

II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) 2022/1264**of 20 July 2022****amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for fludioxonil 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) thereof,

Whereas:

- (1) For fludioxonil maximum residue levels ('MRLs') were set in Annex II to Regulation (EC) No 396/2005.
- (2) An application for import tolerances pursuant to Article 6(2) and (4) of Regulation (EC) No 396/2005 for fludioxonil used in the United States on sugar beet roots, and in Guatemala, Honduras and Colombia on bananas was submitted. The applicant states that the authorised uses of that substance on such crops in those countries lead to residues exceeding the MRLs provided for in Regulation (EC) No 396/2005 and that higher MRLs are necessary to avoid trade barriers for the importation of those crops.
- (3) In accordance with Article 8 of Regulation (EC) No 396/2005, the application was evaluated by the Member State concerned and the evaluation report was forwarded to the Commission.
- (4) The European Food Safety Authority ('the Authority') assessed the application and the evaluation report, examining in particular the risks to consumers and, where relevant, to animals, and gave a reasoned opinion on the proposed MRLs ⁽²⁾. It forwarded that opinion to the applicant, the Commission and the Member States and made it available to the public.

⁽¹⁾ OJ L 70, 16.3.2005, p. 1.

⁽²⁾ Reasoned opinion on the setting of import tolerances for fludioxonil in sugar beet roots and bananas. EFSA Journal 2021;19(11):6919. EFSA scientific reports available online: <http://www.efsa.europa.eu>.

- (5) The Authority concluded that all requirements with respect to completeness of data submission were met and that the modifications to the MRLs requested by the applicant were acceptable with regard to consumer safety on the basis of a consumer exposure assessment for 27 specific European consumer groups. In so concluding, the Authority took into account the most recent information on the toxicological properties of the substance. The lifetime exposure to the substance via consumption of all food products that may contain it showed that there is no risk that the acceptable daily intake is exceeded. Moreover, the Authority concluded that the establishment of an acute reference dose is not necessary on the basis of the low acute toxicity profile of the active substance.
- (6) Based on the reasoned opinion of the Authority and taking into account the factors relevant to the matter under consideration, the proposed modifications to the MRLs fulfil the requirements of Article 14(2) of Regulation (EC) No 396/2005.
- (7) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (8) 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

Annex II to Regulation (EC) No 396/2005 is 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*.

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

Done at Brussels, 20 July 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

In Annex II to Regulation (EC) No 396/2005, the column for fludioxonil is 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 ^(*)	Fludioxonil (R) (F)
0100000	FRUITS, FRESH or FROZEN; TREE NUTS	
0110000	Citrus fruits	10
0110010	Grapefruits	
0110020	Oranges	
0110030	Lemons	
0110040	Limes	
0110050	Mandarins	
0110990	Others (2)	
0120000	Tree nuts	
0120010	Almonds	0,01 (*)
0120020	Brazil nuts	0,01 (*)
0120030	Cashew nuts	0,01 (*)
0120040	Chestnuts	0,01 (*)
0120050	Coconuts	0,01 (*)
0120060	Hazelnuts/cobnuts	0,01 (*)
0120070	Macadamias	0,01 (*)
0120080	Pecans	0,01 (*)
0120090	Pine nut kernels	0,01 (*)
0120100	Pistachios	0,2
0120110	Walnuts	0,01 (*)
0120990	Others (2)	0,01 (*)
0130000	Pome fruits	5
0130010	Apples	
0130020	Pears	
0130030	Quinces	
0130040	Medlars	
0130050	Loquats/Japanese medlars	
0130990	Others (2)	
0140000	Stone fruits	

0140010	Apricots	5
0140020	Cherries (sweet)	5
0140030	Peaches	10
0140040	Plums	5
0140990	Others (2)	0,01 (*)
0150000	Berries and small fruits	
0151000	(a) grapes	
0151010	Table grapes	5
0151020	Wine grapes	4
0152000	(b) strawberries	4
0153000	(c) cane fruits	5
0153010	Blackberries	
0153020	Dewberries	
0153030	Raspberries (red and yellow)	
0153990	Others (2)	
0154000	(d) other small fruits and berries	
0154010	Blueberries	4
0154020	Cranberries	4
0154030	Currants (black, red and white)	4
0154040	Gooseberries (green, red and yellow)	4
0154050	Rose hips	0,01 (*)
0154060	Mulberries (black and white)	0,01 (*)
0154070	Azaroles/Mediterranean medlars	0,01 (*)
0154080	Elderberries	4
0154990	Others (2)	0,01 (*)
0160000	Miscellaneous fruits with	
0161000	(a) edible peel	0,01 (*)
0161010	Dates	
0161020	Figs	
0161030	Table olives	
0161040	Kumquats	
0161050	Carambolas	
0161060	Kaki/Japanese persimmons	
0161070	Jambuls/jambolans	
0161990	Others (2)	
0162000	(b) inedible peel, small	
0162010	Kiwi fruits (green, red, yellow)	15
0162020	Litchis/lychees	0,01 (*)

0162030	Passionfruits/maracujas	0,01 (*)
0162040	Prickly pears/cactus fruits	0,01 (*)
0162050	Star apples/cainitos	0,01 (*)
0162060	American persimmons/Virginia kaki	0,01 (*)
0162990	Others (2)	0,01 (*)
0163000	(c) inedible peel, large	
0163010	Avocados	1,5
0163020	Bananas	2
0163030	Mangoes	2
0163040	Papayas	0,01 (*)
0163050	Granate apples/pomegranates	3
0163060	Cherimoyas	0,01 (*)
0163070	Guavas	0,5
0163080	Pineapples	7
0163090	Breadfruits	0,01 (*)
0163100	Durians	0,01 (*)
0163110	Soursops/guanabanas	0,01 (*)
0163990	Others (2)	0,01 (*)
0200000	VEGETABLES, FRESH or FROZEN	
0210000	Root and tuber vegetables	
0211000	(a) potatoes	5
0212000	(b) tropical root and tuber vegetables	
0212010	Cassava roots/manioc	0,01 (*)
0212020	Sweet potatoes	10
0212030	Yams	10
0212040	Arrowroots	0,01 (*)
0212990	Others (2)	0,01 (*)
0213000	(c) other root and tuber vegetables except sugar beets	
0213010	Beetroots	1
0213020	Carrots	1
0213030	Celeriacs/turnip rooted celeries	0,2
0213040	Horseradishes	1
0213050	Jerusalem artichokes	0,01 (*)
0213060	Parsnips	1
0213070	Parsley roots/Hamburg roots parsley	1
0213080	Radishes	0,3
0213090	Salsifies	1

0213100	Swedes/rutabagas	0,01 (*)
0213110	Turnips	0,01 (*)
0213990	Others (2)	0,01 (*)
0220000	Bulb vegetables	
0220010	Garlic	0,5
0220020	Onions	0,5
0220030	Shallots	0,5
0220040	Spring onions/green onions and Welsh onions	5
0220990	Others (2)	0,5
0230000	Fruiting vegetables	
0231000	(a) Solanaceae and Malvaceae	
0231010	Tomatoes	3
0231020	Sweet peppers/bell peppers	1
0231030	Aubergines/eggplants	0,4
0231040	Okra/lady's fingers	0,01 (*)
0231990	Others (2)	0,01 (*)
0232000	(b) cucurbits with edible peel	0,4
0232010	Cucumbers	
0232020	Gherkins	
0232030	Courgettes	
0232990	Others (2)	
0233000	(c) cucurbits with inedible peel	0,3
0233010	Melons	
0233020	Pumpkins	
0233030	Watermelons	
0233990	Others (2)	
0234000	(d) sweet corn	0,01 (*)
0239000	(e) other fruiting vegetables	0,01 (*)
0240000	Brassica vegetables(excluding brassica roots and brassica baby leaf crops)	
0241000	(a) flowering brassica	
0241010	Broccoli	0,7
0241020	Cauliflowers	0,01 (*)
0241990	Others (2)	0,01 (*)
0242000	(b) head brassica	
0242010	Brussels sprouts	0,01 (*)
0242020	Head cabbages	2
0242990	Others (2)	0,01 (*)

0243000	(c) leafy brassica	
0243010	Chinese cabbages/pe-tsai	10
0243020	Kales	0,01 (*)
0243990	Others (2)	0,01 (*)
0244000	(d) kohlrabies	0,01 (*)
0250000	Leaf vegetables, herbs and edible flowers	
0251000	(a) lettuces and salad plants	
0251010	Lamb's lettuces/corn salads	20
0251020	Lettuces	40
0251030	Escaroles/broad-leaved endives	20
0251040	Cresses and other sprouts and shoots	20
0251050	Land cresses	20
0251060	Roman rocket/rucola	20
0251070	Red mustards	20
0251080	Baby leaf crops (including brassica species)	20
0251990	Others (2)	20
0252000	(b) spinaches and similar leaves	
0252010	Spinaches	30
0252020	Purslanes	20
0252030	Chards/beet leaves	20
0252990	Others (2)	20
0253000	(c) grape leaves and similar species	0,01 (*)
0254000	(d) watercresses	10
0255000	(e) witloofs/Belgian endives	0,02
0256000	(f) herbs and edible flowers	20
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)	
0260000	Legume vegetables	

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

0401070	Soyabeans	0,2
0401080	Mustard seeds	0,3
0401090	Cotton seeds	0,01 (*)
0401100	Pumpkin seeds	0,01 (*)
0401110	Safflower seeds	0,01 (*)
0401120	Borage seeds	0,3
0401130	Gold of pleasure seeds	0,3
0401140	Hemp seeds	0,3
0401150	Castor beans	0,01 (*)
0401990	Others (2)	0,01 (*)
0402000	Oil fruits	0,01 (*)
0402010	Olives for oil production	
0402020	Oil palms kernels	
0402030	Oil palms fruits	
0402040	Kapok	
0402990	Others (2)	
0500000	CEREALS	0,01 (*)
0500010	Barley	
0500020	Buckwheat and other pseudocereals	
0500030	Maize/corn	
0500040	Common millet/proso millet	
0500050	Oat	
0500060	Rice	
0500070	Rye	
0500080	Sorghum	
0500090	Wheat	
0500990	Others (2)	
0600000	TEAS, COFFEE, HERBAL INFUSIONS, COCOA AND CAROBS	
0610000	Teas	0,05 (*)
0620000	Coffee beans	0,05 (*)
0630000	Herbal infusions from	
0631000	(a) flowers	0,05 (*)
0631010	Chamomile	
0631020	Hibiscus/roselle	
0631030	Rose	
0631040	Jasmine	
0631050	Lime/linden	

0631990	Others (2)	
0632000	(b) leaves and herbs	0,05 (*)
0632010	Strawberry	
0632020	Rooibos	
0632030	Mate/maté	
0632990	Others (2)	
0633000	(c) roots	
0633010	Valerian	1
0633020	Ginseng	4
0633990	Others (2)	1
0639000	(d) any other parts of the plant	0,05 (*)
0640000	Cocoa beans	0,05 (*)
0650000	Carobs/Saint John's breads	0,05 (*)
0700000	HOPS	0,05 (*)
0800000	SPICES	
0810000	Seed spices	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	0,05 (*)
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	0,05 (*)

0830010	Cinnamon	
0830990	Others (2)	
0840000	Root and rhizome spices	
0840010	Liquorice	1
0840020	Ginger (10)	
0840030	Turmeric/curcuma	1
0840040	Horseradish (11)	
0840990	Others (2)	1
0850000	Bud spices	0,05 (*)
0850010	Cloves	
0850020	Capers	
0850990	Others (2)	
0860000	Flower pistil spices	0,05 (*)
0860010	Saffron	
0860990	Others (2)	
0870000	Aril spices	0,05 (*)
0870010	Mace	
0870990	Others (2)	
0900000	SUGAR PLANTS	
0900010	Sugar beet roots	4
0900020	Sugar canes	0,01 (*)
0900030	Chicory roots	0,01 (*)
0900990	Others (2)	0,01 (*)
1000000	PRODUCTS OF ANIMAL ORIGIN - TERRESTRIAL ANIMALS	
1010000	Commodities from	
1011000	(a) swine	
1011010	Muscle	0,02
1011020	Fat	0,02
1011030	Liver	0,1
1011040	Kidney	0,1
1011050	Edible offals (other than liver and kidney)	0,1
1011990	Others (2)	0,02
1012000	(b) bovine	
1012010	Muscle	0,02
1012020	Fat	0,02
1012030	Liver	0,1
1012040	Kidney	0,1

1012050	Edible offals (other than liver and kidney)	0,1
1012990	Others (2)	0,02
1013000	(c) sheep	
1013010	Muscle	0,02
1013020	Fat	0,02
1013030	Liver	0,1
1013040	Kidney	0,1
1013050	Edible offals (other than liver and kidney)	0,1
1013990	Others (2)	0,02
1014000	(d) goat	
1014010	Muscle	0,02
1014020	Fat	0,02
1014030	Liver	0,1
1014040	Kidney	0,1
1014050	Edible offals (other than liver and kidney)	0,1
1014990	Others (2)	0,02
1015000	(e) equine	
1015010	Muscle	0,02
1015020	Fat	0,02
1015030	Liver	0,1
1015040	Kidney	0,1
1015050	Edible offals (other than liver and kidney)	0,1
1015990	Others (2)	0,02
1016000	(f) poultry	
1016010	Muscle	0,01 (*)
1016020	Fat	0,01 (*)
1016030	Liver	0,1
1016040	Kidney	0,1
1016050	Edible offals (other than liver and kidney)	0,1
1016990	Others (2)	0,01 (*)
1017000	(g) other farmed terrestrial animals	
1017010	Muscle	0,02
1017020	Fat	0,02
1017030	Liver	0,1
1017040	Kidney	0,1
1017050	Edible offals (other than liver and kidney)	0,1
1017990	Others (2)	0,02

1020000	Milk	0,04
1020010	Cattle	
1020020	Sheep	
1020030	Goat	
1020040	Horse	
1020990	Others (2)	
1030000	Birds eggs	0,02
1030010	Chicken	
1030020	Duck	
1030030	Geese	
1030040	Quail	
1030990	Others (2)	
1040000	Honey and other apiculture products (7)	0,05 (*)
1050000	Amphibians and Reptiles	0,01 (*)
1060000	Terrestrial invertebrate animals	0,01 (*)
1070000	Wild terrestrial vertebrate animals	0,02
1100000	PRODUCTS OF ANIMAL ORIGIN - FISH, FISHPRODUCTS 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 MRL's apply, reference should be made to Annex I

Fludioxonil (R) (F)

(R) The residue definition differs for the following combinations pesticide-code number: Fludioxonil - code 1000000 except 1040000 : sum of fludioxonil and its metabolites oxidized to metabolite 2,2-difluoro-benzo[1,3]dioxole-4 carboxylic acid, expressed as fludioxonil

(F) Fat soluble'