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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 imazalil in or on certain products

(Text with EEA relevance)

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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 imazalil 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/EEC¹, and in particular Article 14(1)(a) and Article 49(2) thereof,

Whereas:

- (1) Maximum residue levels (MRLs) for imazalil were set in Annex II and Part B of Annex III to Regulation (EC) No 396/2005.
- (2) The European Food Safety Authority, hereinafter "the Authority" submitted a reasoned opinion on the existing MRLs for imazalil in accordance with Article 12(1) of Regulation (EC) No 396/2005².
- (3) Independently from the MRL review referred in in recital (1), in accordance with Article 6 of Regulation (EC) No 396/2005, an application to modify the existing maximum residue levels (MRLs) for the active substance imazalil in citrus fruits, apples, pears, bananas and potatoes and in products of animal origin was submitted.
- (4) In accordance with Article 8 of Regulation (EC) No 396/2005, this application was evaluated by the Member State concerned and the evaluation report was forwarded to the Commission.
- (5) The Authority assessed the application and the evaluation report, examining in particular the risks to the consumer and, where relevant, to animals and gave its reasoned opinion on the proposed MRLs. It forwarded this opinion to the applicants, the Commission and the Member States and made them available to the public.
- (6) The Authority concluded in its reasoned opinion³ that the MRLs for the intended uses could not be amended until the risk assessment for the plant metabolites R014821, FK-772 and FK-284 would be completed with regard to genotoxicity and general toxicity.
- (7) Given the adoption of the reasoned opinion under Article 6 of Regulation (EC) No 396/2005 after the adoption of the reasoned opinion on the existing MRLs for imazalil

¹ OJ L 70, 16.3.2005, p. 1.

² European Food Safety Authority; Review of the existing maximum residue levels for imazalil according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2017;15(9):4977.

³ European Food Safety Authority; Modification of the existing maximum residue levels for imazalil in various commodities. EFSA Journal 2018;16(6):5329.

in accordance with Article 12(1) of Regulation (EC) No 396/2005 and the horizontal nature of the toxicity concerns identified for the imazalil metabolites R014821, FK-772 and FK-284, the Commission requested the Authority to update its reasoned opinion on the existing MRLs for imazalil in accordance with Article 43 of Regulation (EC) No 396/2005.

- (8) The Authority submitted a reasoned opinion⁴ updating the review of the existing MRLs for imazalil based on the new toxicological information.
- (9) The Authority identified concerning the MRLs for citrus fruits, apples, pears, quinces, medlars, loquat, loquats/Japanese medlars, bananas, potatoes and melons a risk for consumers. It is therefore appropriate to lower these MRLs. It recommended lowering the MRLs for tomatoes, sweet peppers/bell peppers, courgettes, barley, oat, rye, wheat and animal commodities.
- (10) 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 limit of determination or the default MRL should apply, as provided for in Article 18(1)(b) of Regulation (EC) No 396/2005.
- (11) 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.
- (12) 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.
- (13) 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.
- (14) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (15) 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.
- (16) 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.
- (17) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁴ European Food Safety Authority; EFSA Journal 2018;16(10):5453.

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 before [*Office of Publications please insert date 6 months after entry into force of this Regulation*], except for citrus fruits, apples, pears, quinces, medlars, loquat, loquats/Japanese medlars, bananas, potatoes and melons.

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
Jean-Claude JUNCKER*

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ANNEX

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

- (1) In Annex II, the column for imazalil is replaced by the following:
[Office of Publication: please insert table Annex II]
- (2) In in part B of Annex III, the column for imazalil is deleted.

[Annex II]

Pesticide residues and maximum residue levels (mg/kg)

Code number	Groups and examples of individual products to which the MRLs apply (a)	Imazalil (any ratio of constituent isomers)
0100000	FRUITS, FRESH or FROZEN; TREE NUTS	
0110000	Citrus fruits	0.01*
0110010	Grapefruits	
0110020	Oranges	
0110030	Lemons	
0110040	Limes	
0110050	Mandarins	
0110990	Others (2)	
0120000	Tree nuts	0.01*
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	0.01*
0130010	Apples	
0130020	Pears	
0130030	Quinces	
0130040	Medlars	**
0130050	Loquats/Japanese medlars	**
0130990	Others (2)	
0140000	Stone fruits	0.01*
0140010	Apricots	
0140020	Cherries (sweet)	
0140030	Peaches	
0140040	Plums	
0140990	Others (2)	
0150000	Berries and small fruits	
0151000	(a) grapes	0.01*
0151010	Table grapes	
0151020	Wine grapes	
0152000	(b) strawberries	2
0153000	(c) cane fruits	
0153010	Blackberries	2
0153020	Dewberries	0.01*
0153030	Raspberries (red and yellow)	2
0153990	Others (2)	0.01*
0154000	(d) other small fruits and berries	0.01*
0154010	Blueberries	
0154020	Cranberries	
0154030	Currants (black, red and white)	
0154040	Gooseberries (green, red and yellow)	
0154050	Rose hips	**
0154060	Mulberries (black and white)	**
0154070	Azaroles/Mediterranean medlars	**
0154080	Elderberries	**
0154990	Others (2)	
0160000	Miscellaneous fruits with	0.01*
0161000	(a) edible peel	
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)	
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	
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	0.01*
0211000	(a) potatoes	
0212000	(b) tropical root and tuber vegetables	
0212010	Cassava roots/manioc	
0212020	Sweet potatoes	
0212030	Yams	
0212040	Arrowroots	**
0212990	Others (2)	
0213000	(c) other root and tuber vegetables except sugar beets	
0213010	Beetroots	
0213020	Carrots	
0213030	Celeriacs/turnip rooted celeries	
0213040	Horseradishes	
0213050	Jerusalem artichokes	

Code number	Groups and examples of individual products to which the MRLs apply (a)	Imazaili (any ratio of constituent isomers)
0213060	Parsnips	
0213070	Parsley roots/Hamburg roots parsley	
0213080	Radishes	
0213090	Salsifies	
0213100	Swedes/rutabagas	
0213110	Turnips	
0213990	Others (2)	
0220000	Bulb vegetables	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	0.3
0231020	Sweet peppers/bell peppers	0.01*
0231030	Aubergines/eggplants	0.01*
0231040	Okra/lady's fingers	0.01*
0231990	Others (2)	0.01*
0232000	(b) cucurbits with edible peel	
0232010	Cucumbers	0.5
0232020	Gherkins	0.5
0232030	Courgettes	0.1 (+)
0232990	Others (2)	0.01*
0233000	(c) cucurbits with inedible peel	0.01*
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)	0.01*
0241000	(a) flowering brassica	
0241010	Broccoli	
0241020	Cauliflowers	
0241990	Others (2)	
0242000	(b) head brassica	
0242010	Brussels sprouts	
0242020	Head cabbages	
0242990	Others (2)	
0243000	(c) leafy brassica	
0243010	Chinese cabbages/pe-tsai	
0243020	Kales	
0243990	Others (2)	
0244000	(d) kohlrabies	
0250000	Leaf vegetables, herbs and edible flowers	
0251000	(a) lettuces and salad plants	0.01*
0251010	Lamb's lettuces/corn salads	
0251020	Lettuces	
0251030	Escaroles/broad-leaved endives	
0251040	Cresses and other sprouts and shoots	
0251050	Land cresses	**
0251060	Roman rocket/rucola	**
0251070	Red mustards	**
0251080	Baby leaf crops (including brassica species)	
0251990	Others (2)	
0252000	(b) spinaches and similar leaves	0.01*
0252010	Spinaches	
0252020	Purslanes	**
0252030	Chards/beet leaves	
0252990	Others (2)	
0253000	(c) grape leaves and similar species	**
0254000	(d) watercresses	0.01*
0255000	(e) witloofs/Belgian endives	0.01*
0256000	(f) herbs and edible flowers	0.02*
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	0.01*
0260010	Beans (with pods)	
0260020	Beans (without pods)	
0260030	Peas (with pods)	
0260040	Peas (without pods)	
0260050	Lentils	
0260990	Others (2)	
0270000	Stem vegetables	0.01*
0270010	Asparagus	
0270020	Cardoons	
0270030	Celeriac	
0270040	Florence fennels	
0270050	Globe artichokes	
0270060	Leeks	
0270070	Rhubarbs	
0270080	Bamboo shoots	**
0270090	Palm hearts	**
0270990	Others (2)	
0280000	Fungi, mosses and lichens	0.01*
0280010	Cultivated fungi	
0280020	Wild fungi	
0280990	Mosses and lichens	

Code number	Groups and examples of individual products to which the MRLs apply (a)	Imazalil (any ratio of constituent isomers)
0290000	Algae and prokaryotes organisms	**
0300000	PULSES	0.01*
0300010	Beans	
0300020	Lentils	
0300030	Peas	
0300040	Lupins/lupini beans	
0300990	Others (2)	
0400000	OILSEEDS AND OIL FRUITS	0.01*
0401000	Oilseeds	
0401010	Linseeds	
0401020	Peanuts/groundnuts	
0401030	Poppy seeds	
0401040	Sesame seeds	
0401050	Sunflower seeds	
0401060	Rapeseeds/canola seeds	
0401070	Soyabeans	
0401080	Mustard seeds	
0401090	Cotton seeds	
0401100	Pumpkin seeds	
0401110	Safflower seeds	**
0401120	Borage seeds	**
0401130	Gold of pleasure seeds	**
0401140	Hemp seeds	**
0401150	Castor beans	**
0401990	Others (2)	
0402000	Oil fruits	
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	0.05*
0610000	Teas	
0620000	Coffee beans	**
0630000	Herbal infusions from	**
0631000	(a) flowers	**
0631010	Chamomile	**
0631020	Hibiscus/roselle	**
0631030	Rose	**
0631040	Jasmine	**
0631050	Lime/linden	**
0631990	Others (2)	**
0632000	(b) leaves and herbs	**
0632010	Strawberry	**
0632020	Rooibos	**
0632030	Mate/maté	**
0632990	Others (2)	**
0633000	(c) roots	**
0633010	Valerian	**
0633020	Ginseng	**
0633990	Others (2)	**
0639000	(d) any other parts of the plant	**
0640000	Cocoa beans	**
0650000	Carobs/Saint John's breads	**
0700000	HOPS	0.05*
0800000	SPICES	**
0810000	Seed spices	**
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	**
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	**
0830010	Cinnamon	**
0830990	Others (2)	**
0840000	Root and rhizome spices	**
0840010	Liquorice	**
0840020	Ginger (10)	**
0840030	Turmeric/curcuma	**
0840040	Horseradish (11)	**
0840990	Others (2)	**
0850000	Bud spices	**
0850010	Cloves	**
0850020	Capers	**

Code number	Groups and examples of individual products to which the MRLs apply (a)	Imazalil (any ration of constituent isomers)
0850990	Others (2)	**
0860000	Flower pistil spices	**
0860010	Saffron	**
0860990	Others (2)	**
0870000	Aril spices	**
0870010	Mace	**
0870990	Others (2)	**
0900000	SUGAR PLANTS	**
0900010	Sugar beet roots	**
0900020	Sugar canes	**
0900030	Chicory roots	**
0900990	Others (2)	**
1000000	PRODUCTS OF ANIMAL ORIGIN - TERRESTRIAL ANIMALS	
1010000	Commodities from	0.01*
1011000	(a) swine	
1011010	Muscle	
1011020	Fat	
1011030	Liver	
1011040	Kidney	
1011050	Edible offals (other than liver and kidney)	
1011990	Others (2)	
1012000	(b) bovine	
1012010	Muscle	
1012020	Fat	
1012030	Liver	
1012040	Kidney	
1012050	Edible offals (other than liver and kidney)	
1012990	Others (2)	
1013000	(c) sheep	
1013010	Muscle	
1013020	Fat	
1013030	Liver	
1013040	Kidney	
1013050	Edible offals (other than liver and kidney)	
1013990	Others (2)	
1014000	d) goat	
1014010	Muscle	
1014020	Fat	
1014030	Liver	
1014040	Kidney	
1014050	Edible offals (other than liver and kidney)	
1014990	Others (2)	
1015000	(e) equine	**
1015010	Muscle	**
1015020	Fat	**
1015030	Liver	**
1015040	Kidney	**
1015050	Edible offals (other than liver and kidney)	**
1015990	Others (2)	**
1016000	(f) poultry	
1016010	Muscle	
1016020	Fat	
1016030	Liver	
1016040	Kidney	
1016050	Edible offals (other than liver and kidney)	
1016990	Others (2)	
1017000	(g) other farmed terrestrial animals	**
1017010	Muscle	**
1017020	Fat	**
1017030	Liver	**
1017040	Kidney	**
1017050	Edible offals (other than liver and kidney)	**
1017990	Others (2)	**
1020000	Milk	0.01*
1020010	Cattle	
1020020	Sheep	
1020030	Goat	
1020040	Horse	
1020990	Others (2)	
1030000	Birds eggs	0.01*
1030010	Chicken	
1030020	Duck	**
1030030	Geese	**
1030040	Quail	**
1030990	Others (2)	**
1040000	Honey and other apiculture products (7)	**
1050000	Amphibians and Reptiles	**
1060000	Terrestrial invertebrate animals	**
1070000	Wild terrestrial vertebrate animals	**
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)	

(*) Limit of analytical determination

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

Imazalil (any ration of constituent isomers)

- (+) The European Food Safety Authority identified some information on residue trials as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by [Office of Publication: please insert date 2 years after publication], or, if that information is not submitted by that date, the last of



Electronically signed on 12/12/2018 08:52 (UTC+01) in accordance with article 4.2 (Validity of electronic documents) of Commission Decision 2004/563