

# 2024/2711

### COMMISSION REGULATION (EU) 2024/2711

### of 22 October 2024

amending Annexes II and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for thiacloprid 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 (<sup>1</sup>), and in particular Article 14(1), point (a), Article 18(1), and Article 49(2) thereof,

#### Whereas:

- (1) For the active substance thiacloprid, maximum residue levels ('MRLs') were set in Annex II to Regulation (EC) No 396/2005. The European Food Safety Authority (the 'Authority') reviewed these MRLs in accordance with Article 12 of Regulation (EC) No 396/2005 and recommended MRLs which it found to be safe for consumers (<sup>2</sup>). Commission Regulation (EU) 2015/1200 (<sup>3</sup>) included these MRLs in Annex II to Regulation (EC) No 396/2005.
- (2) In 2020, the approval of this active substance was not renewed (\*) on the basis of Regulation (EC) No 1107/2009 of the European Parliament and of the Council (\*), in view of the critical concerns identified by the Authority in the conclusions of the peer review in relation to the contamination of groundwater with potential carcinogenic metabolites of thiacloprid (\*) and its classification, in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council (7), as toxic for reproduction category 1B. Since the substance did not fulfil the approval criteria, the Authority did not consider it necessary to finalise the assessment of the possible endocrine disrupting properties of thiacloprid on the basis of the most recent criteria in points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009 (\*). The Authority noted, however, that thiacloprid was considered to meet the

<sup>(1)</sup> OJ L 70, 16.3.2005, p. 1, ELI: http://data.europa.eu/eli/reg/2005/396/2024-02-26.

<sup>(2)</sup> EFSA (European Food Safety Authority), 2014. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for thiacloprid according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2014;12(3):3617, https://doi:10.2903/j.efsa.2014.3617.

<sup>(&</sup>lt;sup>3</sup>) Commission Regulation (EU) 2015/1200 of 22 July 2015 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 amidosulfuron, fenhexamid, kresoxim-methyl, thiacloprid and trifloxystrobin in or on certain products (OJ L 195, 23.7.2015, p. 1, ELI: http://data.europa.eu/eli/reg/2015/1200/oj).

<sup>(\*)</sup> Commission Implementing Regulation (EU) 2020/23 of 13 January 2020 concerning the non-renewal of the approval of the active substance thiacloprid, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 8, 14.1.2020, p. 8, ELI: http://data.europa.eu/eli/reg\_impl/2020/23/oj).

<sup>(&</sup>lt;sup>5</sup>) Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1, ELI: http://data.europa.eu/eli/reg/2009/1107/2022-11-21.

<sup>(\*)</sup> EFSA (European Food Safety Authority), 2019. Conclusion on pesticides peer review. Peer review of the pesticide risk assessment of the active substance thiacloprid. EFSA Journal 2019;17(3): e05595, https://doi.org/10.2903/j.efsa.2019.5595.

<sup>(7)</sup> Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1, ELI: http://data.europa.eu/eli/reg/2008/1272/2023-12-01).

<sup>(\*)</sup> Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties (OJ L 101, 20.4.2018, p. 33, ELI: http://data.europa.eu/eli/ reg/2018/605/2018-04-20).

criteria for endocrine disrupting properties set out in 2013 (9) and the WHO definition for endocrine disruptors (10), since it causes adverse effects on the reproductive and endocrine system through an endocrine mode of action.

- (3) All existing authorisations for plant protection products containing thiacloprid have been revoked. It is therefore appropriate to delete the existing MRLs set out for this active substance in Annex II of Regulation (EC) No 396/2005 in accordance with Article 17 of that Regulation in conjunction with Article 14(1), point (a) thereof. In view of the new toxicological reference values, in particular a lower acute reference dose, as proposed in the conclusion of the peer review, the Commission requested the Authority to provide a statement under Article 43 of Regulation (EC) No 396/2005 containing a short-term (acute) dietary risk assessment for the MRLs that are based on non-EU uses, being those that are based on import tolerance requests and those that are based on Codex maximum residue limits ('CXLs') set in 2007.
- (4) In its statement (<sup>11</sup>), the Authority identified a risk for consumers concerning the CXLs for peaches and sweet peppers/bell peppers. It is therefore appropriate to lower the MRLs for those products to the product-specific limits of determination ('LODs'). For the MRLs for papayas and tea, which were derived from import tolerances, and for the MRLs for quinces, medlars, loquats/Japanese medlars, apricots, cherries (sweet), plums, strawberries, 'cane fruits', 'other small fruits and berries', kiwis, potatoes, tomatoes, aubergines/eggplants, 'cucurbits with edible peel', melons, watermelons, rapeseeds/canola seeds, mustards seeds, rice, wheat, 'animal (swine, bovine, sheep, horse, and other farm animals) products from tissues (muscle, liver, kidney and edible offal)', poultry (muscle, liver and edible offal), milk and eggs, which are based on CXLs, the Authority did not identify an acute risk for the consumers but concluded that further consideration by risk managers was required.
- (5) The risk assessment carried out by the Authority was based on existing toxicological reference values. These toxicological reference values do not necessarily reflect endocrine-related effects because they were not assessed according to the new EU criteria established in 2018 (<sup>8</sup>). Furthermore, endocrine-related effects frequently occur at low-dose levels and endocrine disruptor substances often do not have a safe threshold (<sup>12</sup>). As a result, there remain reasonable grounds for concern that the MRLs that are based on non-EU uses have potentially harmful effects on human health and are inconsistent with the high level of consumer protection in the Union. The Commission has therefore requested the Authority to carry out an additional assessment for thiacloprid taking into account the most recent criteria for endocrine disruptors.
- (6) Pending the conclusion of this additional risk assessment by the Authority, and given the available pertinent information with regard to potentially harmful effects on human health, it is appropriate to provisionally lower the MRLs that are based on non-EU uses. These MRLs will be reviewed once the assessment by the Authority is concluded.
- (7) The Commission consulted the European Union reference laboratories for residues of thiacloprid as regards the need to adapt certain LODs. Those laboratories proposed product specific LODs that are analytically achievable for all products.

<sup>(\*)</sup> EFSA (European Food Safety Authority) Scientific Committee, 2013. Scientific Opinion on the hazard assessment of endocrine disruptors: scientific criteria for identification of endocrine disruptors and appropriateness of existing test methods for assessing effects mediated by these substances on human health and the environment. EFSA Journal 2013;11(3):3132.84, https://doi: 10.2903/j.efsa.2013.3132.

<sup>(&</sup>lt;sup>10</sup>) WHO/IPCS (World Health Organization/International Programme on Chemical Safety), 2002. Global Assessment of the State-of-thescience of Endocrine Disruptors. WHO/PCS/EDC/02.2, https://iris.who.int/bitstream/handle/10665/67357/ WHO\_PCS\_EDC\_02.2.pdf?sequence=1.

<sup>(&</sup>lt;sup>11</sup>) EFSA (European Food Safety Authority) 2023; Statement on the short-term (acute) dietary risk assessment and evaluation of confirmatory data for certain maximum residue levels (MRLs) for thiacloprid. EFSA Journal 2023;21(3):7888, https://doi.org/ 10.2903/j.efsa.2023.7888.

<sup>(&</sup>lt;sup>12</sup>) EFSA (European Food Safety Authority) 2010; Scientific report of the Endocrine Active Substances Task Force. EFSA Journal 2010;8(11):1932, https://doi.org/10.2903/j.efsa.2010.1932.

- (8) 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.
- (9) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (10) To allow for the normal marketing, processing and consumption of products, this Regulation should not apply to products which have been placed on the market in the Union before the new MRLs become applicable, except for pears, peaches, raspberries (red and yellow), sweet peppers/bell peppers, Chinese cabbages/pe-tsai and lettuces for which an acute risk to consumers was identified. This transitional measure is justified and proportionate given the limited range of products for which such a period would effectively apply (mainly long shelf life products and not fresh perishable products) and the low exposure of consumers from such products, as evidenced by recent monitoring data representative for the market collected by the Authority (<sup>13</sup>).
- (11) 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.
- (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

Annexes II and V 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 placed on the market in the Union before 12 May 2025, except for pears, peaches, raspberries (red and yellow), sweet peppers/bell peppers, Chinese cabbages/pe-tsai and lettuces.

<sup>(&</sup>lt;sup>13</sup>) EFSA (European Food Safety Authority) 2024; The 2022 European Union report on pesticide residues in food. EFSA Journal 2024;22:e8753, https://doi.org/10.2903/j.efsa.2024.8753.

## 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 12 May 2025.

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

Done at Brussels, 22 October 2024.

For the Commission The President Ursula VON DER LEYEN

## ANNEX

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

- (1) in Annex II the column for thiacloprid is deleted.
- (2) in Annex V the following column for thiacloprid is added:

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

Code number	Groups and examples of individual products to which the MRLs apply (*)	Thiacloprid
(1)	(2)	(3)
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	0,02 (*)
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	0,01 (*)
0130010	Apples	
0130020	Pears	
0130030	Quinces	
0130040	Medlars	
0130050	Loquats/Japanese medlars	
0130990	Others (2)	

EN

0140000	Stone fruits	0,01 (*)
0140010	Apricots	
0140020	Cherries (sweet)	
0140030	Peaches	
0140040	Plums	
0140990	Others (2)	
0150000	Berries and small fruits	0,01 (*)
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	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	
0162050		
	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	<b>0,01</b> (*)
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	
1	Saishies	
0213100	Swedes/rutabagas	

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	0,01 (*)
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)	<b>0,01</b> (*)
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	0,01 (*)
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	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	0,01 (*)
0280010	Cultivated fungi	
0280020	Wild fungi	
0280990	Mosses and lichens	
0290000	Algae and prokaryotes organisms	0,01 (*)
0300000	PULSES	0,01 (*)
0300010	Beans	
0300020	Lentils	
0300030	Peas	
0300040	Lupins/lupini beans	
0300990	Others (2)	
0400000	OILSEEDS AND OIL FRUITS	0,02 (*)
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) <b>flowers</b>	
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	

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	0,05 (*)
0840020	Ginger (10)	
0840030	Turmeric/curcuma	0,05 (*)
0840040	Horseradish (11)	
0840990	Others (2)	0,05 (*)
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	Масе	
0870990	Others (2)	
0900000	SUGAR PLANTS	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	<b>0,01</b> (*)
1011000	(a) swine	
1011010	Muscle	
1011020	Fat	
1011030	Liver	
1011040	Kidney	
1011050	Edible offals (other than liver and kidney)	
1011990	Others (2)	
1012000	(b) <b>bovine</b>	
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) <b>poultry</b>	
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	0,02 (*)
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	0,01 (*)
1100000	PRODUCTS OF ANIMAL ORIGIN - FISH, FISHPRODUCTS AND ANY OTHER MARINE AND FRESHWATER FOOD PRODUCTS (8)	

120	0000	PRODUCTS OR PART OF PRODUCTS EXCLUSIVELY USED FOR ANIMAL FEED PRODUCTION (8)	
130	0000	PROCESSED FOOD PRODUCTS (9)	
(a)	(*) For the complete list of products of plant and animal origin to which MRL's apply, reference should be made to Annex I		