

COMMISSION DIRECTIVE 2007/73/EC

of 13 December 2007

amending certain Annexes to Council Directives 86/362/EEC and 90/642/EEC as regards maximum residue levels for acetamiprid, atrazine, deltamethrin, imazalil, indoxacarb, pendimethalin, pymetrozine, pyraclostrobin, thiacloprid 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 86/362/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on cereals ⁽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.

(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) For atrazine temporary MRLs have been set in Directive 86/362/EEC by Commission Directive 2007/7/EC ⁽⁴⁾, pending submission of data by the applicant. Upon further examination, it appeared that more time should be allowed for the generation of residue trials data. It is therefore appropriate to prolong the validity of temporary MRLs for atrazine.

(4) MRLs for pesticides covered by Directive 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 acetamiprid, deltamethrin, indoxacarb, pendimethalin, pymetrozine, pyraclostrobin, thiacloprid and trifloxystrobin.

(5) For imazalil a Member State informed the Commission of its desire to revise national MRLs in accordance with Article 8 of Directive 90/642/EEC in the light of concerns about consumer intake. Proposals for the review of Community MRLs were submitted to the Commission.

(6) The lifetime exposure of consumers to the pesticides referred to in this Directive 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 ⁽⁵⁾. 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.

⁽¹⁾ OJ L 221, 7.8.1986, p. 37. Directive as last amended by Commission Directive 2007/62/EC (OJ L 260, 5.10.2007, p. 4).

⁽²⁾ OJ L 350, 14.12.1990, p. 71. Directive as last amended by Commission Directive 2007/62/EC.

⁽³⁾ OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2007/52/EC (OJ L 214, 17.8.2007, p. 3).

⁽⁴⁾ OJ L 43, 15.2.2007, p. 19.

⁽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).

- (7) An acute reference dose (ARfD) has been set for acetamiprid, deltamethrin, imazalil, indoxacarb, pymetrozine, pyraclostrobin and thiacloprid. 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 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.
- (8) 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.
- (9) The setting or modification at Community level of provisional MRLs does not prevent the Member States from establishing provisional MRLs for acetamiprid, indoxacarb, pyraclostrobin, thiacloprid 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.
- (10) It is therefore necessary to modify the MRLs set in Directives 86/362/EEC and 90/642/EEC, to allow proper surveillance and control of the uses of the plant protection products concerned 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.
- (11) Through the World Trade Organisation, the Community's trading partners have been consulted about the new MRLs and their comments on these levels have been taken into account.
- (12) Directives 86/362/EEC and 90/642/EEC should therefore be amended accordingly.
- (13) 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 86/362/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

Member States shall adopt and publish, by 14 June 2008 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive, except for deltamethrin and atrazine, for which they shall adopt and publish these by 18 December 2007 and for imazalil, for which they shall adopt and publish these by 14 September 2008. 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 15 June 2008, except for deltamethrin and atrazine for which they shall be applied from 19 December 2007 and for imazalil, for which they shall be applied from 15 September 2008.

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.

Article 4

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

⁽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.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 13 December 2007.

For the Commission
Markos KYPRIANOU
Member of the Commission

ANNEX I

In Part A of Annex II to Directive 86/362/EEC, the line for 'Atrazine' is replaced by the following:

Pesticide residues	Maximum levels in mg/kg
'Atrazine	0,1 ^(†) CEREALS

^(†) Temporary MRLs valid until 1 June 2009, pending submission of residue data by the applicant.'

Groups and examples of individual products to which the MRLs apply	Pesticide residue and maximum residue level (mg/kg)								
	Acetamiprid	Deltamethrin (cis-deltamethrin) ^(e)	Imazalil	Indoxacarb as sum of the isomers S and R	Pendimethalin	Pymetrozine	Pyraclostrobin	Thiacloprid	Trifloxystrobin
Pecans									
Pine nuts									
Pistachios							1 (P)		
Walnuts									
Others							0,02 (*) (P)		
(iii) POME FRUIT	1 (P)		2			0,02 (*)	0,3 (P)	0,3 (P)	0,5 (P)
Apples		0,2		0,5 (P)					
Pears									
Quinces									
Others		0,1		0,3 (P)					
(iv) STONE FRUIT			0,05 (*)						
Apricots	0,1 (P)			0,3 (P)		0,05	0,2 (P)	0,3 (P)	1 (P)
Cherries	0,2 (P)	0,2					0,3 (P)	0,3 (P)	1 (P)
Peaches (including nectarines and similar hybrids)	0,1 (P)			0,3 (P)		0,05	0,2 (P)	0,3 (P)	1 (P)
Plums	0,02 (P)						0,1 (P)	0,1 (P)	0,2 (P)
Others	0,01 (*) (P)	0,1		0,02 (*) (P)		0,02 (*)	0,02 (*) (P)	0,02 (*) (P)	0,02 (*) (P)
(v) BERRIES AND SMALL FRUIT	0,01 (*) (P)		0,05 (*)						
(a) Table and wine grapes		0,2		2 (P)		0,02 (*)		0,02 (*) (P)	5 (P)
Table grapes							1 (P)		
Wine grapes							2 (P)		
(b) Strawberries (other than wild)		0,2		0,02 (*) (P)		0,5	0,5 (P)	0,5 (P)	0,5 (P)

Groups and examples of individual products to which the MRLs apply	Pesticide residue and maximum residue level (mg/kg)								
	Acetamiprid	Deltamethrin (cis-deltamethrin) ^(e)	Imazalil	Indoxacarb as sum of the isomers S and R	Pendimethalin	Pymetrozine	Pyraclostrobin	Thiacloprid	Trifloxystrobin
Mangoes							0,05 ^(p)		0,5 ^(p)
Olives (table consumption)		1							
Olives (oil extraction)		1							
Papaya							0,05 ^(p)	0,5 ^(p)	1 ^(p)
Passion fruit									
Pineapples									
Pomegranate									
Others		0,05 ^(*)	0,05 ^(*)	0,02 ^(*) ^(p)			0,02 ^(*) ^(p)	0,02 ^(*) ^(p)	0,02 ^(*) ^(p)
2. Vegetables, fresh or uncooked, frozen or dry									
(i) ROOT AND TUBER VEGETABLES	0,01 ^(*) ^(p)	0,05 ^(*)	0,05 ^(*)			0,02 ^(*)		0,02 ^(*) ^(p)	
Beetroot									
Carrots					0,2		0,1 ^(p)		0,05 ^(p)
Cassava									
Celeriac					0,1				
Horseradish					0,2		0,3 ^(p)		
Jerusalem artichokes									
Parsnips					0,2		0,3 ^(p)		
Parsley root					0,2		0,1 ^(p)		
Radishes				0,2 ^(p)					
Salsify							0,1 ^(p)		

Groups and examples of individual products to which the MRLs apply	Pesticide residue and maximum residue level (mg/kg)								
	Acetamiprid	Deltamethrin (cis-deltamethrin) ^(e)	Imazalil	Indoxacarb as sum of the isomers S and R	Pendimethalin	Pymetrozine	Pyraclostrobin	Thiacloprid	Trifloxystrobin
(c) Cucurbits — inedible peel	0,01 (*) (p)	0,2		0,1 (p)		0,2	0,02 (*) (p)		
Melons			2					0,2 (p)	0,3 (p)
Squashes									
Watermelons								0,2 (p)	0,2
Others			0,05 (*)					0,02 (*) (p)	0,02 (*) (p)
(d) Sweet corn	0,01 (*) (p)	0,05 (*)	0,05 (*)	0,02 (*) (p)		0,02 (*)	0,02 (*) (p)	0,02 (*) (p)	0,02 (*) (p)
(iv) BRASSICA VEGETABLES	0,01 (*) (p)		0,05 (*)		0,05 (*)				
(a) Flowering brassica		0,1		0,3 (p)		0,02 (*)	0,1 (p)	0,02 (*) (p)	
Broccoli (including Calabrese)									0,05 (p)
Cauliflower									0,05 (p)
Others									0,02 (*) (p)
(b) Head brassica		0,1						0,02 (*) (p)	0,2 (p)
Brussels sprouts							0,2 (p)		
Head cabbage				3 (p)		0,05	0,2 (p)		
Others				0,02 (*) (p)		0,02 (*)	0,02 (*) (p)		
(c) Leafy brassica		0,5				0,2	0,02 (*) (p)	0,02 (*)	0,02 (*) (p)
Chinese cabbage				0,2 (p)					
Kale				0,2 (p)					
Others				0,02 (*) (p)					
(d) Kohlrabi		0,05 (*)		0,02 (*) (p)		0,02 (*)	0,02 (*) (p)	0,02 (*) (p)	0,02 (*) (p)

Groups and examples of individual products to which the MRLs apply	Pesticide residue and maximum residue level (mg/kg)								
	Acetamiprid	Deltamethrin (cis-deltamethrin) ^(e)	Imazalil	Indoxacarb as sum of the isomers S and R	Pendimethalin	Pymetrozine	Pyraclostrobin	Thiacloprid	Trifloxystrobin
Peas									
Lupines									
Others									
4. Oilseeds			0,05 (*)		0,1 (*)		0,02 (*) (p)		0,05 (*) (p)
Linseed									
Peanuts									
Poppy seed									
Sesame seed									
Sunflower seed									
Rape seed		0,1						0,3 (p)	
Soya bean				0,5 (p)					
Mustard seed		0,1						0,2 (p)	
Cotton seed	0,02 (p)					0,05			
Hemp seed									
Pumpkin seed									
Others	0,01 (*) (p)	0,05 (*)		0,05 (*) (p)		0,02 (*)		0,05 (*) (p)	
5. Potatoes	0,01 (*) (p)	0,05 (*)	3	0,02 (*) (p)	0,05 (*)	0,02 (*)	0,02 (*) (p)	0,02 (*) (p)	0,02 (*) (p)
Early potatoes									
Ware potatoes									
6. Tea (dried leaves and stalks, fermented or otherwise, <i>Camellia sinensis</i>)	0,1 (*) (p)	5	0,1 (*)	0,05 (*) (p)	0,1 (*)	0,1 (*)	0,05 (*) (p)	0,05 (*) (p)	0,05 (*) (p)
7. Hops (dried), including hop pellets and unconcentrated powder	0,1 (*) (p)	5	0,1 (*)	0,05 (*) (p)	0,1 (*)	15	10 (p)	0,05 (*) (p)	30 (p)

(*) Indicates lower limit of analytical determination.

(p) Temporary MRLs valid until 1 November 2008, pending review of the Annex III dossier under Directive 91/414/EEC and re-registration of deltamethrin formulations at Member State level.

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