COUNCIL DIRECTIVE 97/41/EC

of 25 June 1997

amending Directives 76/895/EEC, 86/362/EEC, 86/363/EEC and 90/642/EEC relating to the fixing of maximum levels for pesticide residues in and on, respectively, fruit and vegetables, cereals, foodstuffs of animal origin, and certain products of plant origin, including fruit and vegetables

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 43 thereof,

Having regard to the proposal from the Commission (1),

Having regard to the opinion of the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas Council Directives 86/362/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on cereals (4), 86/363/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on foodstuffs of animal origin (5) and 90/642/EEC of 27 November 1990 relating to the fixing of maximum levels for pesticide residues in and on certain products of plant origin, including fruit and vegetables (6) have established a common regime providing for mandatory residue levels applicable throughout the Community;

Whereas this regime provides for a gradual transfer of the maximum residue levels established pursuant to Council Directive 76/895/EEC of 23 November 1976 relating to the fixing of maximum levels for pesticide residues in and on fruit and vegetables (7) to Directive 90/642/EEC after technical consideration; whereas such transfer has already been realized for certain levels and is still in preparation for others;

Whereas Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (8) has provided for a mechanism linking the authorization of a plant protection product containing an active substance included in Annex I of that Directive to the obligation for the Member State having granted the authorization to establish a provisional maximum residue level of the active substance concerned in the treated crops; whereas this mechanism also provides for a mandate to the Commission to establish, on the basis of the provisional maximum residue level set by a Member State, provisional maximum residue levels applicable throughout the Community; whereas for reasons of clarity, the provisional maximum residue levels set according to this mechanism, should be integrated in an appropriate way in the Annexes to Directives 86/362/EEC, 86/363/EEC and 90/642/EEC;

Whereas rules have to be set concerning the maximum residue levels which are acceptable in dried and/or processed single agricultural products and in composite foodstuffs in order to ensure proper human health protection as well as proper functioning of the internal market with regard to such products;

Whereas Member States should provide for the possibility to establish maximum residue levels for products from other Member States in order to prevent as much as possible trade problems due to the absence of harmonized maximum residue levels for certain residue/product combinations;

Whereas a conciliation procedure is necessary in cases where in practice barriers to intra-Community trade have appeared owing to the absence of harmonized maximum residue levels for certain residue/product combinations;

Whereas effective monitoring of pesticide residues should be systematically organized at both national and Community stages in order to ensure compliance with the mandatory levels set and to contribute to the highest degree of consumer confidence in the degree of protection of human health achieved;

Whereas it is essential, in order to guarantee a high level of consumer protection, to ensure that checks on compliance with the maximum residue levels established are carried out; whereas such checks should cover as far as

(1) OJ No C 201, 5. 8. 1995, p. 8, and OJ No C 103, 2. 4. 1997, p. 20.
(2) OJ No C 320, 28. 10. 1996, p. 96.
(3) OJ No C 82, 19. 3. 1996, p. 1.
(4) OJ No L 221, 7. 8. 1986, p. 37. Directive as last amended by Directive 96/33/EC (OJ No L 144, 18. 6. 1996, p. 35).
(5) OJ No L 221, 7. 8. 1986, p. 43. Directive as last amended by Directive 96/33/EC (OJ No L 144, 18. 6. 1996, p. 35).
(6) OJ No L 350, 14. 12. 1990, p. 71. Directive as last amended by Directive 96/32/EC (OJ No L 144, 18. 6. 1996, p. 12).
(7) OJ No L 340, 9. 12. 1976, p. 26. Directive as last amended by Directive 96/32/EC (OJ No L 144, 18. 6. 1996, p. 12).
(8) OJ No L 230, 19. 8. 1991, p. 1. Directive as last amended by Directive 96/32/EC (OJ No L 144, 18. 6. 1996, p. 12).

possible all plant products covered by the residue Directives; whereas, however, optimum use should be made of available resources and therefore it may appear unnecessary to perform checks on processed, dried or composite foods or on intermediate products in processing insofar as sufficient checks are carried out on raw materials;

Whereas it is necessary to update certain provisions of Directives 76/895/EEC, 86/362/EEC and 86/363/EEC in order to align them on the similar provisions in Directive 90/642/EEC to ensure consistency in the implementation of all the provisions concerning maximum residue levels;

Whereas the introduction of amendments in the Annexes as a result of developments in scientific and technical knowledge, the setting of temporary maximum residue levels and the establishment of dilution or concentration factors related to certain drying or processing operations are technical measures; whereas a Regulatory Committee decision procedure seems appropriate for the adoption of such measures in order to ensure an effective and streamlined operation of the implementation measures pursuant to Directives 76/895/EEC, 86/362/EEC, 86/363/EEC, 90/642/EEC, 91/414/EEC and other relevant Directives;

Whereas an adequate protection of human health and the proper functioning of the internal market require that the amendments introduced in the Annexes are swiftly applied by all the Member States,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 76/895/EEC is hereby amended as follows:

1. Article 1 shall be replaced by the following:

'*Article 1*

1. This Directive concerns products intended for human or, in exceptional cases, animal consumption listed under the Common Customs Tariff headings set out in Annex I and in or on which are found the pesticide residues listed in Annex II.

2. This Directive shall also apply to the same products after drying or processing or after inclusion in a composite food in so far as they may contain certain pesticide residues.

3. This Directive shall apply without prejudice to Commission Directive 91/321/EEC of 14 May 1991 on infant formulae and follow-on formulae (*) and Commission Directive 96/5/EC of 16 February 1996 on processed cereal-based foods and baby foods for infants and young children (**). However, until maximum levels have been established in accordance with the provisions of Article 6 of Directive 91/321/EEC or Article 6 of Directive 96/5/EC the provisions of Article 5a (1) and (3) to (6) of this Directive shall apply for the products concerned.

(*) OJ No L 175, 4. 7. 1991, p. 35. Directive as last amended by Directive 96/4/EC (OJ No L 49, 28. 2. 1996, p. 12).
(**) OJ No L 49, 28. 2. 1996, p. 17.';

2. Article 2 shall be replaced by the following:

'*Article 2*

For the purposes of this Directive:

1. "pesticide residues" shall mean residues of the pesticides and of their metabolites, and breakdown or reaction products as defined in Annex II, which are present in or on the products referred to in Article 1;

2. "putting into circulation" shall mean any post-harvest handing over, whether or not for a consideration, of the products referred to in Article 1.';

3. Article 4 (1) shall be replaced by the following:

'1. Where a Member State, as a result of new information or of a reassessment of existing information considers that a maximum level fixed in Annex II endangers human or animal health, and therefore requires swift action to be taken, that Member State may temporarily reduce the level in its own territory. In that case, it shall immediately notify the other Member States and the Commission of the measures taken, attaching a statement of the reasons therefor.';

4. Article 5 shall be replaced by the following:

'*Article 5*

Amendments to Annexes I and II as a result of developments in scientific or technical knowledge shall be adopted in accordance with the procedure laid down in Article 7. In particular, when establishing maximum residue levels, account shall be taken of a relevant dietary intake risk assessment and of the number and quality of the data available.';

5. the following Article shall be inserted:

'Article 5a

1. For the purposes of this Article a Member State of origin shall be defined as the Member State in whose territory a product specified in Article 1 (1) and (2) is either legally produced and marketed or put into free circulation, and a Member State of destination as the Member State into whose territory such product is introduced and put into circulation for operations other than transit to another Member State or third country.

2. Member States shall introduce arrangements for establishing maximum residue levels, whether permanent or temporary, for products referred to in Article 1 (1) and (2), brought into their territories from a Member State of origin, taking into account good agricultural practice in the Member State of origin, and without prejudice to conditions necessary to protect the health of consumers, in cases where no maximum residue levels have been established for these products in accordance with Article 5.

3. Where

— no maximum residue level has been established for a product referred to in Article 1 (1) and (2) in accordance with Article 5, and

— that product, which satisfies the maximum residue levels applied by its Member State of origin, has been subjected in the Member State of destination to measures whose effect is to prohibit or restrict its putting into circulation, on the grounds that the product contains pesticide residue levels in excess of the maximum residue level accepted in the Member State of destination, and

— either the Member State of destination has introduced new maximum residue levels or has altered the levels laid down in its legislation, or it has made changes to its controls which are disproportionate and/or discriminatory compared with those for its domestic production, or the maximum residue level applied by the Member State of destination differs substantially from the corresponding levels established by other Member States, or the maximum residue level applied by the Member State of destination represents a disproportionate level of protection compared with the level of protection applied by the Member State to pesticides carrying a similar risk or to similar agricultural products or foodstuffs,

the following exceptional provisions shall apply:

(a) the Member State of destination shall communicate the measures adopted to the other Member State concerned and the Commission within 20 days of their application. The notification shall document the facts involved;

(b) on the basis of the notification referred to in (a), the two Member States concerned shall contact each other without delay in order to remove, whenever possible, the prohibitive or restrictive effect of the measures adopted by the Member State of destination by means of measures agreed between them; the Member States shall submit all the requiste information to each other.

Within a period of three months of the notification referred to in (a), the Member States concerned shall inform the Commission of the result of such contacts and in particular the measures they intend to apply, if any, including the maximum residue level they have agreed. The Member State of origin shall inform the other Member States of the result of such contacts;

(c) the Commission shall immediately refer the matter to the Standing Committe on Plant Health and, if possible, submit a proposal aimed at establishing in Annex II a temporary maximum residue level, which shall be adopted in accordance with the procedure laid down in Article 7.

In its proposal, the Commission shall take account of existing technical and scientific knowledge on the matter and in particular data submitted by the Member States with an interest, especially the toxicological assessment and estimated ADI, good agricultural practice and the trial data which the Member State of origin used to establish the maximum residue level, together with the reasons given by the Member State of destination for deciding on the measures in question.

The period of validity of the temporary maximum level shall be laid down in the legal act adopted and may not exceed four years. That period may be linked to the supply, by the Member State of origin and/or other Member States with an interest, of the trial data required by the Commission in order to set the maximum residue level in accordance with Article 5. At their request, the Commission and the Member States shall be kept informed regarding the programme of trials established.

4. Any measure provided for in paragraphs 2 or 3 shall be taken by a Member State with due regard for its obligations under the Treaty, in particular Articles 30 to 36 thereof.

5. Council Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and

regulations (*) shall not apply to measures adopted and notified by Member States in accordance with paragraph 3 of this Article.

6. Detailed measures for the implementation of the procedure set out in this Article may be adopted in accordance with the procedure laid down in Article 8.

(*) OJ No L 109, 26. 4. 1983, p. 8. Directive as last amended by Decision 96/139/EC (OJ No L 32, 10. 2. 1996, p. 31).';

6. paragraphs 2, 3 and 4 of Article 7 shall be replaced by the following:

'2. The representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of Decisions which the Council is called upon to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

3. The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the Committee.

4. If the measures are not in accordance with the opinion of the committee, or if no opinion is delivered, the Commission shall without delay submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

5. If, within three months following the date on which the matter was referred to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission save where the Council has decided against the said measures by a simple majority.';

7. paragraphs 2, 3 and 4 of Article 8 shall be replaced by the following:

'2. The representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of Decisions which the Council is called upon to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

3. The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the committee.

4. If the measures are not in accordance with the opinion of the committee, or if no opinion is delivered, the Commission shall without delay submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

5. If, within 15 days, following the date on which the matter was referred to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission save where the Council has decided against the measures by a simple majority.';

8. the following Article shall be added:

'Article 8a

The Commission shall be assisted by a committee composed of the representatives of the Member States and chaired by the representative of the Commission.

The representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of Decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the committee.

If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission.';

9. Article 9 shall be replaced by the following:

'Article 9

1. This Directive shall apply to products referred to in Article 1 intended for export to third countries. However, maximum pesticide residue levels set in accordance with this Directive shall not apply in the case of products treated before export where it can be satisfactorily proved that:

(a) the third country of destination requires a particular treatment in order to prevent the introduction of harmful oganisms into its territory; or

(b) the treatment is necessary in order to protect the products against harmful organims during transport to the third country of destination and storage there.

2. This Directive shall not apply to the products referred to in Article 1 where it can be satisfactorily proved that they are intended for:

(a) the manufacture of products other than foodstuffs or animal feed; or

(b) sowing or planting.';

10. after Article 10, the following Article shall be inserted:

'Article 10a

Member States shall bring into force the laws, regulations and administrative provisions necessary to ensure that the amendments in Annex II resulting from Decisions referred to in Article 5 can be implemented in their territory within a maximum period of eight months from their adoption, and within a shorter implementation period when required for urgent reasons of human health protection.

In order to safeguard legitimate expecations, Community legal implementing acts may provide for transitional periods for the implementation of certain maximum residue levels allowing the normal marketing of the harvested products.'

Article 2

Directive 86/362/EEC is hereby amended as follows:

1. Article 1 shall be replaced by the following:

'Article 1

1. This Directive shall apply to the products listed in Annex I, to the products obtained from them after drying or processing and to the composite foods in which they are included, in so far as they may contain peticide residues.

2. This Directive shall apply without prejudice to:

(a) Council Directive 74/63/EEC of 17 December 1973 on the fixing of maximum permitted levels for undesirable substances and products in feedingstuffs (*);

(b) Council Directive 76/895/EEC of 23 November 1976 relating to the fixing of maximum levels for pesticide residues in and on fruit and vegetables (**);

(c) 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 (***);

(d) Commission Directive 91/321/EEC of 14 May 1991 on infant formulae and follow-on formulae (****) and Commission Directive 96/5/EC of 16 February 1996 on processed cereal-based foods and baby foods for infants and young children (*****). However, until maximum levels have been established in accordance with Article 6 of Directive 91/321/EEC or Article 6 of Directive 96/5/EC the provisions of Article 5a (1) and (3) to (6) of this Directive shall apply for the products concerned.

3. This Directive shall also apply to products referred to in paragraph 1 intended for export to third countries. However, maximum pesticide residue levels set in accordance with this Directive shall not apply in the case of products treated before export where it can be satisfactorily proved that:

(a) the third country of destination requires a particular treatment in order to prevent the introduction of harmful organisms into its territory; or

(b) the treatment is necessary in order to protect the products against harmful organisms during transport to the third country of destination and storage there.

4. This Directive shall not apply to the products referred to in paragraph 1 where it can satisfactorily be proved that they are intended for:

(a) the manufacture of products other than foodstuffs or animal feed; or

(b) sowing or planting.

(*) OJ No L 38, 11. 2. 1974, p. 31. Directive as last amended by Directive 96/25/EC (OJ No L 125, 23. 5. 1996, p. 35).

(**) OJ No L 340, 9. 12. 1976, p. 26. Directive as last amended by Directive 96/32/EC (OJ L 144, 18. 6. 1996, p. 12).

(***) OJ No L 350, 14. 12. 1990, p. 71. Directive as last amended by Directive 96/32/EC (OJ No L 144, 18. 6. 1996, p. 12).

(****) OJ No L 175, 4. 7. 1991, p. 35. Directive as last amended by Directive 96/4/EC (OJ No L 49, 28. 2. 1996, p. 12).

(*****) OJ No L 49, 28. 2. 1996, p. 17.';