



2024/376

25.1.2024

COMMISSION REGULATION (EU) 2024/376

of 24 January 2024

amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for indoxacarb 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), point (a), and Article 18(1), point (b) thereof,

Whereas:

- (1) For the active substance indoxacarb, maximum residue levels ('MRLs') were set in Annex II to Regulation (EC) No 396/2005.
- (2) In the context of the procedure for the renewal of the approval of indoxacarb in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council ⁽²⁾, the European Food Safety Authority ('the Authority') published a conclusion on the peer review of the risk assessment of that active substance ⁽³⁾, establishing a lower acceptable daily intake ('ADI') and a lower acute reference dose ('ARfD').
- (3) The approval of the active substance indoxacarb expired on 19 December 2021 and was non-renewed ⁽⁴⁾. All authorisations for plant protection products containing that active substance have been revoked.
- (4) In accordance with Article 43 of Regulation (EC) No 396/2005, the Commission requested the Authority to provide a reasoned opinion on the risks that the current MRLs for indoxacarb based on import tolerances and Codex maximum residue limits ('CXLs') may pose to consumers in light of the lower ADI and ARfD. In its reasoned opinion ⁽⁵⁾, the Authority identified unacceptable risks concerning the current MRLs based on CXLs for apples, pears, apricots, cherries, peaches, plums, table and wine grapes, tomatoes, peppers, aubergines, cucumbers, gherkins, courgettes, melons, pumpkins, watermelons, broccoli, cauliflower and lettuce. Therefore, MRLs for these products should be lowered to the relevant limit of determination (LOD) in Annex II to Regulation (EC) No 396/2005.
- (5) Furthermore, in its conclusion ⁽⁶⁾ on the peer review published in the context of the procedure for the renewal of the approval of indoxacarb, the Authority explained that, due to insufficient data on the toxicity and genotoxicity of various metabolites and degradation products formed during processing at high temperature, risks for human health could not be excluded. Therefore, further decision by risk managers was needed. For products that are usually processed at high temperature, the MRLs based on CXLs cannot be confirmed as being safe for consumers. This concerns the MRLs for basil, potatoes, sweet corn, beans (dry), peas (dry), peanuts, soya beans, cotton seeds, as

⁽¹⁾ OJ L 70, 16.3.2005, p. 1.

⁽²⁾ Regulation (EC) No 1107/2009 of the European Parliament and of the Council 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).

⁽³⁾ European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance indoxacarb. EFSA Journal 2018;16(1):5140.

⁽⁴⁾ Commission Implementing Regulation (EU) 2021/2081 of 26 November 2021 concerning the non-renewal of approval of the active substance indoxacarb, 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 Commission Implementing Regulation (EU) No 540/2011 (OJ L 426, 29.11.2021, p. 28).

⁽⁵⁾ European Food Safety Authority; Targeted review of maximum residues levels (MRLs) for indoxacarb. EFSA Journal 2022;20(8):7527.

⁽⁶⁾ European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance indoxacarb. EFSA Journal 2018;16(1):5140.

well as for fat, liver, kidney and edible offal of swine, bovine, sheep, goat and equine, for poultry tissues, milks and eggs. Therefore, MRLs for these products should be lowered to the relevant LOD in Annex II to Regulation (EC) No 396/2005 in accordance with Article 17 of Regulation (EC) No 396/2005 in conjunction with Article 14(1), point (a), thereof. For products that are usually not processed at high temperature, and thus for which those metabolites and degradation products would not be formed, existing MRLs based on CXLs can be maintained. This concerns the MRLs for cranberries and teas. Therefore, the MRLs for cranberries and teas should be maintained in Annex II to Regulation (EC) No 396/2005. Additionally, as the MRLs on apples, broccoli, cauliflowers, rucola, baby leaf crops, poultry tissues and eggs are set at the product specific LODs, there is no longer a need for confirmatory data. Therefore, all footnotes containing requests for confirmatory data should be deleted.

- (6) As regards products for which no import tolerances or CXLs exist, MRLs should be set at the product specific LOD or the default MRL should apply, as provided for in Article 18(1), point (b), of Regulation (EC) No 396/2005.
- (7) The Commission consulted the European Union reference laboratories for residues of pesticides as regards the need to adapt certain LODs. For all the active substances covered by this Regulation, those laboratories proposed product specific LODs that are analytically achievable.
- (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) Annexes II and V to Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (10) A reasonable period should be allowed to elapse before the new MRLs become applicable in order to permit Member States, third countries and food business operators to adapt themselves to the requirements which result from the modification of the MRLs.
- (11) 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*.

It shall apply from 14 August 2024.

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

Done at Brussels, 24 January 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

In Annex II to Regulation (EC) No 396/2005, the column for indoxacarb 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 ⁽¹⁾	Indoxacarb (sum of indoxacarb and its R enantiomer)(F)
(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	0,01 (*)
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	0,01 (*)
0153000	(c) cane fruits	0,01 (*)
0153010	Blackberries	
0153020	Dewberries	
0153030	Raspberries (red and yellow)	
0153990	Others (2)	
0154000	(d) other small fruits and berries	
0154010	Blueberries	0,01 (*)
0154020	Cranberries	1
0154030	Currants (black, red and white)	0,01 (*)
0154040	Gooseberries (green, red and yellow)	0,01 (*)
0154050	Rose hips	0,01 (*)
0154060	Mulberries (black and white)	0,01 (*)
0154070	Azaroles/Mediterranean medlars	0,01 (*)
0154080	Elderberries	0,01 (*)
0154990	Others (2)	0,01 (*)
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	
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	
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	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)	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	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	0,01 (*)
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	
0610000	Teas	5
0620000	Coffee beans	0,05 (*)
0630000	Herbal infusions from	0,05 (*)
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	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	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	Mace	
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	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)	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)	
1200000	PRODUCTS OR PART OF PRODUCTS EXCLUSIVELY USED FOR ANIMAL FEED PRODUCTION (8)	
1300000	PROCESSED FOOD PRODUCTS (9)	

(*) Indicates lower limit of analytical determination

(†) For the complete list of products of plant and animal origin to which MRL's apply, reference should be made to Annex I

Indoxacarb (sum of indoxacarb and its R enantiomer) (F)

(F) Fat soluble'