COMMISSION DIRECTIVE 2001/57/EC

of 25 July 2001

amending the Annexes to Council Directives 86/362/EEC, 86/363/EEC and 90/642/EEC on the fixing of maximum levels for pesticide residues in and on cereals, foodstuffs of animal origin and certain products of plant origin, including fruit and vegetables respectively

(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], as last amended by Commission Directive 2001/48/EC [2], and in particular Article 10 thereof,

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 [3], as last amended by Commission Directive 2001/39/EC [4], 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 [5], as last amended by Directive 2001/48/EC, 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 [6], as last amended by Commission Directive 2001/49/EC [7], and in particular Article 4(1)(f) thereof,

Whereas:

(1) The existing active substance, fluroxypyr, was included in Annex I to Directive 91/414/EEC by Commission Directive 2000/10/EC [8]. No harmonised maximum residue levels for this active substance have yet been set by the Commission. The harmonisation of maximum residue levels is desirable both from the public health and from the trade point of view.

(2) Following inclusion of the substance in Annex I, Member States authorised a number of plant protection products containing it in accordance with Article 4 of Directive 91/414/EEC, and established provisional maximum residue levels as required by Article 4(1)(f) thereof. These authorisations concern uses as a herbicide in orchards or as a post emergence herbicide on apples, olives, onions, cereals, meadows and pastures. As required by that Directive, those levels, and the information on which they were based, have been notified to the Commission. This information together with data available from other sources has been reviewed and is sufficient to provisionally fix certain maximum residue levels.

(3) Article 5 of Directive 86/363/EEC requires that provisional maximum residue levels for animal products established pursuant to Article 4(1)(f) of Directive 91/414/EEC be indicated in Annex II to Directive 86/363/EEC.

(4) At the inclusion in Annex I to Directive 91/414/EEC the technical and scientific evaluation of fluroxypyr was finalised on 30 November 1999 in the format of the Commission review report for fluroxypyr. In this review report the acceptable daily intake (ADI) for fluroxypyr was set at 0,8 mg/kg bw/day. The lifetime exposure of consumers of food products treated with fluroxypyr has been assessed and evaluated in accordance with the procedures and practices used within the European Community, taking account of guidelines published by the World Health Organisation [9] and it has been calculated that the maximum residue levels fixed in this Directive do not give rise to an exceeding of this ADI.

(5) Acute toxic effects requiring the setting of an acute reference dose were not noted during the evaluation and discussion that preceded the inclusion of fluroxypyr in Annex I to Directive 91/414/EEC.

(6) To ensure that the consumer is adequately protected from exposure to residues in or on products for which no authorisations have been granted, it is prudent to set maximum residue levels at the lower limit of analytical determination for all such products covered by Directives 86/362/EEC, 86/363/EEC and 90/642/EEC. The setting at Community level of provisional maximum residue levels does not prevent Member States from establishing provisional maximum residue levels for fluroxypyr in accordance with Article 4(1)(f) of Directive 91/414/EEC and Annex VI thereto.

(7) Four years is considered a sufficient period of time during which to establish most further uses of fluroxypyr. After that period, provisional maximum residue levels should become definitive.

[1] OJ L 221, 7.8.1986, p. 37.
[2] OJ L 180, 3.7.2001, p. 26.
[3] OJ L 221, 7.8.1986, p. 43.
[4] OJ L 148, 1.6.2001, p. 70.
[5] OJ L 350, 14.12.1990, p. 71.
[6] OJ L 230, 19.8.1991, p. 1.
[7] OJ L 176, 29.6.2001, p. 61.
[8] OJ L 57, 2.3.2000, p. 28.

[9] 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).

(8) The Community's trading partners have been consulted about the levels set out in this Directive through the World Trade Organisation and their comments on these levels have been considered. No CODEX maximum residue levels are defined for fluroxypyr. The possibility of fixing maximum residue levels for specific pesticide/crop combinations other than those listed herein will be examined by the Commission on the basis of the submission of acceptable data.

(9) The opinions of the Scientific Committee for Plants, in particular advice and recommendations concerning the protection of consumers of food products treated with pesticides, have been taken into account.

(10) This Directive is in accordance with the opinion of the Standing Committee on Plant Health,

HAS ADOPTED THIS DIRECTIVE:

Article 1

In part A of Annex II to Directive 86/362/EEC, the following rows are added:

Pesticide residue	Maximum level (mg/kg)
'Fluroxypyr including its esters expressed as fluroxypyr	0,1 (P) Barley, oats, rye, triticale and wheat 0,05 (*) (P) Other cereals

(*) Indicates lower limit of analytical determination.
(P) Indicates provisional maximum residue level established in accordance with Article 4(1)(f) of Directive 91/414/EEC: all provisional maximum residue levels for these pesticide residues will be treated as definitive in accordance with Article 10 of the Directive with effect from four years after the entry into force of this Directive.'

Article 2

The following row shall be added to part B of Annex II to Directive 86/363/EEC:

Pesticide residue	Maximum level (mg/kg)		
	Of meat, including fat, preparations of meat, offals and animal fats as listed in Annex I within CN codes 0201, 0202, 0203, 0204, 0205 00 00, 0206, 0207, ex 0208, 0209 00, 0210, 1601 00 and 1602	For milk and milk products listed in Annex I within CN codes 0401, 0402, 0405 00 and 0406	Of shelled fresh eggs, for bird's eggs and egg yolks listed in Annex I within CN codes 0407 00 and 0408
'Fluroxypyr	0,5 (P) ex 0206 Kidney 0,05 (*) (P) other products	0,05 (*) (P)	0,05 (*) (P)

(*) Indicates lower limit of analytical determination.
(P) Indicates provisional maximum residue level established in accordance with Article 4(1)(f) of Directive 91/414/EEC: all provisional maximum residue levels for these pesticide residues will be treated as definitive in accordance with Article 10 of the Directive with effect from four years after the entry into force of this Directive.'

Article 3

In Annex II to Directive 90/642/EEC the column headed 'Fluroxypyr including its esters expressed as fluroxypyr', set out in the Annex to this Directive, is added.

Article 4

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

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 28 February 2002 at the latest. They shall forthwith inform the Commission thereof.

They shall apply these provisions as of 1 March 2002.

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 5

This Directive is addressed to the Member States.

Done at Brussels, 25 July 2001.

For the Commission

David BYRNE

Member of the Commission

ANNEX

Groups and examples of individual products to which the maximum residue levels apply	Pesticide residues and maximum residue levels (mg/kg)
	Fluroxypyr including its esters expressed as fluroxypyr
1. **Fruit, fresh, dried or uncooked, preserved by freezing, not containing added sugar; nuts**	0,05 (*) (P)
(i) CITRUS FRUIT	
Grapefruit	
Lemons	
Limes	
Mandarins (including clementines and other hybrids)	
Oranges	
Pomelos	
Others	
(ii) TREE NUTS (shelled or unshelled)	
Almonds	
Brazil nuts	
Cashew nuts	
Chestnuts	
Coconuts	
Hazelnuts	
Macadamia	
Pecans	
Pine nuts	
Pistachios	
Walnuts	
Others	
(iii) POME FRUIT	
Apples	
Pears	
Quinces	
Others	
(iv) STONE FRUIT	
Apricots	
Cherries	
Peaches (including nectarines and similar hybrids)	
Plums	
Others	
(v) BERRIES AND SMALL FRUIT	
(a) Table and wine grapes	
Table grapes	
Wine grapes	
(b) Strawberries (other than wild)	