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COMMISSION REGULATION (EU) .../...

of XXX

amending Annex III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for chlorate in or on certain products

(Text with EEA relevance)

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of **XXX**

amending Annex III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for chlorate 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 16(1)(a) thereof,

Whereas:

- (1) According to Commission Decision 2008/865/EC² all authorisations for plant protection products containing chlorate have been revoked following the non-inclusion of chlorate in Annex I to Council Directive 91/414/EEC³.
- (2) No specific maximum residue levels (MRLs) have been set for chlorate and, as this substance has not been included in Annex IV to Regulation (EC) No 396/2005, currently the default MRL of 0.01 mg/kg applies to all food and feed commodities included in Annex I to Regulation (EC) No 396/2005.
- (3) Apart from its former use in plant protection products, chlorate is also a substance that is formed as by-product resulting from the use of chlorine disinfectants in food and drinking water processing. These uses lead to the current situation of detectable residues of chlorate in food.
- (4) The European Food Safety Authority ('the Authority') collected between 2014 and 2018 monitoring data to investigate the presence of residues of chlorate in food and drinking water. Those data indicated that chlorate residues are present at levels that frequently exceed the default MRL of 0.01 mg/kg and that the levels vary depending on the source and the product. It follows from those findings that even if good practices are used, it is currently not possible to achieve levels of chlorate residues compliant with the current MRL of 0.01 mg/kg.
- (5) The Authority adopted a scientific opinion concerning the risks for public health related to the presence of chlorate in food.⁴ In that opinion the Authority established a

¹ OJ L 70, 16.3.2005, p. 1.

² Commission Decision 2008/865/EC of 10 November 2008 concerning the non-inclusion of chlorate in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance (OJ L 307, 18.11.2008, p. 7).

³ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.08.1991, p. 1).

⁴ EFSA (European Food Safety Authority), 2015. Scientific opinion on the risks for public health related to the presence of chlorate in food. EFSA Journal 2015;13(6):4135, 103 pp.

tolerable daily intake (TDI) of 3 µg/kg body weight per day and an acute reference dose (ARfD) of 36 µg/kg body weight. The Authority concluded that based on the data collected in 2014 the acute dietary exposure to chlorate did not exceed the ARfD. The mean dietary exposures to chlorate in European countries exceeded the TDI in certain subgroups of the population such as infants and young children with mild to moderate iodine deficiency.

- (6) In order to bring chlorate levels down and reduce exposure through coordinated action in several relevant and related sectors, a multi-disciplinary action plan was agreed by the Member States in 2017 comprising a set of actions to be taken in parallel, including actions on drinking water, hygiene, and the setting of temporary maximum residue levels for food and feed.
- (7) This Regulation addresses the setting of temporary maximum levels in food. For this purpose a large number of occurrence data was collected between 2014 and 2018, both by Member States and by food business operators. The data shows a general trend towards decreasing levels, suggesting that manufacturing practices have already improved to a certain extent. In the specific case of chlorate, for which residues do not stem from pesticide use but result from use of chlorine-based solutions in food processing and drinking water treatment, maximum levels should be set at levels which are 'as low as reasonably achievable' (ALARA principle) by following good manufacturing practices while ensuring at the same time that good hygiene practices remain possible. This approach ensures that food business operators apply measures to prevent and reduce the chlorate levels in food as far as possible in order to protect public health, but also take into account the need for microbiological safety of food.
- (8) Temporary MRLs for chlorate according to the ALARA principle are based on the 95th percentile of the occurrence data, taking into account the use of legitimately treated drinking water in food processing. The temporary MRLs should be reviewed at the latest within five years of publication of this Regulation in the light of possible developments in the area of hygiene, of drinking water, further progress made by food business operators to bring chlorate levels down, or whenever new information and data become available that would warrant an earlier review.
- (9) The Commission consulted the European Union reference laboratories on appropriate limits of determination (LODs) for chlorate residues in certain specific commodities.
- (10) Based on the scientific opinion of the Authority and taking into account the factors relevant to the matter under consideration, the proposed MRLs fulfil the requirements of Article 14(2) of Regulation (EC) No 396/2005.
- (11) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (12) 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 III to Regulation (EC) No 396/2005 is amended in accordance with the Annex to this Regulation.

Article 2

The temporary MRLs for chlorate shall be reviewed not later than [*Office of Publication: please insert date 5 years after publication*].

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*.

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

Done at Brussels,

*For the Commission
The President*

EN
ANNEX

In Part A of Annex III to Regulation (EC) No 396/2005 the following column for chlorate is added:

'[Office of Publication: please insert table Annex IIIA]'

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[Annex IIIA]

Pesticide residues and maximum residue levels (mg/kg)

Code number	Groups and examples of individual products to which the MRLs apply (a)	Chlorate (A)
0100000	FRUITS, FRESH or FROZEN; TREE NUTS	
0110000	Citrus fruits	0.05
0110010	Grapefruits	
0110020	Oranges	
0110030	Lemons	
0110040	Limes	
0110050	Mandarins	
0110990	Others (2)	
0120000	Tree nuts	0.1
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	0.05
0130010	Apples	
0130020	Pears	
0130030	Quinces	
0130040	Medlars	
0130050	Loquats/Japanese medlars	
0130990	Others (2)	
0140000	Stone fruits	0.05
0140010	Apricots	
0140020	Cherries (sweet)	
0140030	Peaches	
0140040	Plums	
0140990	Others (2)	
0150000	Berries and small fruits	0.05
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 fruitswith	
0161000	(a) edible peel	
0161010	Dates	0.3
0161020	Figs	0.3
0161030	Table olives	0.7
0161040	Kumquats	0.3
0161050	Carambolas	0.3
0161060	Kaki/Japanese persimmons	0.3
0161070	Jambuls/jambolans	0.3
0161990	Others (2)	0.3
0162000	(b) inedible peel, small	0.3
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	0.3
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	0.05
0212000	(b) tropical root and tuber vegetables	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	0.15
0213010	Beetroots	
0213020	Carrots	
0213030	Celeriacs/turnip rooted celeries	
0213040	Horseradishes	
0213050	Jerusalem artichokes	

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[Annex IIIA]

Pesticide residues and maximum residue levels (mg/kg)

Code number	Groups and examples of individual products to which the MRLs apply (a)	Chlorate (A)
0213060	Parsnips	
0213070	Parsley roots/Hamburg roots parsley	
0213080	Radishes	
0213090	Salsifies	
0213100	Swedes/rutabagas	
0213110	Turnips	
0213990	Others (2)	
0220000	Bulb vegetables	
0220010	Garlic	0.7
0220020	Onions	0.5
0220030	Shallots	0.5
0220040	Spring onions/green onions and Welsh onions	0.5
0220990	Others (2)	0.05
0230000	Fruiting vegetables	
0231000	(a) Solanaceae and Malvaceae	
0231010	Tomatoes	0.1
0231020	Sweet peppers/bell peppers	0.3
0231030	Aubergines/eggplants	0.4
0231040	Okra/lady's fingers	0.1
0231990	Others (2)	0.1
0232000	(b) cucurbits with edible peel	0.2
0232010	Cucumbers	
0232020	Cherkins	
0232030	Courgettes	
0232990	Others (2)	
0233000	(c) cucurbits with inedible peel	0.08
0233010	Melons	
0233020	Pumpkins	
0233030	Watermelons	
0233990	Others (2)	
0234000	(d) sweet corn	0.1
0239000	(e) other fruiting vegetables	0.1
0240000	Brassica vegetables(excluding brassica roots and brassica baby leaf crops)	
0241000	(a) flowering brassica	
0241010	Broccoli	0.4
0241020	Cauliflowers	0.06
0241990	Others (2)	0.06
0242000	(b) head brassica	0.07
0242010	Brussels sprouts	
0242020	Head cabbages	
0242990	Others (2)	
0243000	(c) leafy brassica	0.06
0243010	Chinese cabbages/pe-tsai	
0243020	Kales	
0243990	Others (2)	
0244000	(d) kohlrabies	0.06
0250000	Leaf vegetables, herbs and edible flowers	0.7
0251000	(a) lettuces and salad plants	
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	
0252010	Spinaches	
0252020	Purslanes	
0252030	Chards/beet leaves	
0252990	Others (2)	
0253000	(c) grape leaves and similar species	
0254000	(d) watercresses	
0255000	(e) witloofs/Belgian endives	
0256000	(f) herbs and edible flowers	
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	0.35
0260010	Beans (with pods)	
0260020	Beans (without pods)	
0260030	Peas (with pods)	
0260040	Peas (without pods)	
0260050	Lentils	
0260990	Others (2)	
0270000	Stem vegetables	0.25
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	0.7
0280020	Wild fungi	0.7
0280990	Mosses and lichens	0.05

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[Annex IIIA]

Pesticide residues and maximum residue levels (mg/kg)

Code number	Groups and examples of individual products to which the MRLs apply (a)	Chlorate (A)
0290000	Algae and prokaryotes organisms	0.05
0300000	PULSES	0.35
0300010	Beans	
0300020	Lentils	
0300030	Peas	
0300040	Lupins/lupini beans	
0300990	Others (2)	
0400000	OILSEEDS AND OIL FRUITS	
0401000	Oilseeds	0.05
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	0.7
0402010	Olives for oil production	
0402020	Oil palms kernels	
0402030	Oil palms fruits	
0402040	Kapok	
0402990	Others (2)	
0500000	CEREALS	0.05
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	0.07
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	0.07
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	0.07
0830010	Cinnamon	
0830990	Others (2)	
0840000	Root and rhizome spices	
0840010	Liquorice	0.07
0840020	Ginger (10)	
0840030	Turmeric/curcuma	0.07
0840040	Horseradish (11)	
0840990	Others (2)	0.07
0850000	Bud spices	0.07
0850010	Cloves	
0850020	Capers	

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[Annex IIIA]

Pesticide residues and maximum residue levels (mg/kg)

Code number	Groups and examples of individual products to which the MRLs apply (a)	Chlorate (A)
0850990	Others (2)	
0860000	Flower pistil spices	0.07
0860010	Saffron	
0860990	Others (2)	
0870000	Aril spices	0.07
0870010	Mace	
0870990	Others (2)	
0900000	SUGAR PLANTS	0.05
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	0.05
1011020	Fat	0.1*
1011030	Liver	0.05
1011040	Kidney	0.05
1011050	Edible offals (other than liver and kidney)	0.05
1011990	Others (2)	0.05
1012000	(b) bovine	
1012010	Muscle	0.05
1012020	Fat	0.1*
1012030	Liver	0.05
1012040	Kidney	0.05
1012050	Edible offals (other than liver and kidney)	0.05
1012990	Others (2)	0.05
1013000	(c) sheep	
1013010	Muscle	0.05
1013020	Fat	0.1*
1013030	Liver	0.05
1013040	Kidney	0.05
1013050	Edible offals (other than liver and kidney)	0.05
1013990	Others (2)	0.05
1014000	d) goat	
1014010	Muscle	0.05
1014020	Fat	0.1*
1014030	Liver	0.05
1014040	Kidney	0.05
1014050	Edible offals (other than liver and kidney)	0.05
1014990	Others (2)	0.05
1015000	(e) equine	
1015010	Muscle	0.05
1015020	Fat	0.1*
1015030	Liver	0.05
1015040	Kidney	0.05
1015050	Edible offals (other than liver and kidney)	0.05
1015990	Others (2)	0.05
1016000	(f) poultry	
1016010	Muscle	0.05
1016020	Fat	0.1*
1016030	Liver	0.05
1016040	Kidney	0.05
1016050	Edible offals (other than liver and kidney)	0.05
1016990	Others (2)	0.05
1017000	(g) other farmed terrestrial animals	
1017010	Muscle	0.05
1017020	Fat	0.1*
1017030	Liver	0.05
1017040	Kidney	0.05
1017050	Edible offals (other than liver and kidney)	0.05
1017990	Others (2)	0.05
1020000	Milk	0.1
1020010	Cattle	(+)
1020020	Sheep	(+)
1020030	Goat	(+)
1020040	Horse	(+)
1020990	Others (2)	(+)
1030000	Birds eggs	0.05
1030010	Chicken	
1030020	Duck	
1030030	Geese	
1030040	Quail	
1030990	Others (2)	
1040000	Honey and other apiculture products (7)	0.05*
1050000	Amphibians and Reptiles	0.05
1060000	Terrestrial invertebrate animals	0.05
1070000	Wild terrestrial vertebrate animals	0.05
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.

Chlorate (A)

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[Annex IIIA]

Pesticide residues and maximum residue levels (mg/kg)

Code number	Groups and examples of individual products to which the MRLs apply (a)	Chlorate (A)
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(A) To take into account the specific situation of chlorate residues, in processed food (including for the purpose of this Regulation foodstuffs that have been derived using processes listed in Article 2(1)(n) of Regulation (EC) No 852/2004), that has come in contact with products containing chlorate residues, or that contains ingredients with such residues, such as processing aids or drinking water, used in compliance with the respective legal requirements, these additional contributions of chlorate residues should be taken into account when determining the permitted content of chlorate residues in or on the processed food products in accordance with Article 20 (1) of this Regulation. The burden of proof regarding the level of those additional contributions lies with the food and feed business operator.

(+) Includes raw milk, heat-treated milk and milk for the manufacture of milk-based products as defined in Regulation (EU) No 1308/2013. The MRL applies to milk ready for use (marketed as such or reconstituted as instructed by the manufacturer)

1020010 Cattle

(+) Includes raw milk, heat-treated milk and milk for the manufacture of milk-based products. The MRL applies to milk ready for use (marketed as such or reconstituted as instructed by the manufacturer)

1020020 Sheep

1020030 Goat

1020040 Horse