COMMISSION DIRECTIVE 2000/81/EC

of 18 December 2000

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 Directive 2000/58/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 Directive 2000/58/EC, and in particular Article 10 thereof,

Having regard to Council Directive 90/642/EEC of 27 November 1990 on fixing of maximum levels for pesticide residues in and on certain products of plant origin including fruit and vegetables ([4]), as last amended by Directive 2000/58/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 ([5]), as last amended by Commission Directive 2000/68/EC ([6]), and in particular Article 4(1)(f) thereof,

Whereas:

(1) The new active substance, spiroxamine, was included in Annex I to Directive 91/414/EEC by Commission Directive 1999/73/EC ([7]) for use as fungicide only, without specifying particular conditions having an impact on crops which may be treated with plant protection products containing spiroxamine.

(2) The said inclusion in Annex I was based on assessment of the information submitted concerning proposed use as fungicide on cereals and vines. Information relating to uses on cereals and vines has been submitted by certain Member States in accordance with the requirements of Article 4(1)(f) of Directive 91/414/EEC. The information available has been reviewed and is sufficient to fix certain maximum residue levels.

(3) Where no Community maximum residue level or provisional MRL exists Member States shall establish a national provisional maximum residue level in accordance with Article 4(1)(f) of Directive 91/414/EEC before the authorisation may be granted.

(4) At the inclusion in Annex I to Directive 91/414/EEC the technical and scientific evaluation of spiroxamine has been finalised on 12 May 1999 in the format of the Commission review report for spiroxamine. In this review report the acceptable daily intake (ADI) for spiroxamine was set at 0,025 mg/kg bw/day. The lifetime exposure of consumers of food products treated with spiroxamine 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 ([8]) and it has been calculated that the maximum residue levels fixed in this Directive do not give rise to an exceedence of this ADI.

([1]) OJ L 221, 7.8.1986, p. 37.
([2]) OJ L 244, 29.9.2000, p. 78.
([3]) OJ L 221, 7.8.1986, p. 43.
([4]) OJ L 350, 14.12.1990, p. 71.
([5]) OJ L 230, 19.8.1991, p. 1.
([6]) OJ L 276, 28.10.2000, p. 41.
([7]) OJ L 206, 5.8.1999, p. 16.
([8]) 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/FOS97.7).

(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 spiroxamine in Annex I to Directive 91/414/EEC.

(6) For certain agricultural products the use conditions for spiroxamine were already defined in a manner which permits the establishing of definitive maximum residue levels.

(7) 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 provisional maximum residue levels at the lower limit of analytical determination for all those products covered by Council Directives 86/362/EEC, 86/363/EEC and 90/642/EEC. The setting at Community level of such provisional maximum residue levels does not prevent the Member States from establishing provisional maximum residue levels for spiroxamine in accordance with Article 4(1)(f) of Directive 91/414/EEC, and in accordance with Annex VI to Directive 91/414/EEC, in particular part B, section 2.4.2.3 of this Annex; four years is considered a sufficient period of time during which to establish most further uses of spiroxamine. After that period these provisional maximum residue levels should become definitive.

(8) The Community notified the draft Commission Directive to the World Trade Organisation and the comments received have been considered in finalising the Directive. The possibility of fixing import tolerance maximum residue levels for specific pesticide/crop combinations 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

The following shall be added to part A of Annex II to Directive 86/362/EEC:

Pesticide residue	Maximum level in mg/kg	
'Spiroxamine	0,3 (p)	Barley and oats
	0,05 (p) (*)	Other cereals

(*) Indicates lower limit of analytical determination.
(p) Indicates provisional maximum residue level.'

Article 2

The following 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, offal 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
Spiroxamine carboxylic acid expressed as spiroxamine	0,2 (p) ex 0206 Kidney, liver 0,05 (p) (*) Other products	0,02 (p)	0,05 (p) (*)

(*) Indicates lower limit of analytical determination.
(p) Indicates provisional maximum residue level.'

Article 3

The contents of the Annex to this Directive shall be added to Annex II to Directive 90/642/EEC.

Article 4

1. For those agricultural products listed in Annex II to Directives 86/362/EEC, 86/363/EEC and 90/642/EEC where the maximum residue levels for spiroxamine are indicated as '(p)', this shall mean that they are provisional (p) in accordance with the provisions of Article 4(1)(f) of Directive 91/414/EEC.

2. Four years after the entry into force of this Directive, provisional maximum residue levels for spiroxamine in the Annexes shall cease to be provisional and shall become definitive in the sense of Article 4(1) of Directives 86/362/EEC and 86/363/EEC or Article 3 of Directive 90/642/EEC respectively.

Article 5

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

2. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 1 July 2001 at the latest. They shall forthwith inform the Commission thereof.

3. When Member Sates 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 6

This Directive is addressed to the Member States.

Done at Brussels, 18 December 2000.

For the Commission

David BYRNE

Member of the Commission