

COMMISSION DIRECTIVE 2004/95/EC
of 24 September 2004
amending Council Directive 90/642/EEC as regards the maximum residues levels of bifenthrin and
famoxadone fixed therein
(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 90/642/EEC of 27 November 1990 on the fixing of maximum levels for pesticide residues in and on certain products of plant origin including fruit and vegetables⁽¹⁾, and in particular Article 7 thereof,

Having regard to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market⁽²⁾, and in particular Article 4(1)(f) thereof,

Whereas:

- (1) In accordance with Directive 91/414/EEC, authorisations of plant protection products for use on specific crops are the responsibility of the Member States. Such authorisations are required to be based on the evaluation of effects on human and animal health and influence on the environment. Elements to be taken into account in such evaluations include operator and bystander exposure and impact on the terrestrial, aquatic and aerial environments, as well as impact on humans and animals through consumption of residues on treated crops.
- (2) Maximum residue levels (MRLs) reflect the use of minimum quantities of pesticides to achieve effective protection of plants, applied in such a manner that the amount of residue is the smallest practicable and is toxicologically acceptable, in particular in terms of estimated dietary intake.
- (3) MRLs for pesticides should be kept under review. They may be changed to take account of new uses, new information and data.
- (4) MRLs are fixed at the lower limit of analytical determination where authorised uses of plant protection products do not result in detectable levels of pesticide residue in or on the food product, or where there are no authorised uses, or where uses which have been

authorised by Member States have not been supported by the necessary data, or where uses in third countries resulting in residues in or on food products which may enter into circulation in the Community market have not been supported with such necessary data.

- (5) Information on new or changed uses of certain pesticides covered by Directive 90/642/EEC has been notified to the Commission. This concerns bifenthrin, for which MRLs were set by Commission Directive 2002/79/EC⁽³⁾ and famoxadone for which MRLs were set by Commission Directive 2003/60/EC⁽⁴⁾.
- (6) The lifetime exposure of consumers to these pesticides via food products that may contain residues of these pesticides has been assessed and evaluated in accordance with the procedures and practices used within the Community, taking account of guidelines published by the World Health Organisation⁽⁵⁾. It has been calculated that the MRLs concerned will ensure that the acceptable daily intakes are not exceeded.
- (7) In the case of famoxadone, for which an acute reference (ARfD) dose exists, the acute exposure of consumers via each of the food products that may contain residues of these pesticides has been assessed and evaluated in accordance with the procedures and practices currently used within the European Community, taking account of guidelines published by the World Health Organisation. The opinions of the Scientific Committee for Plants, in particular advice and recommendations concerning the protection of consumers from food products treated with pesticides, have been taken into account. The intake assessment of famoxadone shows, that by setting the MRLs concerned, the ARfD will not be exceeded. In the case of bifenthrin, an assessment of the available information has shown that no ARfD is required and that therefore a short-term assessment is not needed.
- (8) Therefore it is appropriate to fix new maximum levels for residues of those pesticides.
- (9) Directive 90/642/EEC should therefore be amended accordingly.

⁽¹⁾ OJ L 350, 14.12.1990, p. 71. Directive as last amended by Commission Directive 2004/61/EC (OJ L 127, 29.4.2004, p. 81).

⁽²⁾ OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2004/71/EC (OJ L 127, 29.4.2004, p. 104).

⁽³⁾ OJ L 291, 28.10.2002, p. 1.

⁽⁴⁾ OJ L 155, 24.06.2003, p. 15.

⁽⁵⁾ Guidelines for predicting dietary intake of pesticide residues (revised), prepared by the GEMS/Food Programme in collaboration with the Codex Committee on Pesticide Residues, published by the World Health Organisation 1997 (WHO/FSF/FOS/97.7).

- (10) The setting or modification at Community level of provisional MRLs does not prevent the Member States from establishing provisional MRLs for famoxadone in accordance with Article 4(1)(f) of Directive 91/414/EEC and Annex VI thereto. It is considered that a period of four years is sufficient to permit further uses of the active substance concerned. The provisional MRL should then become definitive.
- (11) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DIRECTIVE:

Article 1

The maximum pesticide residue levels for bifenthrin and famoxadone in Annex II to Directive 90/642/EEC are replaced by those in the Annex to this Directive.

Article 2

1. Member States shall adopt and publish, by 25 March 2005 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

They shall apply these provisions from 26 March 2005.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 24 September 2004.

For the Commission

David BYRNE

Member of the Commission

ANNEX

'Groups and examples of individual products to which the MRLs would apply	Pesticide residue and maximum residue level (mg/kg)	
	Bifenthrin	Famoxadone
1. Fruit, fresh, dried or uncooked, preserved by freezing, not containing added sugar; nuts		
(i) CITRUS FRUIT	0,1	0,02 (*) (P)
Grapefruit		
Lemons		
Limes		
Mandarins (including clementines and other hybrids)		
Oranges		
Pomelos		
Others		
(ii) TREE NUTS (shelled or unshelled)	0,05 (*)	0,02 (*) (P)
Almonds		
Brazil nuts		
Cashew nuts		
Chestnuts		
Coconuts		
Hazelnuts		
Macadamia		
Pecans		
Pine nuts		
Pistachios		
Walnuts		
Others		
(iii) POME FRUIT	0,3	0,02 (*) (P)
Apples		
Pears		
Quinces		
Others		

Groups and examples of individual products to which the MRLs would apply	Pesticide residue and maximum residue level (mg/kg)	
	Bifenthrin	Famoxadone
(iv) STONE FRUIT	0,2	0,02 (*) (P)
Apricots		
Cherries		
Peaches (including nectarines and similar hybrids)		
Plums		
Others		
(v) BERRIES & SMALL FRUIT		
(a) Table and wine grapes	0,2	2 (P)
Table grapes		
Wine grapes		
(b) Strawberries (other than wild)	0,5	0,02 (*) (P)
(c) Cane fruit (other than wild)		0,02 (*) (P)
Blackberries	0,3	
Dewberries		
Loganberries		
Raspberries	0,3	
Others	0,05 (*)	
(d) Other small fruit and berries (other than wild)	0,05 (*)	0,02 (*) (P)
Bilberries		
Cranberries		
Currants (red, black and white)		
Gooseberries		
Others		
(e) Wild berries and wild fruit	0,05 (*)	0,02 (*) (P)
(vi) MISCELLANEOUS		0,02 (*) (P)
Avocados		
Bananas	0,1	
Dates		
Figs		

Groups and examples of individual products to which the MRLs would apply	Pesticide residue and maximum residue level (mg/kg)	
	Bifenthrin	Famoxadone
Kiwifruit		
Kumquats		
Lychees		
Mangoes		
Olives		
Passion fruit		
Pineapples		
Pomegranate		
Others	0,05 (*)	
2. Vegetables, fresh or uncooked, frozen or dry		
(i) ROOT AND TUBER VEGETABLES	0,05 (*)	0,02 (*) (P)
Beetroot		
Carrots		
Celeriac		
Horseradish		
Jerusalem artichokes		
Parsnips		
Parsley root		
Radishes		
Salsify		
Sweet potatoes		
Swedes		
Turnips		
Yam		
Others		

Groups and examples of individual products to which the MRLs would apply	Pesticide residue and maximum residue level (mg/kg)	
	Bifenthrin	Famoxadone
(ii) BULB VEGETABLES	0,05 (*)	0,02 (*) (P)
Garlic		
Onions		
Shallots		
Spring onions		
Others		
(iii) FRUITING VEGETABLES		
(a) Solanacea	0,2	
Tomatoes		1 (P)
Peppers		
Aubergines		0,2 (P)
Others		0,02 (*) (P)
(b) Cucurbits - edible peel	0,1	0,2 (P)
Cucumbers		
Gherkins		
Courgettes		
Others		
(c) Cucurbits-inedible peel	0,05 (*)	
Melons		0,3 (P)
Squashes		
Watermelons		
Others		0,02 (*) (P)
(d) Sweet corn	0,05 (*)	0,02 (*) (P)
(iv) BRASSICA VEGETABLES		0,02 (*) (P)
(a) Flowering brassica	0,2	
Broccoli (including Calabrese)		

Groups and examples of individual products to which the MRLs would apply	Pesticide residue and maximum residue level (mg/kg)	
	Bifenthrin	Famoxadone
Cauliflower		
Others		
(b) Head brassica	1	
Brussels sprouts		
Head cabbage		
Others		
(c) Leafy brassica	0,05 (*)	
Chinese cabbage		
Kale		
Others		
(d) Kohlrabi	0,05 (*)	
(v) LEAF VEGETABLES & FRESH HERBS		0,02 (*) (p)
(a) Lettuce and similar	2	
Cress		
Lamb's lettuce		
Lettuce		
Scarole (broad-leaf endive)		
Others		
(b) Spinach and similar	0,05 (*)	
Spinach		
Beet leaves (chard)		
Others		
(c) Water cress	0,05 (*)	
(d) Witloof	0,05 (*)	
(e) Herbs	0,05 (*)	
Chervil		

Groups and examples of individual products to which the MRLs would apply	Pesticide residue and maximum residue level (mg/kg)	
	Bifenthrin	Famoxadone
Chives		
Parsley		
Celery leaves		
Others		
(vi) LEGUME VEGETABLES (fresh)		0,02 (*) (P)
Beans (with pods)	0,5	
Beans (without pods)		
Peas (with pods)	0,1	
Peas (without pods)		
Others	0,05 (*)	
(vii) STEM VEGETABLES (fresh)	0,05 (*)	0,02 (*) (P)
Asparagus		
Cardoons		
Celery		
Fennel		
Globe artichokes		
Leek		
Rhubarb		
Others		
(viii) FUNGI	0,05 (*)	0,02 (*) (P)
(a) Cultivated mushrooms		
(b) Wild mushrooms		
3. Pulses	0,05 (*)	0,02 (*) (P)
Beans		
Lentils		
Peas		

Groups and examples of individual products to which the MRLs would apply	Pesticide residue and maximum residue level (mg/kg)	
	Bifenthrin	Famoxadone
Others		
4. Oilseeds	0,1 (*)	0,05 (*) (P)
Linseed		
Peanuts		
Poppy seed		
Sesame seed		
Sunflower seed		
Rape seed		
Soya bean		
Mustard seed		
Cotton seed		
Others		
5. Potatoes	0,05 (*)	0,02 (*) (P)
Early potatoes		
Ware potatoes		
6. Tea (dried leaves and stalks, fermented or other-wise, <i>Camellia sinensis</i>)	5	0,05 (*) (P)
7. Hops (dried), including hop pellets and unconcentrated powder	10	0,05 (*) (P)

(*) Indicates lower limit of analytical determination

(P) Indicates that the maximum residue level has been established provisionally in accordance with Article 4(1)(f) of Directive 91/414/EEC.