

COMMISSION REGULATION (EU) 2020/192**of 12 February 2020****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 prochloraz 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 prochloraz, maximum residue limits (MRLs) were set in Annex II and Part B of Annex III to Regulation (EC) No 396/2005.
- (2) For that active substance, the European Food Safety Authority ('the Authority') submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005 ⁽²⁾. The Authority proposed to change the residue definition to the sum of prochloraz, BTS 44595 (M201-04) and BTS 44596 (M201-03), expressed as prochloraz. The Authority identified a risk for consumers concerning the MRLs for citrus fruits, kiwi, bananas, mangoes, pineapples and bovine liver. It is therefore appropriate to lower these MRLs to the Limit of Determination (LOD) or the level identified by the Authority. The Authority recommended lowering the MRLs for garlic, shallots, lettuces and salad plants, purslanes, herbs and edible flowers, peas, linseeds, sunflower seeds, rapeseeds/canola seeds, barley, oat, rice, rye, wheat, coffee beans, herbal infusions from flowers, leaves and herbs and roots, spices, sugar beet roots, bovine (fat, kidney), equine fat and poultry liver. As there is no risk for consumers, the MRLs for those products should be set in Annex II to Regulation (EC) No 396/2005 at the level identified by the Authority. The Authority concluded that concerning the Codex maximum residue levels (CXLs) for kumquats, litchis/lychees, passionfruits/maracujas, prickly pears/cactus fruits, star apples/cainitos, American persimmons/Virginia kaki, avocados, papayas, Granate apples/pomegranates, cherimoyas, guavas, breadfruits, durians and soursops/guanabanas, some information was not available in relation to the new residue definition and that further consideration by risk managers was required. As there is no risk for consumers, the MRLs for those products should be set in Annex II to Regulation (EC) No 396/2005 at the level of the existing CXLs. These MRLs will be reviewed; the review will take into account the information available within two years from the publication of this Regulation.
- (3) As regards products on which the use of the plant protection products concerned is not authorised, and for which no import tolerances or 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.
- (4) 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.
- (5) 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.
- (6) 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.

⁽¹⁾ OJ L 70, 16.3.2005, p. 1.

⁽²⁾ European Food Safety Authority; Review of the existing maximum residue levels for prochloraz according to Article 12 of Regulation (EC) No 396/2005. *EFSA Journal* 2018; 16(8):5401.

- (7) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (8) 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.
- (9) 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.
- (10) 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

Annexes II and III to Regulation (EC) No 396/2005 are amended in accordance with the Annex to this Regulation.

Article 2

As regards the active substance prochloraz in and on all products except citrus fruits, kiwi, bananas, mangoes, pineapples and bovine liver, Regulation (EC) No 396/2005 as it stood before being amended by this Regulation shall continue to apply to products which were produced in the Union or imported into the Union before 4 September 2020.

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 4 September 2020.

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

Done at Brussels, 12 February 2020.

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 column for prochloraz is replaced by the following:

Code number	Groups and examples of individual products to which the MRLs apply (a)	Prochloraz (sum of prochloraz, BTS 44595 (M201-04) and BTS 44596 (M201-03), expressed as prochloraz) (F)
0100000	FRUITS, FRESH or FROZEN; TREE NUTS	
0110000	Citrus fruits	0.03*
0110010	Grapefruits	
0110020	Oranges	
0110030	Lemons	
0110040	Limes	
0110050	Mandarins	
0110990	Others (2)	
0120000	Tree nuts	0.03*
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	0.03*
0130010	Apples	
0130020	Pears	
0130030	Quinces	
0130040	Medlars	
0130050	Loquats/Japanese medlars	
0130990	Others (2)	
0140000	Stone fruits	0.03*
0140010	Apricots	
0140020	Cherries (sweet)	
0140030	Peaches	
0140040	Plums	
0140990	Others (2)	

Code number	Groups and examples of individual products to which the MRLs apply (a)	Prochloraz (sum of prochloraz, BTS 44595 (M201-04) and BTS 44596 (M201-03), expressed as prochloraz) (F)
0150000	Berries and small fruits	0.03*
0151000	(a) grapes	
0151010	Table grapes	
0151020	Wine grapes	
0152000	(b) strawberries	
0153000	(c) cane fruits	
0153010	Blackberries	
0153020	Dewberries	
0153030	Raspberries (red and yellow)	
0153990	Others (2)	
0154000	(d) other small fruits and berries	
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	
0161000	(a) edible peel	
0161010	Dates	0.03*
0161020	Figs	0.03*
0161030	Table olives	0.03*
0161040	Kumquats	10 (+)
0161050	Carambolas	0.03*
0161060	Kaki/Japanese persimmons	0.03*
0161070	Jambuls/jambolans	0.03*
0161990	Others (2)	0.03*
0162000	(b) inedible peel, small	
0162010	Kiwi fruits (green, red, yellow)	0.03*
0162020	Litchis/lychees	7 (+)
0162030	Passionfruits/maracujas	7 (+)
0162040	Prickly pears/cactus fruits	7 (+)
0162050	Star apples/cainitos	7 (+)
0162060	American persimmons/Virginia kaki	7 (+)

Code number	Groups and examples of individual products to which the MRLs apply (a)	Prochloraz (sum of prochloraz, BTS 44595 (M201-04) and BTS 44596 (M201-03), expressed as prochloraz) (F)
0162990	Others (2)	0.03*
0163000	(c) inedible peel, large	
0163010	Avocados	7 (+)
0163020	Bananas	0.03*
0163030	Mangoes	0.03*
0163040	Papayas	7 (+)
0163050	Granate apples/pomegranates	7 (+)
0163060	Cherimoyas	7 (+)
0163070	Guavas	7 (+)
0163080	Pineapples	0.03*
0163090	Breadfruits	7 (+)
0163100	Durians	7 (+)
0163110	Soursops/guanabanas	7 (+)
0163990	Others (2)	0.03*
0200000	VEGETABLES, FRESH or FROZEN	
0210000	Root and tuber vegetables	0.03*
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	
0213060	Parsnips	
0213070	Parsley roots/Hamburg roots parsley	
0213080	Radishes	
0213090	Salsifies	
0213100	Swedes/rutabagas	
0213110	Turnips	
0213990	Others (2)	

Code number	Groups and examples of individual products to which the MRLs apply (a)	Prochloraz (sum of prochloraz, BTS 44595 (M201-04) and BTS 44596 (M201-03), expressed as prochloraz) (F)
0220000	Bulb vegetables	0.03*
0220010	Garlic	
0220020	Onions	
0220030	Shallots	
0220040	Spring onions/green onions and Welsh onions	
0220990	Others (2)	
0230000	Fruiting vegetables	0.03*
0231000	(a) Solanaceae and Malvaceae	
0231010	Tomatoes	
0231020	Sweet peppers/bell peppers	
0231030	Aubergines/eggplants	
0231040	Okra/lady's fingers	
0231990	Others (2)	
0232000	(b) cucurbits with edible peel	
0232010	Cucumbers	
0232020	Gherkins	
0232030	Courgettes	
0232990	Others (2)	
0233000	(c) cucurbits with inedible peel	
0233010	Melons	
0233020	Pumpkins	
0233030	Watermelons	
0233990	Others (2)	
0234000	(d) sweet corn	
0239000	(e) other fruiting vegetables	
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	0.03*
0241000	(a) flowering brassica	
0241010	Broccoli	
0241020	Cauliflowers	
0241990	Others (2)	
0242000	(b) head brassica	
0242010	Brussels sprouts	
0242020	Head cabbages	
0242990	Others (2)	

Code number	Groups and examples of individual products to which the MRLs apply (a)	Prochloraz (sum of prochloraz, BTS 44595 (M201-04) and BTS 44596 (M201-03), expressed as prochloraz) (F)
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	0.03*
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	0.03*
0252010	Spinaches	
0252020	Purslanes	
0252030	Chards/beet leaves	
0252990	Others (2)	
0253000	(c) grape leaves and similar species	0.03*
0254000	(d) watercresses	0.03*
0255000	(e) witloofs/Belgian endives	0.03*
0256000	(f) herbs and edible flowers	0.06*
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)	

Code number	Groups and examples of individual products to which the MRLs apply (a)	Prochloraz (sum of prochloraz, BTS 44595 (M201-04) and BTS 44596 (M201-03), expressed as prochloraz) (F)
0260000	Legume vegetables	0.03*
0260010	Beans (with pods)	
0260020	Beans (without pods)	
0260030	Peas (with pods)	
0260040	Peas (without pods)	
0260050	Lentils	
0260990	Others (2)	
0270000	Stem vegetables	0.03*
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	
0280010	Cultivated fungi	3
0280020	Wild fungi	0.03*
0280990	Mosses and lichens	0.03*
0290000	Algae and prokaryotes organisms	0.03*
0300000	PULSES	0.03*
0300010	Beans	
0300020	Lentils	
0300030	Peas	
0300040	Lupins/lupini beans	
0300990	Others (2)	
0400000	OILSEEDS AND OIL FRUITS	
0401000	Oilseeds	
0401010	Linseeds	0.3
0401020	Peanuts/groundnuts	0.03*
0401030	Poppy seeds	0.3
0401040	Sesame seeds	0.03*
0401050	Sunflower seeds	0.3
0401060	Rapeseeds/canola seeds	0.3

Code number	Groups and examples of individual products to which the MRLs apply (a)	Prochloraz (sum of prochloraz, BTS 44595 (M201-04) and BTS 44596 (M201-03), expressed as prochloraz) (F)
0401070	Soyabeans	0.03*
0401080	Mustard seeds	0.03*
0401090	Cotton seeds	0.03*
0401100	Pumpkin seeds	0.03*
0401110	Safflower seeds	0.03*
0401120	Borage seeds	0.03*
0401130	Gold of pleasure seeds	0.03*
0401140	Hemp seeds	0.03*
0401150	Castor beans	0.03*
0401990	Others (2)	0.03*
0402000	Oil fruits	0.03*
0402010	Olives for oil production	
0402020	Oil palms kernels	
0402030	Oil palms fruits	
0402040	Kapok	
0402990	Others (2)	
0500000	CEREALS	
0500010	Barley	0.03*
0500020	Buckwheat and other pseudocereals	0.03*
0500030	Maize/corn	0.03*
0500040	Common millet/proso millet	0.03*
0500050	Oat	0.03*
0500060	Rice	0.03*
0500070	Rye	0.2
0500080	Sorghum	0.03*
0500090	Wheat	0.2
0500990	Others (2)	0.03*
0600000	TEAS, COFFEE, HERBAL INFUSIONS, COCOA AND CAROBS	0.15*
0610000	Teas	
0620000	Coffee beans	
0630000	Herbal infusions from	
0631000	(a) flowers	
0631010	Chamomile	
0631020	Hibiscus/roselle	
0631030	Rose	
0631040	Jasmine	
0631050	Lime/linden	

Code number	Groups and examples of individual products to which the MRLs apply (a)	Prochloraz (sum of prochloraz, BTS 44595 (M201-04) and BTS 44596 (M201-03), expressed as prochloraz) (F)
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	0.15*
0800000	SPICES	
0810000	Seed spices	0.15*
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	0.15*
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)	

Code number	Groups and examples of individual products to which the MRLs apply (a)	Prochloraz (sum of prochloraz, BTS 44595 (M201-04) and BTS 44596 (M201-03), expressed as prochloraz) (F)
0830000	Bark spices	0.15*
0830010	Cinnamon	
0830990	Others (2)	
0840000	Root and rhizome spices	
0840010	Liquorice	0.15*
0840020	Ginger (10)	0.15*
0840030	Turmeric/curcuma	0.15*
0840040	Horseradish (11)	
0840990	Others (2)	0.15*
0850000	Bud spices	0.15*
0850010	Cloves	
0850020	Capers	
0850990	Others (2)	
0860000	Flower pistil spices	0.15*
0860010	Saffron	
0860990	Others (2)	
0870000	Aril spices	0.15*
0870010	Mace	
0870990	Others (2)	
0900000	SUGAR PLANTS	0.03*
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	0.03*
1011020	Fat	0.03*
1011030	Liver	0.3 (+)
1011040	Kidney	0.05 (+)
1011050	Edible offals (other than liver and kidney)	0.03*
1011990	Others (2)	0.03*
1012000	(b) bovine	
1012010	Muscle	0.03*
1012020	Fat	0.07 (+)
1012030	Liver	1 (+)

Code number	Groups and examples of individual products to which the MRLs apply (a)	Prochloraz (sum of prochloraz, BTS 44595 (M201-04) and BTS 44596 (M201-03), expressed as prochloraz) (F)
1012040	Kidney	0.2 (+)
1012050	Edible offals (other than liver and kidney)	0.03*
1012990	Others (2)	0.03*
1013000	(c) sheep	
1013010	Muscle	0.03*
1013020	Fat	0.15 (+)
1013030	Liver	3 (+)
1013040	Kidney	0.5 (+)
1013050	Edible offals (other than liver and kidney)	0.03*
1013990	Others (2)	0.03*
1014000	d) goat	
1014010	Muscle	0.03*
1014020	Fat	0.15 (+)
1014030	Liver	3 (+)
1014040	Kidney	0.5 (+)
1014050	Edible offals (other than liver and kidney)	0.03*
1014990	Others (2)	0.03*
1015000	(e) equine	
1015010	Muscle	0.03*
1015020	Fat	0.07 (+)
1015030	Liver	1 (+)
1015040	Kidney	0.2 (+)
1015050	Edible offals (other than liver and kidney)	0.03*
1015990	Others (2)	0.03*
1016000	(f) poultry	
1016010	Muscle	0.03* (+)
1016020	Fat	0.03* (+)
1016030	Liver	0.04 (+)
1016040	Kidney	0.03* (+)
1016050	Edible offals (other than liver and kidney)	0.03* (+)
1016990	Others (2)	0.03* (+)
1017000	(g) other farmed terrestrial animals	0.03*
1017010	Muscle	
1017020	Fat	
1017030	Liver	
1017040	Kidney	
1017050	Edible offals (other than liver and kidney)	

Code number	Groups and examples of individual products to which the MRLs apply (a)	Prochloraz (sum of prochloraz, BTS 44595 (M201-04) and BTS 44596 (M201-03), expressed as prochloraz) (F)
1017990	Others (2)	
1020000	Milk	0.03*
1020010	Cattle	
1020020	Sheep	
1020030	Goat	
1020040	Horse	
1020990	Others (2)	
1030000	Birds eggs	0.1
1030010	Chicken	(+)
1030020	Duck	(+)
1030030	Geese	(+)
1030040	Quail	(+)
1030990	Others (2)	
1040000	Honey and other apiculture products (7)	0.15*
1050000	Amphibians and Reptiles	0.03*
1060000	Terrestrial invertebrate animals	0.03*
1070000	Wild terrestrial vertebrate animals	0.03*
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.

(F) = Fat soluble

Prochloraz (sum of prochloraz, BTS 44595 (M201-04) and BTS 44596 (M201-03), expressed as prochloraz) (F)

(+) The European Food Safety Authority identified some information on residue trials in relation with the new residue definition 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 lack of it.

- 0161040 Kumquats
- 0162020 Litchis/lychees
- 0162030 Passionfruits/maracujas
- 0162040 Prickly pears/cactus fruits
- 0162050 Star apples/cainitos
- 0162060 American persimmons/Virginia kaki
- 0163010 Avocados
- 0163040 Papayas
- 0163050 Granate apples/pomegranates
- 0163060 Cherimoyas

0163070 Guavas
0163090 Breadfruits
0163100 Durians
0163110 Soursops/guanabanas

- (+) The European Food Safety Authority identified some information on feeding studies analysing both enforcement and risk assessment residue definitions 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 lack of it.

1011030 Liver
1011040 Kidney
1012020 Fat
1012030 Liver
1012040 Kidney
1013020 Fat
1013030 Liver
1013040 Kidney
1014020 Fat
1014030 Liver
1014040 Kidney
1015020 Fat
1015030 Liver
1015040 Kidney
1016010 Muscle
1016020 Fat
1016030 Liver
1016040 Kidney
1016050 Edible offals (other than liver and kidney)
1016990 Others (2)
1030010 Chicken
1030020 Duck
1030030 Geese
1030040 Quail

- (2) in part B of Annex III the column for prochloraz is deleted.
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