COMMISSION DIRECTIVE 2001/48/EC

of 28 June 2001

amending the Annexes to Council Directives 86/362/EEC and 90/642/EEC on the fixing of maximum levels for pesticide residues in and on cereals 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 2001/39/EC [2], and in particular Article 10 thereof,

Having regard to Council Directive 90/642/EEC of 27 November1990 on the fixing of maximum levels for pesticide residues in and on certain products of plant origin including fruit and vegetables [3], as last amended by Directive 2001/39/EC, and in particular Article 7 thereof,

Having regard to Council Directive 91/414/EEC of 15 July 1991 on the placing of plant protection products on the market [4], as last amended by Commission Directive 2001/47/EC [5], and in particular Article 4(1)(f) thereof,

Whereas:

(1) The new active substances, azoxystrobin and kresoxim methyl, were included in Annex I to Directive 91/414/EEC by Commission Directives 98/47/EC [6] and 1999/1/EC [7], respectively, for use as fungicides only, without specifying particular conditions having an impact on crops which may be treated with plant protection products containing these active ingredients.

(2) Maximum residue levels in and on all commodities covered by Directives 86/362/EEC and 90/642/EEC were fixed by Commission Directives 1999/71/EC [8] and 2000/48/EC [9] for azoxystrobin residues, and by Commission Directive 2000/58/EC [10] for kresoxim methyl residues.

(3) In fixing the said maximum residue levels, it was recognised that these levels should be kept under review and should be changed to take account of new information and data. Directives 1999/71/EC, 2000/48/EC and 2000/58/EC acknowledged that national provisional maximum residue levels for other cereals and fruit and vegetables should be fixed by Member States as a part of their authorisation of plant protection products containing azoxystrobin or kresoxim methyl and should be notified to the Commission under the requirements of Article 4(1)(f) to Directive 91/414/EEC. To facilitate this eventuality, some of the levels set in Directives 1999/71/EC and 2000/48/EC and all of the levels set in Directive 2000/58/EC were fixed on a provisional basis, enabling Member States to grant further authorisations for new uses and to notify the Commission under the procedure described by the said Article. This Article provides that where a provisional Community maximum residue level exists and where the new authorised use would lead to higher levels, the authorising Member State 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.

[1] OJ L 221, 7.8.1986, p. 37.
[2] OJ L 148, 1.6.2001, p. 70.
[3] OJ L 350, 14.12.1990, p. 71.
[4] OJ L 230, 19.8.1991, p. 1.
[5] OJ L 175, 28.6.2001, p. 21.
[6] OJ L 191, 7.7.1998, p. 50.
[7] OJ L 21, 28.1.1999, p. 21.
[8] OJ L 194, 27.7.1999, p. 36.
[9] OJ L 197, 3.8.2000, p. 26.
[10] OJ L 244, 29.9.2000, p. 78.

(4) To ensure that the consumer is adequately protected from exposure to residues in or on products for which no authorisations have been granted, it was considered prudent, in adopting Directives 1999/71/EC, 2000/48/EC and 2000/58/EC, to set provisional maximum residue levels at the lower level of analytical determination for such products. The setting at Community level of such provisional maximum residue levels is without prejudice to the granting of provisional authorisations by the Member States for uses of azoxystrobin and/or kresoxim methyl on such products in accordance with Article 4(1)(f) of Directive 91/414/EEC.

(5) In order to authorise a plant protection product, Member States must apply the uniform principles provided for in Annex VI to Directive 91/414/EEC in evaluating, in particular, a dossier conforming to the requirements of Annex III to Directive 91/414/EEC, submitted by the applicant for authorisation. Annex III, Part A, section 8 of Directive 91/414/EEC requires applicants to submit certain information including proposed maximum residue levels together with full justification and estimations of the potential and actual exposure through diet and other means. Annex VI, part B, section 2.4.2 and Part C, section 2.5 of Directive 91/414/EEC requires Member States to evaluate the information submitted concerning impact on human or animal health arising from residues and the impact on the environment and to take decisions on authorisations which ensure that residues occurring reflect the minimum quantities of the plant protection product necessary to achieve adequate control corresponding to good agricultural practice, applied in such a manner that the residues at harvest, slaughter or after storage, as appropriate, are reduced to a minimum.

(6) New data has been provided for uses of azoxystrobin on aubergines, peppers, oats, hops, peas (fresh and dry) and for uses of kresoxim methyl on asparagus, strawberries and other small fruits and berries. This new data has been evaluated and it is considered appropriate to revise the provisional maximum residue levels fixed for these products in Directives 1999/71/EC, 2000/48/EC and 2000/58/EC.

(7) At the inclusion in Annex I to Directive 91/414/EEC the technical and scientific evaluation of azoxystrobin has been finalised on 22 April 1998 in the format of the Commission review report for azoxystrobin. In this review report the acceptable daily intake (ADI) for azoxystrobin was set at 0,1 mg/kg bw/day. At the inclusion in Annex I to Directive 91/414/EEC the technical and scientific evaluation of kresoxim methyl has been finalised on 16 October 1998 in the format of the Commission review report for kresoxim methyl. In this review report the acceptable daily intake (ADI) for kresoxim methyl was set at 0,4 mg/kg bw/day. The lifetime exposure of consumers of food products treated with azoxystrobin or kresoxim methyl 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 [1] and it has been calculated that the maximum residue levels fixed in this Directive do not give rise to an exceedence of these ADIs.

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

(9) 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. 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.

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

(11) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Plant Health,

[1] 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)

HAS ADOPTED THIS DIRECTIVE:

Article 1

In part A of Annex II to Directive 86/362/EEC the following entry shall be added in respect of azoxystrobin:

Pesticide residue	Maximum level in mg/kg
'Azoxystrobin	0,3 (P) Oats

(P) Indicates provisional maximum residue level established in accordance with Directive 91/414/EEC Article 4(1)(f); all provisional maximum residue levels for these pesticide residues will be treated as defintive in accordance with Article 10 of the Directive with effect from 1 August 2003.'

Article 2

In Annex II to Directive 90/642/EEC the columns headed 'azoxystrobin', and 'kresoxim methyl' are replaced by those set out in the Annex to this Directive.

Article 3

The provision in Article 3(2) of Directive 2000/42/EC where 'The maximum level for residues of acephate on peaches shall be fixed at 0,02(*) mg/kg' shall be applied by the Member States as of 1 December 2001.

Article 4

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

2. Member States shall adopt and publish the legislative, regulatory or administrative measures to comply with this Directive by 28 February 2002 at the latest. They shall forthwith inform the Commission thereof.

3. They shall apply these measures as from 1 March 2002.

4. 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, 28 June 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)	
	Azoxystrobin	Kresoxim methyl
1. **Fruit, fresh, dried or uncooked, preserved by freezing, not containing added sugar; nuts**		
(i) CITRUS FRUIT Grapefruit Lemons Limes Mandarins (including clementines and other hybrids) Oranges Pomelos Others	0,05 (P) (*)	0,05 (P) (*)
(ii) TREE NUTS (shelled or unshelled) Almonds Brazil nuts Cashew nuts Chestnuts Coconuts Hazelnuts Macadamia Pecans Pine nuts Pistachios Walnuts Others	0,1 (P) (*)	0,1 (P) (*)
(iii) POME FRUIT Apples Pears Quinces Others	0,05 (P) (*)	0,2 (P)
(iv) STONE FRUIT Apricots Cherries Peaches (including nectarines and similar hybrids) Plums Others	0,05 (P) (*)	0,05 (P) (*)
(v) BERRIES AND SMALL FRUIT		
(a) Table and wine grapes Table grapes Wine grapes	2	1 (P)
(b) Strawberries (other than wild)	0,05 (P) (*)	0,05 (P) (*)