

DIRECTIVES

COMMISSION DIRECTIVE 2007/28/EC

of 25 May 2007

amending certain Annexes to Council Directives 86/363/EEC and 90/642/EEC as regards maximum residue levels for azoxystrobin, chlorfenapyr, folpet, iprodione, lambda-cyhalothrin, maleic hydrazide, metalaxyl-M and trifloxystrobin

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 86/363/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on foodstuffs of animal origin ⁽¹⁾, and in particular Article 10 thereof,

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 ⁽²⁾, 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 ⁽³⁾, 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 have 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.

⁽¹⁾ OJ L 221, 7.8.1986, p. 43. Directive as last amended by Commission Directive 2007/27/EC (OJ L 128, 16.5.2007, p. 31).

⁽²⁾ OJ L 350, 14.12.1990, p. 71. Directive as last amended by Directive 2007/27/EC.

⁽³⁾ OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2007/25/EC (OJ L 106, 24.4.2007, p. 34).

(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 covered by Directives 86/363/EEC and 90/642/EEC are to be kept under review and may be modified to take account of new or changed uses. Information about new or changed uses has been communicated to the Commission which should lead to changes in the residue levels of azoxystrobin, chlorfenapyr, folpet, iprodione, lambda-cyhalothrin, maleic hydrazide, metalaxyl-M and trifloxystrobin.

(4) The lifetime exposure of consumers to those pesticides via food products that may contain residues of those 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 ⁽⁴⁾. Based on those assessments and evaluations, the MRLs for those pesticides should be set so as to ensure that the acceptable daily intake is not exceeded.

(5) In the case of chlorfenapyr, folpet and lambda-cyhalothrin for which an acute reference dose (ARfD) 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 Community, taking account of guidelines published by the World Health Organisation. The opinions of the Scientific Committee on Plants (SCP), in particular advice and recommendations concerning the protection

⁽⁴⁾ 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).

of consumers of food products treated with pesticides ⁽¹⁾, have been taken into account. Based on the dietary intake assessment, the MRLs for those pesticides should be fixed so as to ensure that the ARfD will not be exceeded. In the case of the other substances, an assessment of the available information has shown that no ARfD is required and that therefore a short-term assessment is not needed.

- (6) Where authorised uses of plant protection products do not result in detectable levels of pesticide residues 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, MRLs should be fixed at the lower limit of analytical determination.
- (7) The setting or modification at Community level of provisional MRLs does not prevent the Member States from establishing provisional MRLs for maleic hydrazide and trifloxystrobin in accordance with Article 4(1)(f) of Directive 91/414/EEC and Annex VI to that Directive. It is considered that a period of four years is sufficient to permit further uses of these substances. The provisional Community MRLs should then become definitive.
- (8) It is therefore necessary to modify the MRLs set out in the Annexes to Directives 86/363/EEC and 90/642/EEC, to allow for proper surveillance and control of the uses of the concerned plant protection products and to protect the consumer. Where MRLs have already been defined in the Annexes to those Directives, it is appropriate to amend them. Where MRLs have not yet been defined, it is appropriate to set them for the first time.
- (9) Directives 86/363/EEC and 90/642/EEC should therefore be amended accordingly.
- (10) 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

Directive 86/363/EEC is amended in accordance with Annex I to this Directive.

Article 2

Directive 90/642/EEC is amended in accordance with Annex II to this Directive.

Article 3

1. Member States shall adopt and publish, by 26 November 2007 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 those provisions from 27 November 2007.

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 4

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 25 May 2007.

For the Commission

Markos KYPRIANOU

Member of the Commission

⁽¹⁾ Opinion regarding questions relating to amending the Annexes to Council Directives 86/362/EEC, 86/363/EEC and 90/642/EEC (Opinion expressed by the SCP on 14 July 1998); Opinion regarding variable pesticide residues in fruit and vegetables (Opinion expressed by the SCP on 14 July 1998); http://europa.eu.int/comm/food/fs/sc/scp/outcome_ppp_en.html

ANNEX I

In Part B of Annex II to Directive 86/363/EEC, the following line is added:

	Maximum levels in mg/kg		
Pesticide residues	of meat, including fat, preparations of meat, offal and animal fats listed in Annex I under heading Nos ex 0201, 0202, 0203, 0204, 0205, 0206, 0207, ex 0208, 0209, 0210, 1601 and 1602	for milk and milk products listed in Annex I under heading Nos 0401, 0402, 0405 and 0406	of shelled fresh eggs, for birds' eggs and egg yolks listed in Annex I under heading Nos 0407 and 0408
Maleic hydrazide (a)	meat (except poultry) 0,05 (p) liver (except poultry) 0,05 (p) kidney (except poultry) 0,5 (p) others 0,02 (*) (p)	0,2 (p) (t)	0,1 (p)

(*) Indicates lower limit of analytical determination.

(a) Residue definition for milk and milk products is: maleic hydrazide and its conjugates expressed as maleic hydrazide.

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

(t) Indicates that the maximum residue level has been established temporarily until 30 June 2008 pending data to be submitted by the applicant. If no data has been received by that date, the MRL will be withdrawn by a Directive or a Regulation.'

Pesticide residue and maximum residue level (mg/kg)										
Groups and examples of individual products to which the MRLs apply	Azoxystrobin	Chlorfenapyr	Folpet	Iprodione	Lambda-cyhalothrin	Maleic Hydrazide	Metaxyl including other mixtures of constituent isomers including metaxyl-M (sum of isomers)	Trifloxystrobin		
(c) Cucurbits — inedible peel	0,5		1	1 (p)	0,05					
Melons							0,2			0,3 (p)
Squashes										
Watermelons							0,2			0,2
Others							0,05 (*)			0,02 (*) (p)
(d) Sweetcorn	0,05 (*)		0,02 (*)	0,02 (*) (p)	0,05		0,05 (*)			0,02 (*) (p)
(iv) BRASSICA VEGETABLES										0,02 (*) (p)
(a) Flowering brassica	0,5		0,02 (*)	0,1 (p)	0,1		0,2			
Broccoli (including Calabrese)										
Cauliflower										
Others										
(b) Head brassica	0,3		0,02 (*)							
Brussels sprouts				0,5 (p)	0,05					
Head cabbage				5 (p)	0,2		1			
Others				0,02 (*) (p)	0,02 (*)		0,05 (*)			
(c) Leafy brassica	5		0,02 (*)		1					
Chinese cabbage				5 (p)						
Kale									0,2	
Others				0,02 (*) (p)			0,05 (*)			
(d) Kohlrabi	0,2		0,05	0,02 (*) (p)	0,02 (*)		0,05 (*)			

Groups and examples of individual products to which the MRLs apply	Pesticide residue and maximum residue level (mg/kg)									
	Azoxystrobin	Chlorfenapyr	Folpet	Iprodione	Lambda-cyhalothrin	Maleic Hydrazide	Metaxyl including other mixtures of constituent isomers including metalaxyl-M (sum of isomers)	Trifloxystrobin		
4. Oilseeds										
Linseed			0,05 (*)		0,05 (*)	0,5 (*) (p)	0,1 (*)	0,05 (*) (p)		
Peanuts				0,5 (p)						
Poppy seed										
Sesame seed										
Sunflower seed				0,5 (p)						
Rapeseed	0,5			0,5 (p)						
Soya bean	0,5									
Mustard seed										
Cotton seed										
Hemp seed										
Others	0,05 (*)			0,02 (*) (p)						
5. Potatoes										
Early potatoes	0,05 (*)	0,05 (*)	0,1	0,02 (*) (p)	0,02 (*)	50 (p)	0,05 (*)	0,02 (*) (p)		
Ware potatoes										
6. Tea (dried leaves and stalks, fermented or otherwise, <i>Camellia sinensis</i>)										
	0,1 (*)	50	0,05 (*)	0,1 (*) (p)	1	0,5 (*) (p)	0,1 (*)	0,05 (*) (p)		
7. Hops (dried), including hop pellets and unconcentrated powder										
	20	0,1 (*)	150	0,1 (*) (p)	10	0,5 (*) (p)	10	30 (p)		

(*) Indicates lower limit of analytical determination.

(a) Sum of captan and folpet.

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