



2024/1077

16.4.2024

COMMISSION REGULATION (EU) 2024/1077

of 15 April 2024

amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 2,4-DB, iodosulfuron-methyl, mesotrione and pyraflufen-ethyl 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 2,4-DB, iodosulfuron-methyl, mesotrione and pyraflufen-ethyl, maximum residue levels ('MRLs') were set in Annex II to Regulation (EC) No 396/2005.
- (2) During the review of those MRLs pursuant to Article 12 of Regulation (EC) No 396/2005, the European Food Safety Authority ('the Authority') identified some information as unavailable for certain products. The available information was sufficient for the Authority to propose MRLs that are safe for consumers. Data gaps were indicated in Annex II to that Regulation specifying the date by which the missing information was to be submitted to the Authority by the applicant in support of the proposed MRLs.
- (3) For 2,4-DB, the missing information concerning its metabolism and analytical methods for barley, oats, rye and wheat was submitted by the applicant and the Authority concluded that the data gap indicated in Annex II to Regulation (EC) No 396/2005 was sufficiently addressed ⁽²⁾. Therefore, for these products, the existing MRLs in Annex II to Regulation (EC) No 396/2005 should be maintained, and the footnote requiring the submission of additional information should be deleted from that Annex. For swine (muscle, fat, liver, kidney), bovine (muscle, fat, liver, kidney, edible offals), sheep (muscle, fat, liver, kidney, edible offals), goat (muscle, fat, liver, kidney, edible offals), equine (muscle, fat, liver, kidney, edible offals), other farmed terrestrial animals (muscle, fat, liver, kidney, edible offals) and milk (cattle, sheep, goat, horse), although information on analytical methods was submitted by the applicant, a feeding study for ruminants is still missing. The Authority concluded that this information was not sufficient to address the data gap previously identified and recommended that risk managers consider lowering the MRLs for those products to the limit of determination ('LOD')². Therefore, it is appropriate to set the MRLs for those products in Annex II to Regulation (EC) No 396/2005 at the product-specific LOD, and to delete the footnote indicating a request for a submission additional information from that Annex.
- (4) For iodosulfuron-methyl, the missing information concerning storage stability, crop metabolism and residue trials for linseeds and residue trials for maize/corn was not submitted by the applicant. The Authority therefore concluded that the data gap previously identified was not addressed ⁽³⁾, and recommended that risk managers consider lowering those MRLs to the LOD. Therefore, for these products, it is appropriate to set the MRLs in Annex II to Regulation (EC) No 396/2005 at the product-specific LOD, and to delete the [footnote indicating a] request for the submission of additional information from that Annex.

⁽¹⁾ OJ L 70, 16.3.2005, p. 1.

⁽²⁾ European Food Safety Authority; 'Lack of confirmatory data following Article 12 MRL reviews for 2,4-DB, iodosulfuron-methyl, mesotrione, methoxyfenozide and pyraflufen-ethyl', *EFSA Journal*, 2023;21(5):8013.

⁽³⁾ European Food Safety Authority; 'Lack of confirmatory data following Article 12 MRL reviews for 2,4-DB, iodosulfuron-methyl, mesotrione, methoxyfenozide and pyraflufen-ethyl', *EFSA Journal*, 2023;21(5):8013.

- (5) For mesotrione, the missing information on residue trials investigating residue levels of that substance and its metabolite AMBA (free and conjugate) for sugar canes was not submitted by the applicant. The Authority therefore concluded that the data gap previously identified was not addressed ⁽⁴⁾, and recommended that risk managers consider lowering that MRL to the LOD. Therefore, for sugar canes, it is appropriate to set the MRL in Annex II to Regulation (EC) No 396/2005 at the product-specific LOD, and to delete the requirement to submit additional information from that Annex.
- (6) For pyraflufen-ethyl, the missing information concerning analytical methods for hops was not submitted by the applicant. The Authority therefore concluded that the data gap previously identified was not addressed ⁽⁵⁾, and recommended that risk managers consider lowering that MRL to the LOD. Therefore, for hops, it is appropriate to set the MRL in Annex II to Regulation (EC) No 396/2005 at the product-specific LOD, and to delete the requirement to submit additional information from that Annex.
- (7) The Commission consulted the European Union reference laboratories as regards the need to adapt certain LODs. Those laboratories concluded that for certain products technical developments permit the setting of lower LODs.
- (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) In order 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 before the new MRLs become applicable and for which a high level of consumer protection is maintained.
- (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 adapt themselves to the requirements which 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

Annex II to Regulation (EC) No 396/2005 is 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 have been placed on the market in the Union before 6 November 2024.

⁽⁴⁾ European Food Safety Authority; 'Lack of confirmatory data following Article 12 MRL reviews for 2,4-DB, iodosulfuron-methyl, mesotrione, methoxyfenozide and pyraflufen-ethyl', EFSA Journal, 2023;21(5):8013.

⁽⁵⁾ European Food Safety Authority; 'Lack of confirmatory data following Article 12 MRL reviews for 2,4-DB, iodosulfuron-methyl, mesotrione, methoxyfenozide and pyraflufen-ethyl', EFSA Journal, 2023;21(5):8013.

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 6 November 2024.

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

Done at Brussels, 15 April 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

In Annex II to Regulation (EC) No 396/2005, the columns for 2,4-DB, iodosulfuron-methyl, mesotrione and pyraflufen-ethyl are replaced by the following:

Annex II-1

Pesticide residues and maximum residue levels (mg/kg)

Code number	Groups and examples of individual products to which the MRLs apply ^(a)	2,4-DB (sum of 2,4-DB, its salts, its esters and its conjugates, expressed as 2,4-DB) (R)	Iodosulfuron-methyl (sum of iodosulfuron-methyl and its salts, expressed as iodosulfuron-methyl)	Mesotrione	Pyraflufen-ethyl (Sum of pyraflufen-ethyl and pyraflufen, expressed as pyraflufen-ethyl)
'0100000	FRUITS, FRESH or FROZEN; TREE NUTS			0,01 (*)	0,02 (*)
0110000	Citrus fruits	0,01 (*)	0,01 (*)		
0110010	Grapefruits				
0110020	Oranges				
0110030	Lemons				
0110040	Limes				
0110050	Mandarins				
0110990	Others (2)				
0120000	Tree nuts	0,05 (*)	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 (*)	0,01 (*)		
0130010	Apples				
0130020	Pears				
0130030	Quinces				
0130040	Medlars				
0130050	Loquats/Japanese medlars				
0130990	Others (2)				
0140000	Stone fruits	0,01 (*)	0,01 (*)		
0140010	Apricots				
0140020	Cherries (sweet)				
0140030	Peaches				
0140040	Plums				
0140990	Others (2)				
0150000	Berries and small fruits	0,01 (*)	0,01 (*)		
0151000	(a) <i>grapes</i>				
0151010	Table grapes				
0151020	Wine grapes				
0152000	(b) <i>strawberries</i>				
0153000	(c) <i>cane fruits</i>				
0153010	Blackberries				
0153020	Dewberries				
0153030	Raspberries (red and yellow)				
0153990	Others (2)				

0154000	(d) <i>other small fruits and berries</i>				
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 (*)	0,01 (*)		
0161000	(a) <i>edible peel</i>				
0161010	Dates				
0161020	Figs				
0161030	Table olives				
0161040	Kumquats				
0161050	Carambolas				
0161060	Kaki/Japanese persimmons				
0161070	Jambuls/jambolans				
0161990	Others (2)				
0162000	(b) <i>inedible peel, small</i>				
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) <i>inedible peel, large</i>				

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				0,02 (*)
0210000	Root and tuber vegetables	0,01 (*)	0,01 (*)	0,01 (*)	
0211000	(a) <i>potatoes</i>				
0212000	(b) <i>tropical root and tuber vegetables</i>				
0212010	Cassava roots/manioc				
0212020	Sweet potatoes				
0212030	Yams				
0212040	Arrowroots				
0212990	Others (2)				
0213000	(c) <i>other root and tuber vegetables except sugar beets</i>				
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 (*)	0,01 (*)	0,01 (*)	
0220010	Garlic				
0220020	Onions				
0220030	Shallots				
0220040	Spring onions/green onions and Welsh onions				
0220990	Others (2)				
0230000	Fruiting vegetables	0,01 (*)	0,01 (*)	0,01 (*)	
0231000	(a) <i>Solanaceae and Malvaceae</i>				
0231010	Tomatoes				
0231020	Sweet peppers/bell peppers				
0231030	Aubergines/eggplants				
0231040	Okra/lady's fingers				
0231990	Others (2)				
0232000	(b) <i>cucurbits with edible peel</i>				
0232010	Cucumbers				
0232020	Gherkins				
0232030	Courgettes				
0232990	Others (2)				
0233000	(c) <i>cucurbits with inedible peel</i>				
0233010	Melons				
0233020	Pumpkins				
0233030	Watermelons				
0233990	Others (2)				
0234000	(d) <i>sweet corn</i>				

0239000	(e) <i>other fruiting vegetables</i>				
0240000	Brassica vegetables(excluding brassica roots and brassica baby leaf crops)	0,01 (*)	0,01 (*)	0,01 (*)	
0241000	(a) <i>flowering brassica</i>				
0241010	Broccoli				
0241020	Cauliflowers				
0241990	Others (2)				
0242000	(b) <i>head brassica</i>				
0242010	Brussels sprouts				
0242020	Head cabbages				
0242990	Others (2)				
0243000	(c) <i>leafy brassica</i>				
0243010	Chinese cabbages/pe-tsai				
0243020	Kales				
0243990	Others (2)				
0244000	(d) <i>kohlrabies</i>				
0250000	Leaf vegetables, herbs and edible flowers				
0251000	(a) <i>lettuces and salad plants</i>	0,01 (*)	0,01 (*)	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) <i>spinaches and similar leaves</i>	0,01 (*)	0,01 (*)	0,01 (*)	
0252010	Spinaches				
0252020	Purslanes				

0252030	Chards/beet leaves				
0252990	Others (2)				
0253000	(c) <i>grape leaves and similar species</i>	0,01 (*)	0,01 (*)	0,01 (*)	
0254000	(d) <i>watercresses</i>	0,01 (*)	0,01 (*)	0,01 (*)	
0255000	(e) <i>witloofs/Belgian endives</i>	0,01 (*)	0,01 (*)	0,01 (*)	
0256000	(f) <i>herbs and edible flowers</i>	0,02 (*)	0,02 (*)	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 (*)	0,01 (*)	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 (*)	0,01 (*)	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 (*)	0,01 (*)	0,01 (*)	
0280010	Cultivated fungi				
0280020	Wild fungi				
0280990	Mosses and lichens				
0290000	Algae and prokaryotes organisms	0,01 (*)	0,01 (*)	0,01 (*)	
0300000	PULSES	0,01 (*)	0,01 (*)	0,01 (*)	0,02 (*)
0300010	Beans				
0300020	Lentils				
0300030	Peas				
0300040	Lupins/lupini beans				
0300990	Others (2)				
0400000	OILSEEDS AND OIL FRUITS	0,05 (*)	0,02 (*)		0,02 (*)
0401000	Oilseeds				
0401010	Linseeds			0,01 (*)	
0401020	Peanuts/groundnuts			0,01 (*)	
0401030	Poppy seeds			0,01 (*)	
0401040	Sesame seeds			0,01 (*)	
0401050	Sunflower seeds			0,01 (*)	
0401060	Rapeseeds/canola seeds			0,01 (*)	
0401070	Soyabeans			0,03	
0401080	Mustard seeds			0,01 (*)	
0401090	Cotton seeds			0,01 (*)	
0401100	Pumpkin seeds			0,01 (*)	

0401110	Safflower seeds			0,01 (*)	
0401120	Borage seeds			0,01 (*)	
0401130	Gold of pleasure seeds			0,01 (*)	
0401140	Hemp seeds			0,01 (*)	
0401150	Castor beans			0,01 (*)	
0401990	Others (2)			0,01 (*)	
0402000	Oil fruits			0,01 (*)	
0402010	Olives for oil production				
0402020	Oil palms kernels				
0402030	Oil palms fruits				
0402040	Kapok				
0402990	Others (2)				
0500000	CEREALS		0,01 (*)	0,01 (*)	0,02 (*)
0500010	Barley	0,05			
0500020	Buckwheat and other pseudocereals	0,01 (*)			
0500030	Maize/corn	0,01 (*)			
0500040	Common millet/proso millet	0,01 (*)			
0500050	Oat	0,05			
0500060	Rice	0,01 (*)			
0500070	Rye	0,05			
0500080	Sorghum	0,01 (*)			
0500090	Wheat	0,05			
0500990	Others (2)	0,01 (*)			
0600000	TEAS, COFFEE, HERBAL INFUSIONS, COCOA AND CAROBS	0,05 (*)	0,05 (*)	0,05 (*)	0,1 (*)
0610000	Teas				
0620000	Coffee beans				
0630000	Herbal infusions from				
0631000	(a) <i>flowers</i>				
0631010	Chamomile				

0631020	Hibiscus/roselle				
0631030	Rose				
0631040	Jasmine				
0631050	Lime/linden				
0631990	Others (2)				
0632000	(b) <i>leaves and herbs</i>				
0632010	Strawberry				
0632020	Rooibos				
0632030	Mate/maté				
0632990	Others (2)				
0633000	(c) <i>roots</i>				
0633010	Valerian				
0633020	Ginseng				
0633990	Others (2)				
0639000	(d) <i>any other parts of the plant</i>				
0640000	Cocoa beans				
0650000	Carobs/Saint John's breads				
0700000	HOPS	0,05 (*)	0,05 (*)	0,05 (*)	0,1 (*)
0800000	SPICES				
0810000	Seed spices	0,05 (*)	0,05 (*)	0,05 (*)	0,1 (*)
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 (*)	0,05 (*)	0,05 (*)	0,1 (*)
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 (*)	0,05 (*)	0,05 (*)	0,1 (*)
0830010	Cinnamon				
0830990	Others (2)				
0840000	Root and rhizome spices				
0840010	Liquorice	0,05 (*)	0,05 (*)	0,05 (*)	0,1 (*)
0840020	Ginger (10)				
0840030	Turmeric/curcuma	0,05 (*)	0,05 (*)	0,05 (*)	0,1 (*)
0840040	Horseradish (11)				
0840990	Others (2)	0,05 (*)	0,05 (*)	0,05 (*)	0,1 (*)
0850000	Bud spices	0,05 (*)	0,05 (*)	0,05 (*)	0,1 (*)
0850010	Cloves				
0850020	Capers				
0850990	Others (2)				
0860000	Flower pistil spices	0,05 (*)	0,05 (*)	0,05 (*)	0,1 (*)
0860010	Saffron				
0860990	Others (2)				
0870000	Aril spices	0,05 (*)	0,05 (*)	0,05 (*)	0,1 (*)
0870010	Mace				

0870990	Others (2)				
0900000	SUGAR PLANTS	0,01 (*)	0,01 (*)	0,01 (*)	0,02 (*)
0900010	Sugar beet roots				
0900020	Sugar canes				
0900030	Chicory roots				
0900990	Others (2)				
1000000	PRODUCTS OF ANIMAL ORIGIN -TERRESTRIAL ANIMALS	0,05 (*)			
1010000	Commodities from		0,02 (*)	0,01 (*)	0,02 (*)
1011000	(a) <i>swine</i>				
1011010	Muscle				
1011020	Fat				
1011030	Liver				
1011040	Kidney				
1011050	Edible offals (other than liver and kidney)				
1011990	Others (2)				
1012000	(b) <i>bovine</i>				
1012010	Muscle				
1012020	Fat				
1012030	Liver				
1012040	Kidney				
1012050	Edible offals (other than liver and kidney)				
1012990	Others (2)				
1013000	(c) <i>sheep</i>				
1013010	Muscle				
1013020	Fat				
1013030	Liver				
1013040	Kidney				
1013050	Edible offals (other than liver and kidney)				
1013990	Others (2)				

1014000	d) <i>goat</i>				
1014010	Muscle				
1014020	Fat				
1014030	Liver				
1014040	Kidney				
1014050	Edible offals (other than liver and kidney)				
1014990	Others (2)				
1015000	(e) <i>equine</i>				
1015010	Muscle				
1015020	Fat				
1015030	Liver				
1015040	Kidney				
1015050	Edible offals (other than liver and kidney)				
1015990	Others (2)				
1016000	(f) <i>poultry</i>				
1016010	Muscle				
1016020	Fat				
1016030	Liver				
1016040	Kidney				
1016050	Edible offals (other than liver and kidney)				
1016990	Others (2)				
1017000	(g) <i>other farmed terrestrial animals</i>				
1017010	Muscle				
1017020	Fat				
1017030	Liver				
1017040	Kidney				
1017050	Edible offals (other than liver and kidney)				
1017990	Others (2)				
1020000	Milk		0,02 (*)	0,01 (*)	0,02 (*)

1020010	Cattle				
1020020	Sheep				
1020030	Goat				
1020040	Horse				
1020990	Others (2)				
1030000	Birds eggs		0,02 (*)	0,01 (*)	0,02 (*)
1030010	Chicken				
1030020	Duck				
1030030	Geese				
1030040	Quail				
1030990	Others (2)				
1040000	Honey and other apiculture products (7)		0,05 (*)	0,05 (*)	0,05 (*)
1050000	Amphibians and Reptiles		0,02 (*)	0,01 (*)	0,02 (*)
1060000	Terrestrial invertebrate animals		0,02 (*)	0,01 (*)	0,02 (*)
1070000	Wild terrestrial vertebrate animals		0,02 (*)	0,01 (*)	0,02 (*)
1100000	PRODUCTS OF ANIMAL ORIGIN - FISH, FISHPRODUCTS AND ANY OTHER MARINE AND FRESH-WATER 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

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

2,4-DB (sum of 2,4-DB, its salts, its esters and its conjugates, expressed as 2,4-DB) (R)

(R) The residue definition differs for the following combinations pesticide-code number: 2,4-DB-code 1000000 except 1040000: sum of 2,4-DB and its conjugates, expressed as 2,4-DB.'