

II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) 2023/1049

of 30 May 2023

amending Annexes II and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for fish oil, pendimethalin, sheep fat and spirotetramat 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 5(1) and Article 14(1), point (a), thereof,

Whereas:

- (1) For pendimethalin and spirotetramat, maximum residue levels ('MRLs') were set in Annex II to Regulation (EC) No 396/2005. Fish oil and sheep fat are included in Annex IV to that Regulation.
- (2) As regards the active substance pendimethalin, an application pursuant to Article 6(1) of Regulation (EC) No 396/2005 requesting a modification of the existing MRLs was submitted for peas (with pods), beans (with pods) and leeks. As regards the active substance spirotetramat, such an application was submitted for herbs and edible flowers.
- (3) In accordance with Article 8 of Regulation (EC) No 396/2005, those applications were evaluated by the Member States concerned and the evaluation reports were forwarded to the Commission.
- (4) The European Food Safety Authority ('the Authority') assessed the applications and the evaluation reports, examining in particular the risks to consumers and, where relevant, to animals, and gave reasoned opinions on the proposed MRLs (²). It forwarded those opinions to the applicants, the Commission and the Member States and made them available to the public.
- (5) As regards spirotetramat, in herbs and edible flowers, others, the Authority did not recommend a specific MRL value. Nevertheless, the Authority noted that risk managers may consider to implement the MRL of 10 mg/kg to the whole group of herbs and edible flowers, and that this would be safe for consumers. Therefore, it is appropriate to propose setting the MRL for spirotetramat in herbs and edible flowers, others, at 10 mg/kg in accordance with the relevant Commission Technical Guidelines (³).

(¹) OJ L 70, 16.3.2005, p. 1.

(²) Reasoned Opinion on the modification of the existing maximum residue levels for pendimethalin in peas (with pods), beans (with pods) and leeks. EFSA Journal 2023;21(3):7663.

Reasoned Opinion on the modification of the existing maximum residue levels for spirotetramat in herbs and edible flowers. EFSA Journal 2022;20(12):7668.

(³) Commission Technical Guidelines on data requirements for setting MRLs, comparability of residue trials and extrapolation of residue data on products from plant and animal origin (SANTE/2019/12752)

- (6) For pendimethalin and spirotetramat, the Authority concluded that all requirements with respect to completeness of data submission were met and that the modifications to the MRLs requested by the applicants were acceptable with regard to consumer safety on the basis of a consumer exposure assessment for 27 specific European consumer groups. In so concluding, the Authority took into account the most recent data on the toxicological properties of the substances. Neither the long-term exposure to these substances via consumption of all food products that may contain them, nor the short-term exposure due to high consumption of the relevant products showed a risk that the acceptable daily intake or the acute reference dose is exceeded.
- (7) Based on the reasoned opinions of the Authority and taking into account the relevant factors listed in Article 14(2) of Regulation (EC) No 396/2005, it is appropriate to conclude that the proposed modifications to the MRLs fulfil the requirements of that article.
- (8) Fish oil and sheep fat were temporarily included in Annex IV to Regulation (EC) No 396/2005 pending the finalisation of their evaluation either under Council Directive 91/414/EEC⁽⁴⁾ or under Regulation (EC) No 1107/2009 of the European Parliament and of the Council⁽⁵⁾, and pending the review of MRLs on those active substances in accordance with Article 12 of Regulation (EC) No 396/2005. In the context of applications for renewal of the approval of those active substances under Regulation (EC) No 1107/2009, the Authority issued conclusions on the peer review of the pesticide risk assessment of fish oil and sheep fat⁽⁶⁾. Based on those conclusions, no MRLs are required for fish oil and sheep fat. Therefore, it is appropriate for those substances to remain in Annex IV to Regulation (EC) No 396/2005.
- (9) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (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 IV to Regulation (EC) No 396/2005 are 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*.

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

Done at Brussels, 30 May 2023.

*For the Commission
The President
Ursula VON DER LEYEN*

⁽⁴⁾ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

⁽⁵⁾ 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).

⁽⁶⁾ Conclusion on the peer review of the pesticide risk assessment of the active substance fish oil. EFSA Journal 2022;20(1):7079.
Conclusion on the peer review of the pesticide risk assessment of the active substance sheep fat. EFSA Journal 2022;20(1):7073.

ANNEX

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

- (1) in Annex II, the columns for pendimethalin and spirotetramat are replaced by the following:

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

Code number (1)	Groups and examples of individual products to which the MRLs apply ^(a) (2)	Pendimethalin (F) (3)	Spirotetramat and spirotetramat-enol (sum of), expressed as spirotetramat (R) (4)
0100000	FRUITS, FRESH or FROZEN; TREE NUTS	0,05 (*)	
0110000	Citrus fruits		0,5
0110010	Grapefruits		
0110020	Oranges		
0110030	Lemons		
0110040	Limes		
0110050	Mandarins		
0110990	Others (2)		
0120000	Tree nuts		0,5
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		0,7
0130010	Apples		
0130020	Pears		
0130030	Quinces		
0130040	Medlars		
0130050	Loquats/Japanese medlars		
0130990	Others (2)		

(1)	(2)	(3)	(4)
0140000	Stone fruits		3
0140010	Apricots		
0140020	Cherries (sweet)		
0140030	Peaches		
0140040	Plums		
0140990	Others (2)		
0150000	Berries and small fruits		
0151000	(a) grapes		2
0151010	Table grapes		
0151020	Wine grapes		
0152000	(b) strawberries		0,3
0153000	(c) cane fruits		0,02 (*)
0153010	Blackberries		
0153020	Dewberries		
0153030	Raspberries (red and yellow)		
0153990	Others (2)		
0154000	(d) other small fruits and berries		1,5
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		0,02 (*)
0161020	Figs		0,02 (*)
0161030	Table olives		1,5
0161040	Kumquats		0,02 (*)
0161050	Carambolas		0,02 (*)

(1)	(2)	(3)	(4)
0161060	Kaki/Japanese persimmons		0,4
0161070	Jambuls/jambolans		0,02 (*)
0161990	Others (2)		0,02 (*)
0162000	(b) inedible peel, small		
0162010	Kiwi fruits (green, red, yellow)		3
0162020	Litchis/lychees		15
0162030	Passionfruits/maracujas		0,02 (*)
0162040	Prickly pears/cactus fruits		0,02 (*)
0162050	Star apples/caimitos		0,02 (*)
0162060	American persimmons/Virginia kaki		0,02 (*)
0162990	Others (2)		0,02 (*)
0163000	(c) inedible peel, large		
0163010	Avocados		0,4
0163020	Bananas		0,4
0163030	Mangoes		0,3
0163040	Papayas		0,4
0163050	Granate apples/pomegranates		0,4
0163060	Cherimoyas		0,02 (*)
0163070	Guavas		2
0163080	Pineapples		0,15
0163090	Breadfruits		0,02 (*)
0163100	Durians		0,02 (*)
0163110	Soursops/guanabanas		0,02 (*)
0163990	Others (2)		0,02 (*)
0200000	VEGETABLES, FRESH or FROZEN		
0210000	Root and tuber vegetables		
0211000	(a) potatoes	0,05 (*)	0,8
0212000	(b) tropical root and tuber vegetables	0,05 (*)	0,02 (*)
0212010	Cassava roots/manioc		
0212020	Sweet potatoes		
0212030	Yams		
0212040	Arrowroots		
0212990	Others (2)		

(1)	(2)	(3)	(4)
0213000	(c) other root and tuber vegetables except sugar beets		0,07
0213010	Beetroots	0,05 (*)	
0213020	Carrots	0,7	
0213030	Celeriacs/turnip rooted celeries	0,2	
0213040	Horseradishes	0,7	
0213050	Jerusalem artichokes	0,05 (*)	
0213060	Parsnips	0,7	
0213070	Parsley roots/Hamburg roots parsley	0,7	
0213080	Radishes	0,05 (*)	
0213090	Salsifies	0,7	
0213100	Swedes/rutabagas	0,4	
0213110	Turnips	0,4	
0213990	Others (2)	0,05 (*)	
0220000	Bulb vegetables	0,05 (*)	
0220010	Garlic		0,3
0220020	Onions		0,4
0220030	Shallots		0,3
0220040	Spring onions/green onions and Welsh onions		0,9
0220990	Others (2)		0,02 (*)
0230000	Fruiting vegetables	0,05 (*)	
0231000	(a) Solanaceae and Malvaceae		1
0231010	Tomatoes		
0231020	Sweet peppers/bell peppers		
0231030	Aubergines/eggplants		
0231040	Okra/lady's fingers		
0231990	Others (2)		
0232000	(b) cucurbits with edible peel		0,2
0232010	Cucumbers		
0232020	Gherkins		
0232030	Courgettes		
0232990	Others (2)		
0233000	(c) cucurbits with inedible peel		0,2
0233010	Melons		

(1)	(2)	(3)	(4)
0233020	Pumpkins		
0233030	Watermelons		
0233990	Others (2)		
0234000	(d) sweet corn		1,5
0239000	(e) other fruiting vegetables		0,02 (*)
0240000	Brassica vegetables(excluding brassica roots and brassica baby leaf crops)		
0241000	(a) flowering brassica	0,05 (*)	1
0241010	Broccoli		
0241020	Cauliflowers		
0241990	Others (2)		
0242000	(b) head brassica	0,05 (*)	
0242010	Brussels sprouts		0,3(+)
0242020	Head cabbages		2
0242990	Others (2)		0,02 (*)
0243000	(c) leafy brassica	0,5	7
0243010	Chinese cabbages/pe-tsai		
0243020	Kales		
0243990	Others (2)		
0244000	(d) kohlrabies	0,3	1,5(+)
0250000	Leaf vegetables, herbs and edible flowers		
0251000	(a) lettuces and salad plants		7
0251010	Lamb's lettuces/corn salads	0,6	
0251020	Lettuces	4	
0251030	Escaroles/broad-leaved endives	0,05 (*)	
0251040	Cresses and other sprouts and shoots	0,6	
0251050	Land cresses	0,05 (*)	
0251060	Roman rocket/rucola	0,6	
0251070	Red mustards	0,05 (*)	
0251080	Baby leaf crops (including brassica species)	0,6	
0251990	Others (2)	0,05 (*)	
0252000	(b) spinaches and similar leaves	0,05 (*)	7
0252010	Spinaches		
0252020	Purslanes		

(1)	(2)	(3)	(4)
0252030	Chards/beet leaves		
0252990	Others (2)		
0253000	(c) grape leaves and similar species	0,05 (*)	0,02 (*)
0254000	(d) watercresses	0,05 (*)	7
0255000	(e) witloofs/Belgian endives	0,05 (*)	0,03
0256000	(f) herbs and edible flowers		
0256010	Chervil	0,6	7
0256020	Chives	0,6	7
0256030	Celery leaves	0,6	7
0256040	Parsley	2	7
0256050	Sage	2	10
0256060	Rosemary	0,6	10
0256070	Thyme	0,6	10
0256080	Basil and edible flowers	0,6	7
0256090	Laurel/bay leaves	0,6	10
0256100	Tarragon	0,6	7
0256990	Others (2)	0,6	10
0260000	Legume vegetables		
0260010	Beans (with pods)	0,06	2
0260020	Beans (without pods)	0,05 (*)	1,5
0260030	Peas (with pods)	0,09	2
0260040	Peas (without pods)	0,05 (*)	1,5
0260050	Lentils	0,05 (*)	1,5
0260990	Others (2)	0,05 (*)	0,02 (*)
0270000	Stem vegetables		
0270010	Asparagus	0,1	0,02 (*)
0270020	Cardoons	0,05 (*)	0,02 (*)
0270030	Celeries	0,1	4
0270040	Florence fennels	0,1	4
0270050	Globe artichokes	0,05 (*)	1
0270060	Leeks	0,3	0,9
0270070	Rhubarbs	0,05 (*)	4
0270080	Bamboo shoots	0,05 (*)	0,02 (*)
0270090	Palm hearts	0,05 (*)	0,02 (*)

(1)	(2)	(3)	(4)
0270990	Others (2)	0,05 (*)	0,02 (*)
0280000	Fungi, mosses and lichens	0,05 (*)	0,02 (*)
0280010	Cultivated fungi		
0280020	Wild fungi		
0280990	Mosses and lichens		
0290000	Algae and prokaryotes organisms	0,05 (*)	0,02 (*)
0300000	PULSES	0,15	2
0300010	Beans		
0300020	Lentils		
0300030	Peas		
0300040	Lupins/lupini beans		
0300990	Others (2)		
0400000	OILSEEDS AND OIL FRUITS	0,05 (*)	
0401000	Oilseeds		
0401010	Linseeds		0,02 (*)
0401020	Peanuts/groundnuts		0,02 (*)
0401030	Poppy seeds		0,02 (*)
0401040	Sesame seeds		0,02 (*)
0401050	Sunflower seeds		0,02 (*)
0401060	Rapeseeds/canola seeds		0,02 (*)
0401070	Soyabeans		4
0401080	Mustard seeds		0,02 (*)
0401090	Cotton seeds		0,4
0401100	Pumpkin seeds		0,02 (*)
0401110	Safflower seeds		0,02 (*)
0401120	Borage seeds		0,02 (*)
0401130	Gold of pleasure seeds		0,02 (*)
0401140	Hemp seeds		0,02 (*)
0401150	Castor beans		0,02 (*)
0401990	Others (2)		0,02 (*)
0402000	Oil fruits		
0402010	Olives for oil production		1,5
0402020	Oil palms kernels		0,02 (*)
0402030	Oil palms fruits		0,02 (*)

(1)	(2)	(3)	(4)
0402040	Kapok		0,02 (*)
0402990	Others (2)		0,02 (*)
0500000	CEREALS	0,05 (*)	0,02 (*)
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	0,05 (*)	0,1 (*)
0620000	Coffee beans	0,05 (*)	0,1 (*)
0630000	Herbal infusions from		
0631000	(a) flowers	0,05 (*)	0,1 (*)
0631010	Chamomile		
0631020	Hibiscus/roselle		
0631030	Rose		
0631040	Jasmine		
0631050	Lime/linden		
0631990	Others (2)		
0632000	(b) leaves and herbs	0,05 (*)	50
0632010	Strawberry		
0632020	Rooibos		
0632030	Mate/maté		
0632990	Others (2)		
0633000	(c) roots	0,5	0,1 (*)
0633010	Valerian		
0633020	Ginseng		
0633990	Others (2)		

(1)	(2)	(3)	(4)
0639000	(d) any other parts of the plant	0,05 (*)	0,1 (*)
0640000	Cocoa beans	0,05 (*)	0,1 (*)
0650000	Carobs/Saint John's breads	0,05 (*)	0,1 (*)
0700000	HOPS	0,05 (*)	15
0800000	SPICES		
0810000	Seed spices	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 (*)	0,1 (*)
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 (*)	0,1 (*)
0830010	Cinnamon		
0830990	Others (2)		
0840000	Root and rhizome spices		
0840010	Liquorice	0,05 (*)	0,1 (*)
0840020	Ginger (10)		
0840030	Turmeric/curcuma	0,05 (*)	0,1 (*)

(1)	(2)	(3)	(4)
0840040	Horseradish (11)		
0840990	Others (2)	0,05 (*)	0,1 (*)
0850000	Bud spices	0,05 (*)	0,1 (*)
0850010	Cloves		
0850020	Capers		
0850990	Others (2)		
0860000	Flower pistil spices	0,05 (*)	0,1 (*)
0860010	Saffron		
0860990	Others (2)		
0870000	Aril spices	0,05 (*)	0,1 (*)
0870010	Mace		
0870990	Others (2)		
0900000	SUGAR PLANTS		
0900010	Sugar beet roots	0,05 (*)	0,06
0900020	Sugar canes	0,05 (*)	0,02 (*)
0900030	Chicory roots	0,2	0,07
0900990	Others (2)	0,05 (*)	0,02 (*)
1000000	PRODUCTS OF ANIMAL ORIGIN -TERRESTRIAL ANIMALS		
1010000	Commodities from		
1011000	(a) swine		
1011010	Muscle	0,01 (*)	0,05
1011020	Fat	0,2	0,02 (*)
1011030	Liver	0,05	0,7
1011040	Kidney	0,05	0,7
1011050	Edible offals (other than liver and kidney)	0,05	0,7
1011990	Others (2)	0,01 (*)	0,02 (*)
1012000	(b) bovine		
1012010	Muscle	0,01 (*)	0,05
1012020	Fat	0,2	0,02 (*)
1012030	Liver	0,05	0,7
1012040	Kidney	0,05	0,7
1012050	Edible offals (other than liver and kidney)	0,05	0,7
1012990	Others (2)	0,01 (*)	0,02 (*)

(1)	(2)	(3)	(4)
1013000	(c) sheep		
1013010	Muscle	0,01 (*)	0,05
1013020	Fat	0,2	0,02 (*)
1013030	Liver	0,05	0,7
1013040	Kidney	0,05	0,7
1013050	Edible offals (other than liver and kidney)	0,05	0,7
1013990	Others (2)	0,01 (*)	0,02 (*)
1014000	(d) goat		
1014010	Muscle	0,01 (*)	0,05
1014020	Fat	0,2	0,02 (*)
1014030	Liver	0,05	0,7
1014040	Kidney	0,05	0,7
1014050	Edible offals (other than liver and kidney)	0,05 (*)	0,7
1014990	Others (2)	0,01 (*)	0,02 (*)
1015000	(e) equine		
1015010	Muscle	0,01 (*)	0,05
1015020	Fat	0,2	0,02 (*)
1015030	Liver	0,05	0,7
1015040	Kidney	0,05	0,7
1015050	Edible offals (other than liver and kidney)	0,05	0,7
1015990	Others (2)	0,01 (*)	0,02 (*)
1016000	(f) poultry	0,01 (*)	0,02 (*)
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	0,01 (*)	0,05
1017020	Fat	0,2	0,02 (*)
1017030	Liver	0,05	0,7
1017040	Kidney	0,05	0,7
1017050	Edible offals (other than liver and kidney)	0,05	0,7
1017990	Others (2)	0,01 (*)	0,02 (*)

(1)	(2)	(3)	(4)
1020000	Milk	0,02	0,01 (*)
1020010	Cattle		
1020020	Sheep		
1020030	Goat		
1020040	Horse		
1020990	Others (2)		
1030000	Birds eggs	0,01 (*)	0,01 (*)
1030010	Chicken		
1030020	Duck		
1030030	Geese		
1030040	Quail		
1030990	Others (2)		
1040000	Honey and other apiculture products (7)	0,05 (*)	0,5
1050000	Amphibians and Reptiles	0,01 (*)	0,02 (*)
1060000	Terrestrial invertebrate animals	0,01 (*)	0,02 (*)
1070000	Wild terrestrial vertebrate animals	0,01 (*)	0,02 (*)
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

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

Pendimethalin (F)

(F) Fat soluble

Spirotetramat and spirotetramat-enol (sum of), expressed as spirotetramat (R)

(R) The residue definition differs for the following combinations pesticide-code number: Spirotetramat - Code 1000000 except 1040000: spirotetramat-enol expressed as spirotetramat
The European Food Safety Authority identified some information on residue trials 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 20 April 2023, or, if that information is not submitted by that date, the lack of it.

0242010 Brussels sprouts

0244000 (d) kohlrabies'

(2) Annex IV is amended as follows:

(a) the entry for 'Repellants: Fish oil⁽¹⁾' is replaced by the following:

'Repellants: Fish oil';

(b) the entry for 'Repellants: Sheep fat⁽¹⁾' is replaced by the following:

'Repellants: Sheep fat'.
