Commission Regulation (EU) 2019/977 of 13 June 2019 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 aclonifen, Beauveria bassiana strain PPRI 5339, Clonostachys rosea strain J1446, fenpyrazamine, mefentrifluconazole and penconazole in or on certain products (Text with EEA relevance)

COMMISSION REGULATION (EU) 2019/977

of 13 June 2019

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 aclonifen, *Beauveria bassiana* strain PPRI 5339, *Clonostachys rosea* strain J1446, fenpyrazamine, mefentrifluconazole and penconazole 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)(a) thereof,

Whereas:

(1) For aclonifen, fenpyrazamine and penconazole, maximum residue levels (MRLs) were set in Annex II to Regulation (EC) No 396/2005. For *Beauveria bassiana* strain PPRI 5339 and mefentrifluconazole, no specific MRLs were set nor were those substances included in Annex IV to that Regulation, so the default value of 0,01 mg/kg laid down in Article 18(1)(b) thereof applies. *Clonostachys rosea* strain J1446 was included in Annex IV to Regulation (EC) No 396/2005 under the entry *Gliocladium catenulatum* strain J1446.

(2) On 22 July 2017, Codex Alimentarius Commission (CAC) adopted Codex maximum residue limits (CXLs) for penconazole[(2)]. On 6 July 2018, CAC adopted CXLs for fenpyrazamine[(3)].

(3) In accordance with Article 5(3) of Regulation (EC) No 178/2002 of the European Parliament and of the Council[(4)], where international standards exist or their completion is imminent, they are to be taken into consideration in the development or adaptation of food law, except where such standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives of food law or where there is a scientific justification, or where they would result in a different level of protection from the one determined as appropriate in the Union. Moreover, in accordance with point (e) of Article 13 of that Regulation, the Union is to promote

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consistency between international technical standards and food law while ensuring that the high level of protection adopted in the Union is not reduced.

(4) The CXLs for penconazole and fenpyrazamine are safe for consumers in the Union[(5)] and should therefore be included in Regulation (EC) No 396/2005 as MRLs.

(5) In the context of a procedure for the authorisation of the use of a plant protection product containing the active substance aclonifen on 'herbs and edible flowers' and celeriacs, an application was submitted in accordance with Article 6(1) of Regulation (EC) No 396/2005 for modification of the existing MRLs.

(6) In accordance with Article 8 of Regulation (EC) No 396/2005, that application was evaluated by the Member State concerned and the evaluation report was forwarded to the Commission.

(7) The European Food Safety Authority ('the Authority') assessed the application and the evaluation report, examining in particular the risks to the consumer and, where relevant, to animals and gave a reasoned opinion on the proposed MRLs[(6)]. It forwarded that opinion to the applicant, the Commission and the Member State concerned and made it available to the public.

(8) The Authority concluded 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. It 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.

(9) In the context of the approval of the active substance mefentrifluconazole, an MRL application was included in the summary dossier in accordance with Article 8(1)(g) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council[(7)]. The application was evaluated by the Member State concerned in accordance with Article 11(2) of that Regulation. The Authority assessed the application and delivered a conclusion on the peer review of the pesticide risk assessment of the active substance, where it recommended setting MRLs covering the representative uses on barley, oat, rye and wheat according to Good Agricultural Practices (GAPs) in the Union[(8)].

(10) In the context of the renewal of the approval of the active substance *Gliocladium catenulatum* strain J1446, the Authority recommended its inclusion in Annex IV to Regulation (EC) No 396/2005[(9)]. Due to recent changes in taxonomic rules, the strain J1446 was transferred to the species *Clonostachys rosea*.

(11) In the context of the approval of the active substance *Beauveria bassiana* strain PPRI 5339, the Authority submitted a conclusion on the peer review of the pesticide risk assessment[(10)]. In that framework, the Authority could not conclude on the dietary risk assessment for consumers as some information was not available and further consideration by risk managers was required. Such further consideration was reflected in the review report[(11)] which concluded that the organism is not pathogenic to

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humans and no toxins or toxic metabolites are expected to occur in food following the use of the active substance. In view of those conclusions, the Commission considers that *Beauveria bassiana* strain PPRI 5339 should be included in Annex IV to Regulation (EC) No 396/2005.

(12) As regards penconazole, several MRLs were modified by Commission Regulation (EU) 2019/89[(12)]. That Regulation lowers the MRLs for several products to the limit of determination as of 13 August 2019. In the interest of legal certainty, it is appropriate for the MRLs for penconazole, provided for by this Regulation, to apply from the same date.

(13) Based on the reasoned opinions and the conclusions of the Authority and taking into account the factors relevant to the matter under consideration, the appropriate modifications to the MRLs fulfil the requirements of Article 14(2) of Regulation (EC) No 396/2005.

(14) Regulation (EC) No 396/2005 should therefore be amended accordingly.

(15) 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*.

It shall however apply from 13 August 2019 for the MRLs for penconazole.

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

Done at Brussels, 13 June 2019.

For the Commission

The President

Jean-Claude JUNCKER

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ANNEX

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

(1) Annex II is amended as follows:

(a) The columns for aclonifen, fenpyrazamine and penconazole are 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**[b]	**Aclonifen**	**Fenpyrazamine (F)**	**Penconazole (sum of constituent isomers) (F)**
(1)	(2)	(3)	(4)	(5)
0100000	**FRUITS, FRESH or FROZEN; TREE NUTS**	0,01[a]		
0110000	**Citrus fruits**		0,01[a]	0,01[a]
0110010	Grapefruits			
0110020	Oranges			
0110030	Lemons			
0110040	Limes			
0110050	Mandarins			
0110990	Others (2)			
0120000	**Tree nuts**		0,01[a]	0,01[a]
0120010	Almonds			
0120020	Brazil nuts			
0120030	Cashew nuts			
0120040	Chestnuts			
0120050	Coconuts			
0120060	Hazelnuts/ cobnuts			
0120070	Macadamias			

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0120080	Pecans			
0120090	Pine nut kernels			
0120100	Pistachios			
0120110	Walnuts			
0120990	Others (2)			
0130000	**Pome fruits**		0,01[a]	
0130010	Apples			0,15 (+)
0130020	Pears			0,15 (+)
0130030	Quinces			0,15 (+)
0130040	Medlars			0,15 (+)
0130050	Loquats/ Japanese medlars			0,07 (+)
0130990	Others (2)			0,01[a]
0140000	**Stone fruits**			
0140010	Apricots		5	0,08 (+)
0140020	Cherries (sweet)		4	0,15 (+)
0140030	Peaches		5	0,15 (+)
0140040	Plums		3	0,09 (+)
0140990	Others (2)		0,01[a]	0,01[a]
0150000	**Berries and small fruits**			
0151000	(a) *grapes*		3	0,5 (+)
0151010	Table grapes			
0151020	Wine grapes			
0152000	(b) *strawberries*		3	**0,5**
0153000	(c) *cane fruits*		5	
0153010	Blackberries			0,1 (+)
0153020	Dewberries			0,01[a]
0153030	Raspberries (red and yellow)			0,1 (+)