



COMMISSION OF THE EUROPEAN COMMUNITIES

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Proposal for a
COUNCIL DIRECTIVE

amending 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,

Council Directive 86/362/EEC of 24 July 1986
on the fixing of maximum levels for
pesticide residues in and on cereals,

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, and

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

(presented by the Commission)

EXPLANATORY MEMORANDUM

1. The use of pesticides in modern agriculture is considered essential to minimize crop losses resulting from pest and disease attacks. Their use has contributed significantly to improvements in agricultural productivity and also in produce quality. However, it must be realised that pesticides may be dangerous and accordingly their residues should only be present in amounts that are absolutely necessary for optimum pesticidal effect and then only if toxicologically acceptable.
2. The necessity to regulate pesticide residues was formally recognised by the Council in its resolution of 22 July 1974¹ relating to veterinary, phytosanitary and animal nutrition sectors, and subsequently by the adoption in 1976 of Council Directive 76/895/EEC relating to the fixing of maximum levels for pesticide residues in and on fruit and vegetables².

The scope of Community coverage of maximum levels for pesticide residues was significantly enlarged in 1986 by adoption of Council Directives 86/362/EEC and 86/363/EEC³ covering cereals and products of animal origin respectively, and in 1990 by adoption of Council Directive 90/642/EEC⁴ on the fixing of maximum levels for pesticide residues in and on certain products of plant origin, including fruit and vegetables. Since the adoption of Directive 90/642/EEC the Community regime covers in principle most important components of the diet, which allows a more systematic approach being taken for establishing Community maximum residue limits than was previously possible.

The Commission never considered Directive 76/895/EEC entirely satisfactory due to the fact that Member States are not required to adopt for their national trade the maximum levels laid down in the Directive.

By adopting Directive 90/642/EEC - where the levels fixed are binding for all trade - the Council created a framework for improving the system applicable to fruit and vegetables and allowed the progressive transferral of existing maximum levels in Directive 76/895/EEC to

¹ OJ N° C92 of 6.8.1974, p.2

² OJ N° L340 of 9.12.1976, p.26

³ OJ N° L221 of 7.8.1986, p.37

⁴ OJ N° L350 of 14.12.1990, p.71

Directive 90/642/EEC. This transferral already started with the adoption of Council Directives 93/58/EC⁵ and 94/30/EC⁶. Further transfers in the future will finally result in the regime of Directive 76/895/EEC being completely replaced by the one provided for in Directive 90/642/EEC.

In this way, the increased degree of harmonisation already achieved by Directives 86/362/EEC for cereals and 86/363/EEC for foodstuffs of animal origin, providing for maximum levels to be applied in all Member States, will gradually be extended to all other agricultural products by setting maximum residue levels in the framework of Directive 90/642/EEC. In this context the Council has already adopted several directives (93/57/EC⁷ and 94/29/EC)⁸.

Moreover in 1991, the Council adopted Directive 91/414/EEC⁹ concerning the placing of plant protection products on the market which provided in its Article 4 (1)(f) for a formal link between the authorization of a plant protection product by a Member State and the establishment of corresponding maximum residue levels in the agricultural products. The Directive provides for the establishment of provisional Community maximum residue levels following notification by a Member State. Whilst this system should be efficient and practicable for new active substance as their Good Agricultural Practices gradually evolve in Member States, it would be clearly impracticable for existing active substances with their already existing wide spectrum of uses. In such cases, it could involve reexamining single pesticide/product combination many times over a relatively short period of time, notwithstanding the fact that most Good Agricultural Practices in Member States will have been known at the time of the examination of an active substance for inclusion in Annex I to Directive 91/414/EEC. The Commission is of the opinion that it would be preferable to systematically fix maximum residues levels, where possible, at the time of inclusion of an active substance in Annex I to Directive 91/414/EEC. Indeed it is foreseen that the present

⁵ OJ N° L211 of 23.8.93, p.6

⁶ OJ N° L189 of 23.7.94, p.70

⁷ OJ N° L211 of 23.8.93, p.1

⁸ OJ N° L189 of 23.7.94, p.67

⁹ OJ N° L230 of 19.8.91, p.1

successful approach used to establish MRLs since the adoption of Directive 90/642/EEC should continue, although at significantly increased rate than was previously possible. This approach should allow the application of the most appropriate mechanism for new and existing active substances, thereby allowing the Community to expeditiously and systematically approach the establishment of MRLs, ensuring a high level of consumer protection and contributing to the efficient functioning of the Single Market.

3. The Commission is of opinion that the current framework for maximum residue level setting established in the Directives 76/895/EEC, 86/362/EEC, 86/363/EEC and 90/642/EEC needs to be improved in order to permit the Community to react more adequately to the increased tasks it will be confronted with in future. The current proposal has provided for the amendments the Commission feels necessary to be introduced in the current legislation.

- (a) Extension of the scope of the Directives to dried and/or processed individual agricultural products and to composite processed products.

Article 3(1) of Directive 90/642/EEC already provides, only for dried products of plant origin covered by that Directive, that the maximum residue level applied must be the level laid down for the raw product, taking into account the residue concentration caused by the drying process. Problems of human health protection and adequate functioning of the single market can however also arise for other dried products, or for products having undergone other types of processing or for products having been incorporated into composite products. In line with the principle established in Article 3(1) of Directive 90/642/EEC, the Commission proposes in the present proposal the levels applied by Member States to such products being based on maximum residue levels set in the Annexes II to Directives 86/362/EEC, 86/363/EEC and 90/642/EEC taking into account the dilution or concentration of the pesticide residue in the agricultural products resulting from processing and/or, where relevant, incorporation in a composite food. It is also proposed that the dilution or concentration factors related to certain drying or processing operations may be harmonised at Community level, if this would appear necessary.

- (b) Introduction of an adequate framework for setting provisional maximum residue levels throughout the Community according to the provisions of Article 4

(1) (f) of Directive 91/414/EEC.

According to these provisions, provisional maximum residue levels will have to be set by the Commission - within 3 months from notification by a Member State - on the basis of the good agricultural practice in only one or few Member States and of the toxicological data made available for the evaluation of the active substance in view of its inclusion in Annex I to Directive 91/414/EEC. In order to avoid maximum residue levels being dispersed over several legal instruments, the Commission proposes that the provisional maximum residue levels be incorporated in the annexes II of Directives 86/362/EEC, 86/363/EEC and 90/642/EEC with a specific reference to the procedure of Article 4 (1)(f). Such a procedure seems justified given that provisional maximum residue levels only differ from final maximum residue levels in the fact that an adaptation is more likely due to the ongoing evolution of good agricultural practice in Member States, in particular in those which did not yet grant an authorization at the time the proposal for a maximum residue level was first notified to the Commission.

- (c) Introduction of procedures for situations where barriers to intra community trade may be expected or have appeared as the result of the absence of harmonised maximum residue levels for certain pesticide/product combinations.

Despite the increased progress in fixing new maximum residue levels since the adoption of Directive 90/642/EEC and the impetus which may be expected in the forthcoming years in the setting of maximum residue levels throughout the Community, it is evident that for many pesticide/product combinations common maximum residue levels will only be set after several years, where already now it is required that the single market can operate adequately. The current provisions of Directives 86/362/EEC, 86/363/EEC and 90/642/EEC do not provide for a conflict resolving procedure in cases where, in the absence of harmonised maximum residue levels, barriers may be expected to appear or have appeared for products satisfying the maximum residue levels applied in the producing Member State but not those applied by the importing Member State.

To ensure the best possible functioning of the single market in these situations the following procedures are proposed.

- 1) In cases where prohibitions or restrictions to trade are expected by a producing Member State.

The proposal provides that every Member State shall provide for a system enabling the establishment of "import tolerances" in those cases where no Community harmonization has yet been adopted. When establishing such maximum residue levels Member States have to take into account the good agricultural practice in the producing Member State. This system would enable a producing Member State, who is expecting trade problems, to provide all necessary data, including its good agricultural practice, to enable the importing Member State to establish such an "import tolerance". This system is already in place in some of the Member States.

- 2) In cases where prohibitions or restrictions have effectively taken place, a two step conciliation procedure has been provided.
 - 2.1. a bilateral discussion phase between the 2 Member States concerned with the aim to remove, if possible, the barrier taking into account the Member States' rights and obligations under the provisions of Articles 30 and 36 of the Treaty; a report of this discussion is submitted to the Commission, which shall then submit the report to the Standing Committee for examination;
 - 2.2. as a result of this examination, the Commission will open a procedure which may lead to setting a maximum residue level applicable throughout the Community. Such action would be appropriate when the bilateral discussion phase would not have led to an adequate solution or when the case would seem to exceed the interests of the two Member States concerned. Such action would however only be possible as far as the toxicological data necessary to ensure that the levels set satisfy the human health safety requirements are available. Moreover the common maximum residue level would only be set for a limited time period if it would appear that at the time the conflict arises not sufficient data from supervised trials in crops are available to establish with sufficient precision the residue level resulting from the good agricultural practice in the producing Member State, while at the same time this Member State has undertaken that

these data will be submitted within the set time limit which may not exceed 4 years. For the same reasons of clarity mentioned under (b), it is proposed that these temporary maximum residue levels also are incorporated in the annexes II of Directives 86/362/EEC, 86/363/EEC and 90/642/EEC, together with the specified time limit.

(d) Increased harmonisation of the measures with regard to monitoring.

Check sampling and monitoring of pesticide residues in and on cereals, foodstuffs of animal origin and products of plant origin, including fruit and vegetables, is essential to ensure compliance with maximum levels specified in Community legislation. In particular, effective and systematic monitoring of pesticide residues in food will increase the confidence of consumers in the levels of protection of human health provided by the Community system of maximum residue levels. The current provisions on monitoring and check sampling contained in Directives 86/362/EEC and 90/642/EEC are inconsistent and incomplete: the proposed replacement provisions would harmonise the requirements on pesticide monitoring for the foodstuffs concerned and would in particular:

- establish a clear and logical time-table for the reporting of intended future monitoring programmes and the results of previous monitoring programmes by Member State and for the establishment of annual co-ordinated monitoring programmes, and
- set out clearly the minimum content and basic objectives of the various monitoring programmes.

This amendment is not proposed for Directive 86/363/EEC, as monitoring of pesticide residues in animal products is addressed, together with monitoring of other contaminants or undesirable substances in animal products, in the context of the veterinary legislation.

(e) Updating of certain provisions of Directives 76/895/EEC, 86/362/EEC and 86/363/EEC to the equivalent provisions in Directive 90/642/EEC.

In order to ensure coherent implementation of the three main Directives, the following provisions are proposed for being updated:

- the provisions concerning exemptions and concerning exports to third countries;
- the safeguard clauses provided for in Directives 86/362/EEC and 86/363/EEC;
- the provisions concerning the Regulatory Committee procedure.

(f) Introduction of a Regulatory Committee decision procedure, in particular for the following measures:

- adoption of the necessary amendments in the annexes as a result of developments in scientific and technical knowledge, i.e. the necessary amendments with regard to the description of the agricultural products concerned as well as the amendments with regard to establishment of maximum residue levels based on submitted data on good agricultural practices in the Community and corresponding supervised trial data as well as on submitted toxicological data;
- adoption of the temporary maximum residue levels in the framework of the conciliation procedure;
- adoption of the dilution or concentration factors related to certain drying or processing operations.

The Commission is of opinion that for these matters a Council decision is not justified given that the measures concerned are technical measures based on examination of technical data submitted by Member States and/or operators which can be handled more swiftly by a Commission decision according to the Regulatory Committee procedure. Moreover such procedure brings the decision making procedure in coherence with the following matters for which a Regulatory Committee procedure has already been provided for:

- in Directive 91/414/EEC with regard to the inclusion of active substances in Annex I to that Directive and with regard to the establishment of provisional maximum residue levels, (Article 4 (1)(f));
- in Directive 90/642/EEC with regard to amendments to the annexes to this Directive resulting from the implementation of the safeguard clause;
- in Regulation (EEC) n°2377/90 with regard to the establishment of maximum residue levels resulting from veterinary medicines.

The Commission is of opinion that for an effective and streamlined operation of the provisions of Directive 91/414/EEC and the above mentioned provisions in the Directives 76/895/EEC, 86/362/EEC, 86/363/EEC and 90/642/EEC similar decision making procedures are required. Moreover, as already mentioned under point (b), the provisional maximum residue levels of Directive 91/414/EEC are based on notifications from one or two Member States who granted the first authorization; they are only to be adapted afterwards to take into account the good agricultural practice which may later on have been developed and notified by other Member States.

- (g) Measures ensuring rapid transposal of the amendments introduced in the annexes by the Member States.

Proper functioning of the single market implies that the decisions, once they have been taken at Community level are swiftly applied in the Member States.

In 1989 the Commission proposed a Regulation with regard to the fixing of maximum residue levels in and on certain products of plant origin, which would have permitted to operate a system of directly applicable levels throughout the Community. This approach was not accepted by the Council when it adopted Directive 90/642/EEC. The Commission therefore now proposes that Member States take, if necessary, a general legal or administrative measure permitting them to transpose rapidly any amendments to the annexes of the 4 directives concerned.

4. Coherence of the proposed action with Article 3b of the Treaty establishing the European Community (subsidiarity)

From the foregoing points it results that the proposed legislative action, which envisages to improve and update the currently applicable legislation on pesticide residues, is in line with the objectives of The Common agricultural policy and the establishment of a single market taking into account the necessity of preserving a high level of protection of human health, and is already covered under exclusive competence of the Community. The proposed legislative action is necessary to ensure that the above mentioned objectives are realised in a more effective way than the current provisions permit.

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in and on fruit and vegetables,

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on the fixing of maximum levels for
pesticide residues in and on cereals,

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, and

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

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,

Having regard to the opinion of the European Parliament,

Having regard to the opinion of the Economic and Social
Committee,

Whereas Council Directives 86/362/EEC of 24 July 1986 on the
fixing of maximum levels for pesticide residues in and on
cereals¹⁰; 86/363/EEC of 24 July 1986 on the fixing of maximum
levels for pesticide residues in and on foodstuffs of animal
origin¹¹; 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
vegetables¹² have established a common regime providing for
mandatory residue levels applicable throughout the European
Community;

Whereas this regime provides for a gradual transfer of the
maximum residue levels established under Directive 76/895/EEC
to Directive 90/642/EEC after technical consideration; whereas
such transfer has already been realised for certain levels and
is still in preparation for others;

Whereas Directive 91/414/EEC¹³ concerning the placing of plant
protection products on the market 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

¹⁰ OJ N° L221, 7.8.1986, p. 37. Directive as last amended
by Directive 94/29/EC (OJ N° L189, 23.7.1994, p.67)

¹¹ OJ N° L221, 7.8.1986, p.43. Directive as last amended
by 94/29/EC (OJ N° L189, 23.7.1994, p.67)

¹² OJ N° L350, 14.12.1990, p.71. Directive as last
amended by Directive 94/30/EC (OJ N° L189, 23.7.94,
p.70)

¹³ OJ N°L230, 19.8.1991 p.1. Directive as last amended
by Directive 94/79/EC (OJ N° L354, 31.12.1994, p.16).

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 single market with regard to such products;

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

Whereas a conciliation procedure is necessary in cases where in practice barriers to intracommunity trade have appeared due to the absence of harmonised maximum residue levels for certain residue/product combinations;

Whereas effective monitoring of pesticide residues should be systematically organised 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 necessary to update certain provisions of Directives 76/895/EEC relating to the fixing of maximum levels for pesticide residues in and on fruit and vegetables¹⁴, 86/362/EEC and 86/363/EEC to the similar provisions in Directive 90/642/EEC to ensure coherence in the implementation of the whole regime concerning maximum residue levels;

Whereas the introduction of amendments in the annexes as a result of developments in scientific and technical knowledge, as well as 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 under Directives 76/895/EEC, 86/362/EEC, 86/363/EEC and 90/642/EEC and the implementation measures under Directive 91/414/EEC and other relevant

¹⁴ OJ N° L340, 9.12.1976, p.26. Directive as last amended by Directive 93/58/EEC (OJ N° L211, 23.8.93, p.6)

Directives;

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

HAS ADOPTED THIS DIRECTIVE

Article 1

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 is hereby amended as follows:

1. The first sentence of article 5 is replaced by the following :

"Without prejudice to Article 4, any amendments to be made to the Annexes shall be adopted in accordance with the procedure laid down in Article 7."
2. Paragraphs 2, 3 and 4 of Article 7 are 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."

3. Paragraphs 2,3 and 4 of Article 8 are 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."

4. The text of Article 9 is replaced by the following:

- "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 that 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.

2. This Directive shall not apply to the products referred to in Article 1 where it can be established by appropriate evidence that they are intended for:
 - (a) the manufacture of products other than foodstuffs and animal feed; or
 - (b) sowing or planting."

5. After Article 10, the following Article is inserted:

"Article 10a

The Member States shall bring into force laws, regulations and administrative provisions necessary to ensure that the amendments referred to in Article 5 can be implemented in their territory within a period of maximum 4 months from their adoption, and within a shorter implementation period when this is required for reasons of human health protection."

Article 2

Council Directive 86/362/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on cereals, is amended as follows:

1. Article 1 is replaced by the following:

"Article 1

1. This Directive shall apply to the cereal products listed in Annex I in so far as these products may contain certain pesticide residues.

The 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.

2. This Directive shall apply without prejudice to:
 - (a) the provisions of Council Directive 74/63/EEC¹⁵ of 17 December 1973 on the fixing of maximum permitted levels for undesirable substances and products in feedingstuffs;
 - (b) the provisions of 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) the provisions of 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.
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 that particular treatment in order to prevent the introduction of harmful organisms into its territory; or

¹⁵ OJ N° L38, 11.2.1974, p.31. Directive as last amended by Directive 94/16/EC (OJ N° L104, 23.4.94, p.32)

- (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 be established by appropriate evidence that they are intended for:
- (a) the manufacture of products other than foodstuffs and animal feed; or
 - (b) sowing or planting."
2. In Article 2(1) the words "listed in Annex II" are deleted.
3. Article 4 is replaced by the following :

"Article 4

1. Notwithstanding the provisions of Article 6, the products referred to in Article 1 shall not contain, from the time they are put into circulation, pesticide residue levels higher than those specified in the list referred to in Annex II.
- The list of pesticide residues concerned and their maximum levels shall be established in Annex II in accordance with the procedure laid down in Article 12 having regard to current scientific and technical knowledge.
2. In the case of dried and processed products for which maximum levels are not explicitly fixed in Annex II, the maximum residue level applicable shall be that laid down in Annex II, taking into account respectively the concentration caused by the drying process or the concentration or dilution caused by processing. In accordance with the procedure laid down in Article 12 a concentration or dilution factor covering the concentration and/or dilution caused by certain drying or processing operations may be determined for certain dried or processed products.
3. In the case of composite foods containing a mixture of ingredients and for which maximum residue levels are not fixed, the maximum residue levels applied may not exceed the levels laid down in Annex II,

taking into account the relative concentrations of the ingredients in the mixture and also the provisions laid down in paragraph 2.

4. Member states shall ensure, at least by monitoring and check sampling, compliance with the maximum levels referred to in paragraph 1. The necessary inspections and control measures shall be carried out in accordance with Council Directive 89/397/EEC¹⁶ of 14 June 1989 on the official control of foodstuffs, and in particular Article 4 thereof, and Directive 93/99/EEC¹⁷ on the subject of additional measures concerning the official control of foodstuffs".

4. Article 5 is replaced by the following two articles:

"Article 5

Where for a product belonging to a group specified in Annex I, a provisional maximum residue level throughout the Community is set by the Commission in accordance with the provisions of Article 4(1)(f) of Directive 91/414/EEC concerning the placing of plant protection products on the market, this level will be listed in Annex II with a reference to that procedure.

Article 5a

1. For the purposes of this article a Member State of origin is defined as the Member State on which territory a product specified in Article 1 (1), 1st subparagraph is legally produced or commercialised and a destination Member State is defined as the Member State into which 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 provide for a regime to enable the establishment of maximum residue levels for products referred to in Article 1(1), first subparagraph, introduced into their territories from a Member State of origin, and taking into account the good agricultural practice in the Member State of origin, in cases where no maximum residue levels have been established for these

¹⁶ OJ N° L186, 30.6.89, P.23

¹⁷ OJ N° L290, 24.11.1993, p.14

products in accordance with the provisions of Article 4(1) or 5.

3. Moreover in cases where no maximum residue levels have been established in accordance with the provisions of Article 4(1) or 5 the following shall apply.
 1. Where a product specified in Article 1 (1), 1st subparagraph satisfying the maximum residue levels applied by its Member State of origin, has been submitted in the destination Member State to measures with the effect to prohibit or submit to special restrictions the putting into circulation of the product concerned on the grounds that such product contains pesticide residue levels exceeding the maximum residue level accepted in the destination Member State, the destination Member State shall inform thereof the other Member State concerned and the Commission. In the communication the cases on which the information is based, shall be documented.
 2. On basis of the communication referred to in subparagraph 1, the two Member States concerned shall open without delay a discussion in order to remove, whenever possible, the prohibitive or restrictive effect of the measures applied by the destination Member State by means of measures agreed between the Member States and they shall, within a period of 3 months from the communication, notify to the Commission and the other Member States the result of this discussion, and in particular the agreed measures if any, including the maximum residue level the destination Member State intends to set in the framework of the regime referred to in paragraph 2.

The Member States shall submit to each other all required information; in particular the producing Member State shall indicate the data, including its toxicological assessment and estimation of an ADI, its good agricultural practice and corresponding trial data it relied upon to establish its own maximum residue level; the destination Member State shall indicate the reasons justifying the measures it applies.

3. The Commission shall refer the matter to the Standing Committee on Plant Health. A temporary maximum level may be established in Annex II for a limited period of time in accordance with the procedure laid down in Article 12. For the establishment of this temporary maximum level, the

Commission takes into account the state of the technical and scientific knowledge.

Moreover the Member State of origin and/or other interested Member States shall give, where relevant, a satisfactory undertaking that the necessary trial data will be submitted within a time limit set in accordance with Article 12; this time limit will not exceed 4 years.

4. Any measure provided for in paragraphs 2 or 3 shall be taken by a Member State in due respect of its obligations under the Treaty and in particular the Articles 30 to 36 thereof.
 5. The provisions of Council Directive 83/189/EEC¹⁸ of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations do not apply to the measures applied and notified by Member States in accordance with the provisions of 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 12."
5. Article 7 is replaced by the following:

"Article 7

1. Member States shall designate an authority to ensure that the monitoring specified in Article 4 (4) is carried out; the designated authority may be the same as the single liaison body designated under Article 6 of Directive 93/99/EEC.
2. (a) By 30 June each year, the Member States shall send to the Commission their intended national monitoring programmes for the following calendar year. These forward programmes shall specify at least:
 - the products to be inspected and the number of inspections to be carried out,

¹⁸ OJ N° L109, 26.4.1983, p.8. Directive as last amended by Directive 94/10/EEC (OJ N° L100, 19.04.94, p.30)

- the pesticide residues to be inspected for,
 - the criteria applied in drawing up these programmes.
- (b) By 30 September each year, the Commission shall refer a draft Decision setting out a coordinated monitoring programme to the Standing Committee on Plant Health. The Decision will be adopted in accordance with the procedure laid down in Article 13. The basic objective of the coordinated monitoring programme will be to maximise the check sampling of cereals included in the groups listed in Annex I, produced in the Community and imported into it, in order to ensure compliance with the maximum levels for pesticide residues set out in annex II. This co-ordinated monitoring programme may be subsequently adjusted as required during its implementation.
- (c) By 28 February each year the Member States shall send to the Commission reports on the implementation in the preceding calendar year of their national monitoring programmes and of the co-ordinated monitoring programme communicated by the Commission in accordance with subparagraph (b). These reports shall include at least the following information:
- the products inspected and the number of inspections carried out,
 - the pesticide residues analyzed for or to be analyzed for.
3. By 31 August each year, the Member States shall send to the Commission the results of the analyses of the check samples taken during the previous year under their national monitoring programmes and under the co-ordinated monitoring programme. The Commission shall collate and combine this information and shall communicate it to the Member States in the framework of the Standing Committee on Plant Health together with any recommendations for consequent action. In particular, the recommendations should cover:
- any action to be taken in the case of reported infringements of the maximum levels,
 - the desirability of publication of the collated and combined information,
 - specific conclusions as to modifications which

might be made to national monitoring programmes.

4. In accordance with the procedure laid down in Article 12 the following may be adopted:
 - (a) amendments to paragraphs (2) and (3) of this Article as far as these amendments concern the dates for communication;
 - (b) detailed implementation rules necessary for proper functioning of the provisions of paragraphs (2) and (3).
5. Not later than 31 December 1999 the Commission shall forward to the Council a report on the application of this Article, accompanied, if necessary, by any appropriate proposals."
6. Article 9 is replaced by the following:

"Article 9

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, attaching a statement of the reasons therefore.
2. The Commission shall quickly examine the grounds given by the Member State referred to in the first subparagraph and shall consult the Member States within the Standing Committee on Plant Health, hereinafter referred to as 'the Committee'; it shall then deliver its opinion forthwith and take the appropriate measures. The Commission shall immediately notify the Council and the Member States of any measures taken. Any Member State may refer the Commission's measures to the Council within 15 days of such notification. The Council acting by a qualified majority may take a different decision within 15 days of the date on which the matter was referred to it.
3. If the Commission considers that the maximum levels laid down in the list referred to in Article 1 should be amended to resolve the difficulties mentioned in paragraph 1 and to ensure the

protection of human health, it shall initiate the procedure laid down in Article 13, with a view to adopting those amendments. In this case, the Member State which has taken measures under paragraph 1 may in that event maintain them until the Council or the Commission has taken a decision in accordance with the said procedure."

7. Article 10 is replaced by the following:

"Article 10

Without prejudice to Article 9, amendments to the annexes shall be adopted in accordance with the procedure laid down in article 12, having regard to current scientific and technical knowledge."

8. The provisions of Article 11 are deleted.
9. Paragraphs 2, 3 and 4 of Article 12 are 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".

10. Paragraphs 2, 3 and 4 of Article 13 are 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 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."

11. Article 14 is replaced by the following:

"Article 14

The Member States shall bring into force laws, regulations and administrative provisions necessary to ensure that the amendments in Annex II resulting from decisions referred to in Articles 4(1) and (2), 5, 5a(3), 9(3) and 10 can be implemented in their territory within a period of maximum 4 months from their adoption, and within a shorter implementation period when this was prescribed for reasons of human health protection."

Article 3

Council Directive 86/363/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in foodstuffs of animal origin, is amended as follows:

1. The text of Article 1, is replaced by the following:

"1. This Directive shall apply to the foodstuffs of animal origin listed in Annex I in so far as these products may of a contain certain pesticide residues.

The 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.

2. This Directive shall apply without prejudice to the provisions of Council Directive 74/63/EEC of 17 December 1973 on the fixing of maximum permitted levels for undesirable substances and products in feedingstuffs, as last amended by Directive 87/519/EEC.

3. This Directive shall also apply to products referred to in paragraph 1 intended for export to third countries.

4. This Directive shall not apply to the products referred to in paragraph 1 where it can be established by appropriate evidence that they are intended for the manufacture of products other than foodstuffs and animal feed."

2. In Article 2(1) the words "listed in Annex II" are deleted.

3. Article 4 is replaced by the following :

"Article 4

1. The products referred to in Article 1 shall not contain, from the time they are put into circulation, pesticide residue levels higher than those specified in the list referred to in Annex II.

The list of pesticide residues concerned and their

maximum levels shall be established in Annex II in accordance with the procedure laid down in Article 12 having regard to current scientific and technical knowledge.

2. In the case of dried and processed products for which maximum levels are not explicitly fixed in Annex II, the maximum residue level applicable shall be that laid down in Annex II, taking into account respectively the concentration caused by the drying process or the concentration or dilution caused by processing. In accordance with the procedure laid down in Article 12 a concentration or dilution factor covering the concentration and/or dilution caused by certain drying or processing operations may be determined for certain dried or processed products.
3. In the case of composite foods containing a mixture of ingredients and for which maximum residue levels are not fixed, the maximum residue limits applied may not exceed the levels laid down in Annex II, taking into account the relative concentrations of the ingredients in the mixture and also the provisions laid down in paragraph 2.
4. Member states shall ensure, at least by monitoring and check sampling, compliance with the maximum levels referred to in paragraph 1. The necessary inspections and control measures shall be carried out in accordance with Directive 89/397/EEC, and in particular Article 4 thereof, and Directive 93/99/EEC on the subject of additional measures concerning the official control of foodstuffs and other relevant legislation concerning monitoring of residues in foodstuffs of animal origin".

4. Article 5 is replaced by the following two articles:

"Article 5

Where for a product belonging to a group specified in Annex I, a provisional maximum residue level throughout the Community is set by the Commission in accordance with the provisions of Article 4(1)(f) of Directive 91/414/EEC concerning the placing of plant protection products on the market, this level will be listed in Annex II with a reference to that procedure.

Article 5a

1. For the purposes of this article a Member State of origin is defined as the Member State on which territory a product specified in Article 1 (1), 1st subparagraph is legally produced or commercialised and a destination Member State is defined as the Member State into which 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 provide for a regime to enable the establishment of maximum residue levels for products referred to in Article 1(1), first subparagraph, introduced into their territories from a Member State of origin, and taking into account the good agricultural practice in the Member State of origin, in cases where no maximum residue levels have been established for these products in accordance with the provisions of Article 4(1) or 5.
3. Moreover in cases where no maximum residue levels have been established in accordance with the provisions of Article 4(1) or 5 the following shall apply.
 1. Where a product specified in Article 1 (1), 1st subparagraph satisfying the maximum residue levels applied by its Member State of origin, has been submitted in the destination Member State to measures with the effect to prohibit or submit to special restrictions the putting into circulation of the product concerned on the grounds that such product contains pesticide residue levels exceeding the maximum residue level accepted in the destination Member State, the destination Member State shall inform thereof the other Member State concerned and the Commission. In the communication the cases on which the information is based, shall be documented.
 2. On basis of the communication referred to in subparagraph 1, the two Member States concerned shall open without delay a discussion in order to remove, whenever possible, the prohibitive or restrictive effect of the measures applied by the destination Member State by means of measures agreed between the Member States and they shall, within a period of 3 months from the communication, notify to the Commission and the other Member States the result of this discussion, and in particular the

agreed measures if any, including the maximum residue level the destination Member State intends to set in the framework of the regime referred to in paragraph 2.

The Member States shall submit to each other all required information; in particular the producing Member State shall indicate the data, including its toxicological assessment and estimation of an ADI, its good agricultural practice and corresponding trial data it relied upon to establish its own maximum residue level; the destination Member State shall indicate the reasons justifying the measures it applies.

3. The Commission shall refer the matter to the Standing Committee on Plant Health. A temporary maximum level may be established in Annex II for a limited period of time in accordance with the procedure laid down in Article 12. For the establishment of this temporary maximum level, the Commission takes into account the state of the technical and scientific knowledge.

Moreover the Member State of origin and/or other interested Member States shall give, where relevant, a satisfactory undertaking that the necessary trial data will be submitted within a time limit set in accordance with Article 12; this time limit will not exceed 4 years.

4. Any measure provided for in paragraphs 2 or 3 shall be taken by a Member State in due respect of its obligations under the Treaty and in particular the Articles 30 to 36 thereof.
5. The provisions of 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 do not apply to the measures applied and notified by Member States in accordance with the provisions of 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 12."
5. Article 9 is replaced by the following:

"Article 9

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, attaching a statement of the reasons therefore.
 2. The Commission shall quickly examine the grounds given by the Member State referred to in the first subparagraph and shall consult the Member States within the Standing Committee on Plant Health, hereinafter referred to as 'the Committee'; it shall then deliver its opinion forthwith and take the appropriate measures. The Commission shall immediately notify the Council and the Member States of any measures taken. Any Member State may refer the Commission's measures to the Council within 15 days of such notification. The Council acting by a qualified majority may take a different decision within 15 days of the date on which the matter was referred to it.
 3. If the Commission considers that the maximum levels laid down in the list referred to in Article 1 should be amended to resolve the difficulties mentioned in paragraph 1 and to ensure the protection of human health, it shall initiate the procedure laid down in Article 13, with a view to adopting those amendments. In this case, the Member State which has taken measures under paragraph 1 may in that event maintain them until the Council or the Commission has taken a decision in accordance with the said procedure."
6. Article 10 is replaced by the following:

"Article 10

Without prejudice to Article 9, amendments to the annexes shall be adopted in accordance with the procedure laid down in article 12, having regard to current scientific and technical knowledge."

7. The provisions of Article 11 are deleted.

8. Paragraphs 2, 3 and 4 of Article 12 are 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".

9. Paragraphs 2, 3 and 4 of Article 13 are 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 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."

10. Article 14 is replaced by the following:

"Article 14

The Member States shall bring into force laws, regulations and administrative provisions necessary to ensure that the amendments in Annex II resulting from decisions referred to in Articles 4(1) and (2), 5, 5a (3), 9 (3) and 10 can be implemented in their territory within a period of maximum 4 months from their adoption, and within a shorter implementation period when this was prescribed for reasons of human health protection."

Article 4

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, is amended as follows :

1. Article 1(1), is replaced by the following:

"1. This Directive shall apply to products within the groups specified in column 1 of the Annex I, examples of which are given in column 2, in so far as products in these groups, or the parts of product described in column 3, may contain certain pesticide residues.

The 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."

2. Article 2 (a) is replaced by the following:

"(a) 'pesticide residues' shall mean residues of the pesticides and of their metabolites, and breakdown or reaction products, which are present in or on the products referred to in Article 1;"

3. Article 3 is replaced by the following:

"Article 3

1. The products in the groups or, as the case may be, the parts of products referred to in Article 1 shall not contain, from the time they are put into circulation, pesticide residue levels higher than those specified in the list referred to in Annex II.

The list of pesticide residues concerned and their maximum levels shall be established in Annex II in accordance with the procedure laid down in Article 9 having regard to current scientific and technical knowledge. A pesticide residue shall not be included on the list for as long as a maximum level is fixed for it by Directive 76/895/EEC.

2. In the case of dried and processed products for which maximum levels are not explicitly fixed in Annex II, the maximum residue level applicable shall be that laid down in Annex II, taking into account respectively the concentration caused by the drying process or the concentration or dilution caused by processing. According to the procedure laid down in Article 9 the concentration or dilution factor covering the concentration and/or the dilution caused by certain drying or processing operations may be determined with regard to certain dried or processed products.

3. In the case of composite foods containing a mixture of ingredients and for which maximum residue levels are not fixed, the maximum residue levels applied may not exceed the levels laid down in Annex II, taking into account the relative concentrations of the ingredients in the mixture and also the provisions laid down in paragraph 2.

4. Member States shall ensure, at least by monitoring and check sampling compliance with the maximum levels referred to in paragraph 1. The necessary inspections and control measures shall be carried out in accordance with Directive 89/397/EEC, and in particular Article 4 thereof, and Directive 93/99/EEC on the subject of additional measures concerning the official control of foodstuffs".

4. Article 4 is replaced by the following:

"Article 4

1. Member States shall designate an authority to ensure that the monitoring specified in Article 3 (4) is carried out; the designated authority may be the same as the single liaison body designated under Article 6 of Directive 93/99/EEC.
2. (a) By 30 June each year, the Member States shall send to the Commission their intended national monitoring programmes for the following calendar year. These forward programmes shall specify at least:
 - the products to be inspected and the number of inspections to be carried out,
 - the pesticide residues to be inspected for,
 - the criteria applied in drawing up these programmes.
- (b) By 30 September each year, the Commission shall refer a draft Decision setting out a coordination monitoring programme to the Standing Committee on Plant Health. The Decision will be adopted in accordance with the procedure laid down in Article 10. The basic objective of the coordinated monitoring programme will be to maximise the check sampling of products of plant origin included in the groups listed in Annex I, produced in the Community and imported into it, in order to ensure compliance with the maximum levels for pesticide residues set out in Annex II. This co-ordinated monitoring programme may be subsequently adjusted as required during its implementation.
- (c) By 28 February each year the Member States shall send to the Commission reports on the implementation in the preceding calendar year of their national monitoring programmes and of the co-ordinated monitoring programme communicated by the Commission in accordance with sub-paragraph (b). These reports shall include at least the following information:
 - the products inspected and the number of inspections carried out,

- the pesticide residues analyzed for or to be analyzed for.

3. By 31 August each year, the Member States shall send to the Commission the results of the analyses of the check samples taken during the previous year under their national monitoring programmes and under the co-ordinated monitoring programme. The Commission shall collate and combine this information and shall communicate it to the Member States in the framework of the Standing Committee on Plant Health together with any appropriate recommendations for consequent action, if necessary.
4. In accordance with the procedure laid down in Article 9 the following may be adopted:
 - (a) amendments to paragraphs (2) and (3) of this Article as far as these amendments concern the dates for communication;
 - (b) detailed implementation rules necessary for proper functioning of the provisions of paragraphs (2) and (3).
5. Not later than 31 December 1999 the Commission shall forward to the Council a report on the application of this Article, accompanied, if necessary, by any appropriate proposals."

5. After Article 5, the following articles are inserted :

"Article 5a

Where for a product belonging to a group specified in Annex I, a provisional maximum residue level throughout the Community is set by the Commission in accordance with the provisions of Article 4(1)(f) of Directive 91/414/EEC concerning the placing of plant protection products on the market, this level will be listed in Annex II with a reference to that procedure.

Article 5b

1. For the purposes of this article a Member State of origin is defined as the Member State on which territory a product specified in Article 1 (1), 1st subparagraph is legally produced or commercialised and a destination Member State is defined as the Member State into which 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 provide for a regime to enable the establishment of maximum residue levels for products referred to in Article 1(1), first subparagraph, introduced into their territories from a Member State of origin, and taking into account the good agricultural practice in the Member State of origin, in cases where no maximum residue levels have been established for these products in accordance with the provisions of Article 3(1) or 5a.
3. Moreover in cases where no maximum residue levels have been established in accordance with the provisions of Article 3(1) or 5a the following shall apply.
 1. Where a product specified in Article 1 (1), 1st subparagraph satisfying the maximum residue levels applied by its Member State of origin, has been submitted in the destination Member State to measures with the effect to prohibit or submit to special restrictions the putting into circulation of the product concerned on the grounds that such product contains pesticide residue levels exceeding the maximum residue level accepted in the destination Member State, the destination Member State shall inform thereof the other Member State concerned and the Commission. In the communication the cases on which the information is based, shall be documented.
 2. On basis of the communication referred to in subparagraph 1, the two Member States concerned shall open without delay a discussion in order to remove, whenever possible, the prohibitive or restrictive effect of the measures applied by the destination Member State by means of measures agreed between the Member States and they shall, within a period of 3 months from the communication, notify to the Commission and the other Member States the result of this discussion, and in particular the agreed measures if any, including the maximum residue level the destination Member State intends to set in the framework of the regime referred to in paragraph 2.

The Member States shall submit to each other all required information; in particular the producing Member State shall indicate the data, including its toxicological assessment and estimation of an ADI,

its good agricultural practice and corresponding trial data it relied upon to establish its own maximum residue level; the destination Member State shall indicate the reasons justifying the measures it applies.

3. The Commission shall refer the matter to the Standing Committee on Plant Health. A temporary maximum level may be established in Annex II for a limited period of time in accordance with the procedure laid down in Article 9. For the establishment of this temporary maximum level, the Commission takes into account the state of the technical and scientific knowledge.

Moreover the Member State of origin and/or other interested Member States shall give, where relevant, a satisfactory undertaking that the necessary trial data will be submitted within a time limit set in accordance with Article 9; this time limit will not exceed 4 years.

4. Any measure provided for in paragraphs 2 or 3 shall be taken by a Member State in due respect of its obligations under the Treaty and in particular the Articles 30 to 36 thereof.
5. The provisions of 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 do not apply to the measures applied and notified by Member States in accordance with the provisions of 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 9."
6. The text of Article 7 is replaced by the following :

"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 9."

7. After article 10, the following article is inserted :

"Article 10a

The Member States shall bring into force laws, regulations and administrative provisions necessary to ensure that the amendments to Annex II resulting from decisions referred to in Articles 3(1) and (2), 5a, 5b, 7 and 8(3) can be implemented in their territory within a period of maximum 4 months from their adoption, and within a shorter implementation period when this is prescribed for reasons of human health protection."

Article 5

Member States shall bring into force laws, regulations and administrative provisions necessary to comply with this Directive not later than 31 December 1996.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.

Article 6

This Directive is addressed to the Member States.

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