

## II

(*Non-legislative acts*)

## REGULATIONS

### COMMISSION REGULATION (EU) 2019/88

of 18 January 2019

amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acetamiprid in 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)(a) thereof,

Whereas:

- (1) For acetamiprid, maximum residue levels (MRLs) were set in Annex II to Regulation (EC) No 396/2005.
- (2) In the context of a procedure for the authorisation of the use of a plant protection product containing the active substance acetamiprid on table olives and olives for oil production, an application was submitted in accordance with Article 6(1) of Regulation (EC) No 396/2005 for modification of the existing MRLs.
- (3) Such an application was also submitted for the use of acetamiprid on barley and oats.
- (4) 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.
- (5) The European Food Safety Authority ('the Authority') assessed the applications and the evaluation reports, examining in particular the risks to the consumer and, where relevant, to animals and gave a reasoned opinion on the proposed MRLs (<sup>2</sup>). The Authority forwarded that opinion to the applicant, the Commission and the Member States and made it available to the public.
- (6) The Authority concluded in its reasoned opinion that all requirements with respect to data were met and that the modifications to the MRLs requested by the applicant were acceptable with regard to consumer safety on the basis of a consumer exposure assessment for 27 specific European consumer groups. The Authority took into account the most recent information on the toxicological properties of the substance. Neither the lifetime exposure to this substance via consumption of all food products that may contain it, nor the short-term exposure due to high consumption of the relevant products showed that there is a risk that the acceptable daily intake or the acute reference dose is exceeded.

(<sup>1</sup>) OJ L 70, 16.3.2005, p. 1.

(<sup>2</sup>) EFSA scientific reports available online: <http://www.efsa.europa.eu>:

Reasoned opinion on the focussed assessment of certain existing MRLs of concern for acetamiprid and modification of the existing MRLs for table olives, olives for oil production, barley and oats. EFSA Journal 2018;16(5):5262.

- (7) In the context of the procedure for the renewal of the approval of the active substance acetamiprid in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council (<sup>3</sup>), the Authority submitted a conclusion on the peer review of the pesticide risk assessment concerning that active substance (<sup>4</sup>), where new toxicological endpoints were proposed. These endpoints were agreed by the Standing Committee on Plants, Animals, Food and Feed on 13 December 2017 (<sup>5</sup>).
- (8) In accordance with Article 43 of Regulation (EC) No 396/2005, the Commission requested the Authority to assess the risks the current MRLs for acetamiprid may pose to consumers in the light of the resulting lower acute reference dose (ARfD).
- (9) The Authority identified in its reasoned opinion (<sup>6</sup>) consumer intake concerns for apples, pears, peaches, head cabbages, Chinese cabbages, kales, lettuces, escaroles, spinaches, purslanes, chards and celeries. Member States were consulted to report potential fall-back Good Agricultural Practices (GAPs) that would not lead to an unacceptable risk for consumers. Member States identified fall-back GAPs for all concerned products except for Chinese cabbages, kales and celeries, for which the MRLs should be set at the relevant limit of determination.
- (10) As regards escaroles, the Authority concluded that some information was not available and that further consideration by risk managers was required. As there is no risk for consumers in relation to the fall-back GAP, the MRL for that product should be set in Annex II to Regulation (EC) No 396/2005 at the level identified by the Authority. This MRL will be reviewed; the review will take into account the information available within two years from the publication of this Regulation.
- (11) 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.
- (12) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (13) 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.
- (14) 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 13 August 2019.

However, for acetamiprid in olives for oil production, table olives, barley and oats, it shall apply from 13 February 2019.

(<sup>3</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).

(<sup>4</sup>) Conclusion on the peer review of the pesticide risk assessment of the active substance acetamiprid. EFSA Journal 2016;14(11):4610.

(<sup>5</sup>) Review report for the active substance acetamiprid (SANTE/10502/2017 Rev. 4).

(<sup>6</sup>) Reasoned opinion on the focussed assessment of certain existing MRLs of concern for acetamiprid and modification of the existing MRLs for table olives, olives for oil production, barley and oats. EFSA Journal 2018;16(5):5262.

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

Done at Brussels, 18 January 2019.

*For the Commission*

*The President*

Jean-Claude JUNCKER

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## ANNEX

In Annex II to Regulation (EC) No 396/2005, the column for acetamiprid 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 ( <sup>(a)</sup> )	Acetamiprid(R)
(1)	(2)	(3)
0100000	<b>FRUITS, FRESH or FROZEN; TREE NUTS</b>	
0110000	<b>Citrus fruits</b>	0,9
0110010	Grapefruits	
0110020	Oranges	
0110030	Lemons	
0110040	Limes	
0110050	Mandarins	
0110990	Others (2)	
0120000	<b>Tree nuts</b>	0,07
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	<b>Pome fruits</b>	
0130010	Apples	0,4
0130020	Pears	0,4
0130030	Quinces	0,8
0130040	Medlars	0,8
0130050	Loquats/Japanese medlars	0,8
0130990	Others (2)	0,8
0140000	<b>Stone fruits</b>	
0140010	Apricots	0,8
0140020	Cherries (sweet)	1,5
0140030	Peaches	0,2
0140040	Plums	0,03
0140990	Others (2)	0,01 (*)
0150000	<b>Berries and small fruits</b>	
0151000	(a) grapes	0,5
0151010	Table grapes	
0151020	Wine grapes	

(1)	(2)	(3)
0152000	(b) strawberries	0,5
0153000	(c) cane fruits	2
0153010	Blackberries	
0153020	Dewberries	
0153030	Raspberries (red and yellow)	
0153990	Others (2)	
0154000	(d) other small fruits and berries	
0154010	Blueberries	2
0154020	Cranberries	2
0154030	Currants (black, red and white)	2
0154040	Gooseberries (green, red and yellow)	2
0154050	Rose hips	2
0154060	Mulberries (black and white)	2
0154070	Azaroles/Mediterranean medlars	0,01 (*)
0154080	Elderberries	2
0154990	Others (2)	0,01 (*)
0160000	<b>Miscellaneous fruits with</b>	
0161000	(a) edible peel	
0161010	Dates	0,01 (*)
0161020	Figs	0,03
0161030	Table olives	3
0161040	Kumquats	0,01 (*)
0161050	Carambolas	0,01 (*)
0161060	Kaki/Japanese persimmons	0,01 (*)
0161070	Jambuls/jambolans	0,01 (*)
0161990	Others (2)	0,01 (*)
0162000	(b) inedible peel, small	0,01 (*)
0162010	Kiwi fruits (green, red, yellow)	
0162020	Litchis/lychees	
0162030	Passionfruits/maracujas	
0162040	Prickly pears/cactus fruits	
0162050	Star apples/caimitos	
0162060	American persimmons/Virginia kaki	
0162990	Others (2)	
0163000	(c) inedible peel, large	
0163010	Avocados	0,01 (*)
0163020	Bananas	0,4
0163030	Mangoes	0,01 (*)
0163040	Papayas	0,01 (*)
0163050	Granate apples/pomegranates	0,01 (*)
0163060	Cherimoyas	0,01 (*)
0163070	Guavas	0,01 (*)
0163080	Pineapples	0,01 (*)
0163090	Breadfruits	0,01 (*)
0163100	Durians	0,01 (*)
0163110	Soursops/guanabanas	0,01 (*)
0163990	Others (2)	0,01 (*)

(1)	(2)	(3)
0200000	<b>VEGETABLES, FRESH or FROZEN</b>	
0210000	<b>Root and tuber vegetables</b>	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	<b>Bulb vegetables</b>	
0220010	Garlic	0,02
0220020	Onions	0,02
0220030	Shallots	0,01 (*)
0220040	Spring onions/green onions and Welsh onions	0,01 (*)
0220990	Others (2)	0,01 (*)
0230000	<b>Fruiting vegetables</b>	
0231000	(a) Solanaceae and Malvaceae	
0231010	Tomatoes	0,5
0231020	Sweet peppers/bell peppers	0,3
0231030	Aubergines/eggplants	0,2
0231040	Okra/lady's fingers	0,2
0231990	Others (2)	0,2
0232000	(b) cucurbits with edible peel	
0232010	Cucumbers	0,3
0232020	Gherkins	0,6
0232030	Courgettes	0,3
0232990	Others (2)	0,3
0233000	(c) cucurbits with inedible peel	0,2
0233010	Melons	
0233020	Pumpkins	
0233030	Watermelons	
0233990	Others (2)	
0234000	(d) sweet corn	0,01 (*)
0239000	(e) other fruiting vegetables	0,2

(1)	(2)	(3)
0240000	<b>Brassica vegetables (excluding brassica roots and brassica baby leaf crops)</b>	
0241000	(a) <i>flowering brassica</i>	0,4
0241010	Broccoli	
0241020	Cauliflowers	
0241990	Others (2)	
0242000	(b) <i>head brassica</i>	
0242010	Brussels sprouts	0,05
0242020	Head cabbages	<b>0,4</b>
0242990	Others (2)	0,01 (*)
0243000	(c) <i>leafy brassica</i>	0,01 (*)
0243010	Chinese cabbages/pe-tsai	
0243020	Kales	
0243990	Others (2)	
0244000	(d) <i>kohlrabies</i>	0,01 (*)
0250000	<b>Leaf vegetables, herbs and edible flowers</b>	
0251000	(a) <i>lettuces and salad plants</i>	
0251010	Lamb's lettuces/corn salads	3
0251020	Lettuces	<b>1,5</b>
0251030	Escaroles/broad-leaved endives	<b>0,4 (+)</b>
0251040	Cresses and other sprouts and shoots	3
0251050	Land cresses	3
0251060	Roman rocket/rucola	3
0251070	Red mustards	3
0251080	Baby leaf crops (including brassica species)	3
0251990	Others (2)	0,01 (*)
0252000	(b) <i>spinaches and similar leaves</i>	<b>0,6</b>
0252010	Spinaches	
0252020	Purslanes	
0252030	Chards/beet leaves	
0252990	Others (2)	
0253000	(c) <i>grape leaves and similar species</i>	0,01 (*)
0254000	(d) <i>watercresses</i>	0,01 (*)
0255000	(e) <i>witloofs/Belgian endives</i>	0,01 (*)
0256000	(f) <i>herbs and edible flowers</i>	3
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	<b>Legume vegetables</b>	
0260010	Beans (with pods)	0,6
0260020	Beans (without pods)	0,3

(1)	(2)	(3)
0260030	Peas (with pods)	0,6
0260040	Peas (without pods)	0,3
0260050	Lentils	0,01 (*)
0260990	Others (2)	0,01 (*)
0270000	<b>Stem vegetables</b>	
0270010	Asparagus	0,8
0270020	Cardoons	0,01 (*)
0270030	Celeries	<b>0,01 (*)</b>
0270040	Florence fennels	0,01 (*)
0270050	Globe artichokes	0,7
0270060	Leeks	0,01 (*)
0270070	Rhubarbs	0,01 (*)
0270080	Bamboo shoots	0,01 (*)
0270090	Palm hearts	0,01 (*)
0270990	Others (2)	0,01 (*)
0280000	<b>Fungi, mosses and lichens</b>	0,01 (*)
0280010	Cultivated fungi	
0280020	Wild fungi	
0280990	Mosses and lichens	
0290000	<b>Algae and prokaryotes organisms</b>	0,01 (*)
0300000	<b>PULSES</b>	0,15
0300010	Beans	
0300020	Lentils	
0300030	Peas	
0300040	Lupins/lupini beans	
0300990	Others (2)	
0400000	<b>OILSEEDS AND OIL FRUITS</b>	
0401000	<b>Oilseeds</b>	
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	0,4
0401070	Soyabeans	0,01 (*)
0401080	Mustard seeds	0,01 (*)
0401090	Cotton seeds	0,7
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	<b>Oil fruits</b>	
0402010	Olives for oil production	<b>3</b>
0402020	Oil palms kernels	0,01 (*)
0402030	Oil palms fruits	0,01 (*)
0402040	Kapok	0,01 (*)
0402990	Others (2)	0,01 (*)

(1)	(2)	(3)
0500000	<b>CEREALS</b>	
0500010	Barley	<b>0,05</b>
0500020	Buckwheat and other pseudocereals	0,01 (*)
0500030	Maize/corn	0,01 (*)
0500040	Common millet/proso millet	0,01 (*)
0500050	Oat	<b>0,05</b>
0500060	Rice	0,01 (*)
0500070	Rye	0,01 (*)
0500080	Sorghum	0,01 (*)
0500090	Wheat	0,1
0500990	Others (2)	0,01 (*)
0600000	<b>TEAS, COFFEE, HERBAL INFUSIONS, COCOA AND CAROBS</b>	0,05 (*)
0610000	<b>Teas</b>	
0620000	<b>Coffee beans</b>	
0630000	<b>Herbal infusions from</b>	
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	<b>Cocoa beans</b>	
0650000	<b>Carobs/Saint John's breads</b>	
0700000	<b>HOPS</b>	0,05 (*)
0800000	<b>SPICES</b>	
0810000	<b>Seed spices</b>	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)	

(1)	(2)	(3)
0820000	<b>Fruit spices</b>	
0820010	Allspice/pimento	0,05 (*)
0820020	Sichuan pepper	0,05 (*)
0820030	Caraway	0,05 (*)
0820040	Cardamom	0,1
0820050	Juniper berry	0,05 (*)
0820060	Peppercorn (black, green and white)	0,1
0820070	Vanilla	0,05 (*)
0820080	Tamarind	0,05 (*)
0820990	Others (2)	0,05 (*)
0830000	<b>Bark spices</b>	0,05 (*)
0830010	Cinnamon	
0830990	Others (2)	
0840000	<b>Root and rhizome spices</b>	
0840010	Liquorice	0,05 (*)
0840020	Ginger (10)	0,05 (*)
0840030	Turmeric/curcuma	0,05 (*)
0840040	Horseradish (11)	(+)
0840990	Others (2)	0,05 (*)
0850000	<b>Bud spices</b>	0,05 (*)
0850010	Cloves	
0850020	Capers	
0850990	Others (2)	
0860000	<b>Flower pistil spices</b>	0,05 (*)
0860010	Saffron	
0860990	Others (2)	
0870000	<b>Aril spices</b>	0,05 (*)
0870010	Mace	
0870990	Others (2)	
0900000	<b>SUGAR PLANTS</b>	0,01 (*)
0900010	Sugar beet roots	
0900020	Sugar canes	
0900030	Chicory roots	
0900990	Others (2)	
1000000	<b>PRODUCTS OF ANIMAL ORIGIN -TERRESTRIAL ANIMALS</b>	
1010000	<b>Commodities from</b>	
1011000	(a) <i>swine</i>	
1011010	Muscle	0,5
1011020	Fat	0,3
1011030	Liver	1
1011040	Kidney	1
1011050	Edible offals (other than liver and kidney)	1
1011990	Others (2)	0,02 (*)
1012000	(b) <i>bovine</i>	
1012010	Muscle	0,5
1012020	Fat	0,3
1012030	Liver	1
1012040	Kidney	1

(1)	(2)	(3)
1012050	Edible offals (other than liver and kidney)	1
1012990	Others (2)	0,02 (*)
1013000	(c) <i>sheep</i>	
1013010	Muscle	0,5
1013020	Fat	0,3
1013030	Liver	1
1013040	Kidney	1
1013050	Edible offals (other than liver and kidney)	1
1013990	Others (2)	0,02 (*)
1014000	d) <i>goat</i>	
1014010	Muscle	0,5
1014020	Fat	0,3
1014030	Liver	1
1014040	Kidney	1
1014050	Edible offals (other than liver and kidney)	1
1014990	Others (2)	0,02 (*)
1015000	(e) <i>equine</i>	
1015010	Muscle	0,5
1015020	Fat	0,3
1015030	Liver	1
1015040	Kidney	1
1015050	Edible offals (other than liver and kidney)	1
1015990	Others (2)	0,02 (*)
1016000	(f) <i>poultry</i>	
1016010	Muscle	0,02 (*)
1016020	Fat	0,02 (*)
1016030	Liver	0,1 (*)
1016040	Kidney	0,1 (*)
1016050	Edible offals (other than liver and kidney)	0,02 (*)
1016990	Others (2)	0,02 (*)
1017000	(g) <i>other farmed terrestrial animals</i>	
1017010	Muscle	0,5
1017020	Fat	0,3
1017030	Liver	1
1017040	Kidney	1
1017050	Edible offals (other than liver and kidney)	1
1017990	Others (2)	0,02 (*)
1020000	<b>Milk</b>	0,2
1020010	Cattle	
1020020	Sheep	
1020030	Goat	
1020040	Horse	
1020990	Others (2)	
1030000	<b>Birds eggs</b>	0,02 (*)
1030010	Chicken	
1030020	Duck	
1030030	Geese	
1030040	Quail	
1030990	Others (2)	

(1)	(2)	(3)
1040000	<b>Honey and other apiculture products (7)</b>	0,05 (*)
1050000	<b>Amphibians and Reptiles</b>	0,02 (*)
1060000	<b>Terrestrial invertebrate animals</b>	0,02 (*)
1070000	<b>Wild terrestrial vertebrate animals</b>	0,02 (*)
1100000	<b>PRODUCTS OF ANIMAL ORIGIN - FISH, FISHPRODUCTS AND ANY OTHER MARINE AND FRESHWATER FOOD PRODUCTS (8)</b>	
1200000	<b>PRODUCTS OR PART OF PRODUCTS EXCLUSIVELY USED FOR ANIMAL FEED PRODUCTION (8)</b>	
1300000	<b>PROCESSED FOOD PRODUCTS (9)</b>	

(\*) Limit of analytical determination

(<sup>a</sup>) For the complete list of products of plant and animal origin to which MRLs apply, reference should be made to Annex I.

#### **Acetamiprid (R)**

(R) = The residue definition differs for the following combinations pesticide-code number:

Acetamiprid - code 1000000 except 1040000: Sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid

(+) 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 24 January 2021, or, if that information is not submitted by that date, the lack of it.

**0251030 Escaroles/broad-leaved endives**