in Annex II to Regulation (EC) No 396/2005 at the existing levels or the levels identified by the Authority.
- (9) Based on the reasoned opinions of the Authority and taking into account the factors relevant to the matter under consideration, the respective modifications to the MRLs fulfil the requirements of Article 14(2) of Regulation (EC) No 396/2005.
- (10) 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.
- (11) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (12) In order to allow for the normal marketing, processing and consumption of products, this Regulation should provide for a transitional measure 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.
- (13) 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.
- (14) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽³⁾ EFSA scientific reports available online: <http://www.efsa.europa.eu>:

Reasoned opinion on the setting of import tolerances, modification of existing maximum residue levels and evaluation of confirmatory data following the Article 12 MRL review for flupyradifurone and DFA. *EFSA Journal* 2020;18(6):6133.

Reasoned opinion on the modification of the existing maximum residue levels for flupyradifurone and DFA in rapeseeds/canola seeds and mustard seeds. *EFSA Journal* 2020;18(11):6298.

Reasoned opinion on the modification of the existing maximum residue levels for flupyradifurone and DFA in okra/lady's finger. *EFSA Journal* 2021;19(5):6581.

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 flupyradifurone in grape leaves and difluoroacetic acid in maize, cocoa beans and swine liver, for products which were produced in the Union or imported into the Union before 10 May 2022.

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 10 May 2022 as regards the MRLs for flupyradifurone in grape leaves and difluoroacetic acid in maize, cocoa beans and swine liver.

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

Done at Brussels, 20 October 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

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

(1) in Annex II, the following columns for difluoroacetic acid and flupyradifurone are added:

'Pesticide residues and maximum residue levels (mg/kg)

Code number	Groups and examples of individual products to which the MRLs apply ⁽¹⁾	Difluoroacetic acid (DFA)	Flupyradifurone
(1)	(2)	(3)	(4)
0100000	FRUITS, FRESH or FROZEN; TREE NUTS		
0110000	Citrus fruits		
0110010	Grapefruits	0,05	3
0110020	Oranges	0,05	3
0110030	Lemons	0,05	1,5
0110040	Limes	0,05	1,5
0110050	Mandarins	0,05	1,5
0110990	Others (2)	0,02 (*)	0,01 (*)
0120000	Tree nuts	0,04	0,02
0120010	Almonds		
0120020	Brazil nuts		
0120030	Cashew nuts		
0120040	Chestnuts		
0120050	Coconuts		
0120060	Hazelnuts/cobnuts		
0120070	Macadamias		
0120080	Pecans		
0120090	Pine nut kernels		
0120100	Pistachios		
0120110	Walnuts		
0120990	Others (2)		
0130000	Pome fruits	0,2	0,6
0130010	Apples		
0130020	Pears		
0130030	Quinces		
0130040	Medlars		
0130050	Loquats/Japanese medlars		
0130990	Others (2)		

(1)	(2)	(3)	(4)
0140000	Stone fruits	0,02 (*)	0,01 (*)
0140010	Apricots		
0140020	Cherries (sweet)		
0140030	Peaches		
0140040	Plums		
0140990	Others (2)		
0150000	Berries and small fruits		
0151000	(a) grapes	0,15	3
0151010	Table grapes		
0151020	Wine grapes		
0152000	(b) strawberries	0,3	0,4
0153000	(c) cane fruits		
0153010	Blackberries	0,07	1,5
0153020	Dewberries	0,02 (*)	0,01 (*)
0153030	Raspberries (red and yellow)	0,07	1,5
0153990	Others (2)	0,02 (*)	0,01 (*)
0154000	(d) other small fruits and berries		
0154010	Blueberries	0,05	4
0154020	Cranberries	0,02 (*)	0,01 (*)
0154030	Currants (black, red and white)	0,02 (*)	0,01 (*)
0154040	Gooseberries (green, red and yellow)	0,02 (*)	0,01 (*)
0154050	Rose hips	0,02 (*)	0,01 (*)
0154060	Mulberries (black and white)	0,02 (*)	0,01 (*)
0154070	Azaroles/Mediterranean medlars	0,02 (*)	0,01 (*)
0154080	Elderberries	0,02 (*)	0,01 (*)
0154990	Others (2)	0,02 (*)	0,01 (*)
0160000	Miscellaneous fruitswith		
0161000	(a) edible peel		
0161010	Dates	0,02 (*)	0,01 (*)
0161020	Figs	0,02 (*)	0,01 (*)
0161030	Table olives	0,15	5
0161040	Kumquats	0,02 (*)	0,01 (*)
0161050	Carambolas	0,02 (*)	0,01 (*)
0161060	Kaki/Japanese persimmons	0,02 (*)	0,01 (*)
0161070	Jambuls/jambolans	0,02 (*)	0,01 (*)
0161990	Others (2)	0,02 (*)	0,01 (*)
0162000	(b) inedible peel, small	0,02 (*)	0,01 (*)
0162010	Kiwi fruits (green, red, yellow)		

(1)	(2)	(3)	(4)
0162020	Litchis/lychees		
0162030	Passionfruits/maracujas		
0162040	Prickly pears/cactus fruits		
0162050	Star apples/cainitos		
0162060	American persimmons/Virginia kaki		
0162990	Others (2)		
0163000	(c) inedible peel, large	0,02 (*)	0,01 (*)
0163010	Avocados		
0163020	Bananas		
0163030	Mangoes		
0163040	Papayas		
0163050	Granate apples/pomegranates		
0163060	Cherimoyas		
0163070	Guavas		
0163080	Pineapples		
0163090	Breadfruits		
0163100	Durians		
0163110	Soursops/guanabanas		
0163990	Others (2)		
0200000	VEGETABLES, FRESH or FROZEN		
0210000	Root and tuber vegetables		
0211000	(a) potatoes	0,2	0,05
0212000	(b) tropical root and tuber vegetables	0,2	0,05
0212010	Cassava roots/manioc		
0212020	Sweet potatoes		
0212030	Yams		
0212040	Arrowroots		
0212990	Others (2)		
0213000	(c) other root and tuber vegetables except sugar beets	0,4	0,9
0213010	Beetroots		
0213020	Carrots		
0213030	Celeriacs/turnip rooted celeries		
0213040	Horseradishes		
0213050	Jerusalem artichokes		
0213060	Parsnips		
0213070	Parsley roots/Hamburg roots parsley		
0213080	Radishes		

(1)	(2)	(3)	(4)
0213090	Salsifies		
0213100	Swedes/rutabagas		
0213110	Turnips		
0213990	Others (2)		
0220000	Bulb vegetables	0,15	0,01 (*)
0220010	Garlic		
0220020	Onions		
0220030	Shallots		
0220040	Spring onions/green onions and Welsh onions		
0220990	Others (2)		
0230000	Fruiting vegetables		
0231000	(a) Solanaceae and Malvaceae		
0231010	Tomatoes	0,4	0,7
0231020	Sweet peppers/bell peppers	0,9	0,9
0231030	Aubergines/eggplants	0,9	1
0231040	Okra/lady's fingers	0,4	0,9
0231990	Others (2)	0,15	0,01 (*)
0232000	(b) cucurbits with edible peel	0,7	0,6
0232010	Cucumbers		
0232020	Gherkins		
0232030	Courgettes		
0 232 990	Others (2)		
0233000	(c) cucurbits with inedible peel		
0233010	Melons	0,3	0,01 (*)
0233020	Pumpkins	0,3	0,01 (*)
0233030	Watermelons	0,15	0,15
0233990	Others (2)	0,15	0,01 (*)
0234000	(d) sweet corn	0,2	0,05
0239000	(e) other fruiting vegetables	0,15	0,01 (*)
0240000	Brassica vegetables(excluding brassica roots and brassica baby leaf crops)		
0241000	(a) flowering brassica	0,7	0,6
0241010	Broccoli		
0241020	Cauliflowers		
0241990	Others (2)		
0242000	(b) head brassica		
0242010	Brussels sprouts	0,4	0,09
0242020	Head cabbages	0,4	0,3

(1)	(2)	(3)	(4)
0242990	Others (2)	0,02 (*)	0,01 (*)
0243000	(c) leafy brassica		
0243010	Chinese cabbages/pe-tsai	0,02 (*)	0,01 (*)
0243020	Kales	0,6	5
0243990	Others (2)	0,02 (*)	0,01 (*)
0244000	(d) kohlrabies	0,4	0,09
0250000	Leaf vegetables, herbs and edible flowers		
0251000	(a) lettuces and salad plants		
0251010	Lamb's lettuces/corn salads	0,3	6
0251020	Lettuces	0,2	6
0251030	Escaroles/broad-leaved endives	0,08	0,07
0251040	Cresses and other sprouts and shoots	0,3	6
0251050	Land cresses	0,3	6
0251060	Roman rocket/rucola	0,3	6
0251070	Red mustards	0,3	6
0251080	Baby leaf crops (including brassica species)	0,3	6
0251990	Others (2)	0,3	6
0252000	(b) spinaches and similar leaves	0,3	6
0252010	Spinaches		
0252020	Purslanes		
0252030	Chards/beet leaves		
0252990	Others (2)		
0253000	(c) grape leaves and similar species	0,04	0,01 (*)
0254000	(d) watercresses	0,08	0,07
0255000	(e) witloofs/Belgian endives	0,08	0,07
0256000	(f) herbs and edible flowers	0,3	6
0256010	Chervil		
0256020	Chives		
0256030	Celery leaves		
0256040	Parsley		
0256050	Sage		
0256060	Rosemary		
0256070	Thyme		
0256080	Basil and edible flowers		
0256090	Laurel/bay leaves		
0256100	Tarragon		
0256990	Others (2)		

(1)	(2)	(3)	(4)
0260000	Legume vegetables		
0260010	Beans (with pods)	0,9	0,5
0260020	Beans (without pods)	1	0,4
0260030	Peas (with pods)	0,9	0,5
0260040	Peas (without pods)	1	0,4
0260050	Lentils	1	0,4
0260990	Others (2)	0,4	0,01 (*)
0270000	Stem vegetables	0,2	0,01 (*)
0270010	Asparagus		
0270020	Cardoons		
0270030	Celeries		
0270040	Florence fennels		
0270050	Globe artichokes		
0270060	Leeks		
0270070	Rhubarbs		
0270080	Bamboo shoots		
0270090	Palm hearts		
0270990	Others (2)		
0280000	Fungi, mosses and lichens	0,02 (*)	0,01 (*)
0280010	Cultivated fungi		
0280020	Wild fungi		
0280990	Mosses and lichens		
0290000	Algae and prokaryotes organisms	0,02 (*)	0,01 (*)
0300000	PULSES	3	3
0300010	Beans		
0300020	Lentils		
0300030	Peas		
0300040	Lupins/lupini beans		
0300990	Others (2)		
0400000	OILSEEDS AND OIL FRUITS		
0401000	Oilseeds		
0401010	Linseeds	0,05	0,01 (*)
0401020	Peanuts/groundnuts	0,06	0,04
0401030	Poppy seeds	0,05	0,01 (*)
0401040	Sesame seeds	0,05	0,01 (*)
0401050	Sunflower seeds	0,05	0,01 (*)
0401060	Rapeseeds/canola seeds	0,3	0,3
0401070	Soyabeans	0,7	1,5

(1)	(2)	(3)	(4)
0401080	Mustard seeds	0,3	0,3
0401090	Cotton seeds	0,08	0,8
0401100	Pumpkin seeds	0,05	0,01 (*)
0401110	Safflower seeds	0,05	0,01 (*)
0401120	Borage seeds	0,05	0,01 (*)
0401130	Gold of pleasure seeds	0,05	0,01 (*)
0401140	Hemp seeds	0,05	0,01 (*)
0401150	Castor beans	0,05	0,01 (*)
0401990	Others (2)	0,05	0,01 (*)
0402000	Oil fruits		
0402010	Olives for oil production	0,15	5
0402020	Oil palms kernels	0,02 (*)	0,01 (*)
0402030	Oil palms fruits	0,02 (*)	0,01 (*)
0402040	Kapok	0,02 (*)	0,01 (*)
0402990	Others (2)	0,02 (*)	0,01 (*)
0500000	CEREALS		
0500010	Barley	0,8	3
0500020	Buckwheat and other pseudocereals	0,3	0,01 (*)
0500030	Maize/corn	0,1	0,02
0500040	Common millet/proso millet	0,3	0,01 (*)
0500050	Oat	0,3	0,01 (*)
0500060	Rice	0,3	0,01 (*)
0500070	Rye	0,3	0,01 (*)
0500080	Sorghum	0,3	3
0500090	Wheat	1,5	1
0500990	Others (2)	0,3	0,01 (*)
0600000	TEAS, COFFEE, HERBAL INFUSIONS, COCOA AND CAROBS		
0610000	Teas	0,1 (*)	0,05 (*)
0620000	Coffee beans	0,2	1
0630000	Herbal infusions from		0,05 (*)
0631000	(a) flowers	0,1 (*)	
0631010	Chamomile		
0631020	Hibiscus/roselle		
0631030	Rose		
0631040	Jasmine		
0631050	Lime/linden		
0631990	Others (2)		

(1)	(2)	(3)	(4)
0632000	(b) leaves and herbs	0,1 (*)	
0632010	Strawberry		
0632020	Rooibos		
0632030	Mate/maté		
0632990	Others (2)		
0633000	(c) roots	0,1 (*)	
0633010	Valerian		
0633020	Ginseng		
0633990	Others (2)		
0639000	(d) any other parts of the plant		
0640000	Cocoa beans	0,06	0,05 (*)
0650000	Carobs/Saint John's breads	0,1 (*)	0,05 (*)
0700000	HOPS	0,3	4
0800000	SPICES		
0 810 000	Seed spices	0,1 (*)	0,05 (*)
0810010	Anise/aniseed		
0810020	Black caraway/black cumin		
0810030	Celery		
0810040	Coriander		
0810050	Cumin		
0810060	Dill		
0810070	Fennel		
0810080	Fenugreek		
0810090	Nutmeg		
0810990	Others (2)		
0820000	Fruit spices	0,1 (*)	0,05 (*)
0820010	Allspice/pimento		
0820020	Sichuan pepper		
0820030	Caraway		
0820040	Cardamom		
0820050	Juniper berry		
0820060	Peppercorn (black, green and white)		
0820070	Vanilla		
0820080	Tamarind		
0820990	Others (2)		
0830000	Bark spices	0,1 (*)	0,05 (*)
0830010	Cinnamon		
0830990	Others (2)		

(1)	(2)	(3)	(4)
0840000	Root and rhizome spices		
0840010	Liquorice	0,1 (*)	0,05 (*)
0840020	Ginger (10)		
0840030	Turmeric/curcuma	0,1 (*)	0,05 (*)
0840040	Horseradish (11)		
0840990	Others (2)	0,1 (*)	0,05 (*)
0850000	Bud spices	0,1 (*)	0,05 (*)
0850010	Cloves		
0850020	Capers		
0850990	Others (2)		
0860000	Flower pistil spices	0,1 (*)	0,05 (*)
0860010	Saffron		
0860990	Others (2)		
0870000	Aril spices	0,1 (*)	0,05 (*)
0870010	Mace		
0870990	Others (2)		
0900000	SUGAR PLANTS	0,02 (*)	0,01 (*)
0900010	Sugar beet roots		
0900020	Sugar canes		
0900030	Chicory roots		
0900990	Others (2)		
1000000	PRODUCTS OF ANIMAL ORIGIN - TERRESTRIAL ANIMALS		
1010000	Commodities from		
1011000	(a) swine		
1011010	Muscle	0,15	0,03
1011020	Fat	0,1	0,015
1011030	Liver	0,09	0,08
1011040	Kidney	0,2	0,09
1011050	Edible offals (other than liver and kidney)	0,2	0,09
1011990	Others (2)	0,2	0,09
1012000	(b) bovine		
1012010	Muscle	0,4	0,3
1012020	Fat	0,5	0,2
1012030	Liver	0,4	1
1012040	Kidney	0,5	1
1012050	Edible offals (other than liver and kidney)	0,5	1
1012990	Others (2)	0,5	1

(1)	(2)	(3)	(4)
1013000	(c) sheep		
1013010	Muscle	0,2	0,3
1013020	Fat	0,15	0,2
1013030	Liver	0,15	1
1013040	Kidney	0,3	1
1013050	Edible offals (other than liver and kidney)	0,3	1
1013990	Others (2)	0,3	1
1014000	(d) goat		
1014010	Muscle	0,2	0,3
1014020	Fat	0,15	0,2
1014030	Liver	0,15	1
1014040	Kidney	0,3	1
1014050	Edible offals (other than liver and kidney)	0,3	1
1014990	Others (2)	0,3	1
1015000	(e) equine		
1015010	Muscle	0,4	0,3
1015020	Fat	0,5	0,2
1015030	Liver	0,4	1
1015040	Kidney	0,5	1
1015050	Edible offals (other than liver and kidney)	0,5	1
1015990	Others (2)	0,5	1
1016000	(f) poultry		0,01 (*)
1016010	Muscle	0,15	
1016020	Fat	0,03	
1016030	Liver	0,3	
1016040	Kidney	0,02 (*)	
1016050	Edible offals (other than liver and kidney)	0,02 (*)	
1016990	Others (2)	0,02 (*)	
1017000	(g) other farmed terrestrial animals		
1017010	Muscle	0,4	0,3
1017020	Fat	0,5	0,2
1017030	Liver	0,4	1
1017040	Kidney	0,5	1
1017050	Edible offals (other than liver and kidney)	0,5	1
1017990	Others (2)	0,5	1
1020000	Milk		
1020010	Cattle	0,07	0,15
1020020	Sheep	0,03	0,15

(1)	(2)	(3)	(4)
1020030	Goat	0,03	0,15
1020040	Horse	0,03	0,01 (*)
1020990	Others (2)	0,03	0,01 (*)
1030000	Birds eggs	0,1	0,01 (*)
1030010	Chicken		
1030020	Duck		
1030030	Geese		
1030040	Quail		
1030990	Others (2)		
1040000	Honey and other apiculture products (7)	0,05 (*)	0,05 (*)
1050000	Amphibians and Reptiles	0,02 (*)	0,01 (*)
1060000	Terrestrial invertebrate animals	0,02 (*)	0,01 (*)
1070000	Wild terrestrial vertebrate animals	0,02 (*)	0,01 (*)
1100000	PRODUCTS OF ANIMAL ORIGIN - FISH, FISH PRODUCTS AND ANY OTHER MARINE AND FRESHWATER FOOD PRODUCTS (8)		
1200000	PRODUCTS OR PART OF PRODUCTS EXCLUSIVELY USED FOR ANIMAL FEED PRODUCTION (8)		
1300000	PROCESSED FOOD PRODUCTS (9)		

(*) Indicates lower limit of analytical determination

(^e) For the complete list of products of plant and animal origin to which MRLs apply, reference should be made to Annex I'

(2) in Part A of Annex III, the columns for difluoroacetic acid and flupyradifurone are deleted.