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## S E C O N D   R E P O R T

of the Committee on the Environment, Public Health and  
Consumer Protection

on the Commission's amended proposal for a Council directive  
concerning the placing of EEC-accepted plant protection  
products on the market

(COM(89) 34 final - C3-0064/89)

Rapporteur: Mr José-Luis VALVERDE LOPEZ

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A Series: Reports - B Series: Motions for Resolutions, Oral Questions - C Series: Documents received from other Institutions (e.g. Consultations) Or. FR

\* = Consultation procedure requiring a single reading

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At the sitting of 14 June 1990 the first report was referred back to the Committee on the Environment, Public Health and Consumer Protection pursuant to Rule 103 of the Rules of Procedure.

At its meeting of 28 August 1989 the committee had appointed Mr Valverde Lopez rapporteur.

At its meetings of 17 September and 30 October 1990 it considered the draft second report.

At the latter meeting it adopted the draft legislative resolution by 16 votes to 4 with 2 abstentions

The following took part in the vote: Schleicher, acting chairman; Sir James Scott-Hopkins, vice-chairman; Valverde Lopez, rapporteur; Alber, Amendola, Bjørnvig, Breyer (for Monnier-Besombes), Chanterie, di Rupo, Florenz, Green, Hadjigeorgiou (for Banotti), Lannoye (for Quistorp), Llorca Vilaplana, Simone Martin (for Bertens), Muntingh, Partsch, Pimenta, Schwartzenberg, Seligman, Llewelyn Smith and Vernier.

The explanatory statement will be presented orally in plenary sitting.

The opinions of the Committee on Economic and Monetary Affairs and Industrial Policy and the Committee on Agriculture, Fisheries and Rural Development, together with the opinion of the Committee on Legal Affairs and Citizens' Rights on the legal basis, are attached.

The second report was tabled on 12 November 1990.

The deadline for tabling amendments will appear on the draft agenda for the part-session at which the report is to be considered.

A  
Commission proposal for a Council directive  
concerning the placing of EEC-accepted plant protection products  
on the market

Commission text<sup>1</sup>

Amendments

(Amendment No. 1)

Title

Amended proposal for a Council directive (COM(89) 34 final) concerning the placing of EEC-accepted plant protection products on the market

Amended proposal for a Council directive concerning the placing of plant health products on the market

(Amendment No. 2)

Preamble, first citation

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

Having regard to the Treaty establishing the European Community, and in particular Article 100a thereof,

(Amendment No. 3)

Preamble, third citation

Having regard to the opinion of the European Parliament

In cooperation with the European Parliament,

(Amendment No. 4)

Fourth recital

Whereas the use of these plant protection products has consequences other than a favourable effect on plant production; whereas their use may involve risks for man and the environment since, in the main, they are toxic substances or preparations with hazardous effects;

Whereas the use of these plant health preparations has consequences other than a favourable effect on plant production; whereas their use may involve risks for man, animals and the environment since, in the main, they are toxic substances or preparations with hazardous effects;

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<sup>1</sup> For full text, see COM(89) 34 final, OJ No. C 89, 10.4.1989, p. 22

Commission text

Amendments

(Amendment No. 5)  
Sixth recital a (new)

Whereas in this connection steps must be taken to ensure that, in the interests of preventive health protection, plant health preparations or active substances, or the waste products thereof, which possess mutagenic or carcinogenic properties or are suspected of doing so are not authorized and may not be placed on the market;

(Amendment No. 6)  
Seventh recital a (new)

Whereas the criterion must be a high standard of protection in terms of the provisions governing authorization, which must prevent the authorization of plant health preparations whose danger to health, groundwater and the environment has not been adequately investigated; whereas the protection of the environment and human and animal health take priority over the objective of increasing plant production;

(Amendment No. 7)  
Eighth recital

Whereas such rules should provide that plant protection products should not be put on the market unless they have been officially accepted and should be used properly having regard to the principles of integrated pest control;

Whereas efforts should be made to ensure that future legislation provides that plant health preparations should not be put on the market if they are officially banned in any Member State on the grounds of environmental, health or consumer protection; whereas they should be used properly having regard to the principles of integrated plant protection; whereas in order to ensure this sensible use of pesticides there is a need to take action to provide technical assistance for farmers and training for distributors and farmers;

Commission text

Amendments

(Amendment No. 8)  
Ninth recital

Whereas it is necessary, at the time when plant protection products are accepted, to make sure that, when properly applied for the purpose intended, they are sufficiently effective and have no unacceptable effect on plants or plant products, no unacceptable adverse influence on the environment in general and, in particular, no harmful effect on human or animal health;

Whereas it is necessary, at the time when plant health preparations are authorized, to make sure that, when properly applied for the purpose intended, they are sufficiently effective and have no harmful effect on plants or plant products, or on the balance of the agricultural ecosystem, no adverse influence on the environment in general and, in particular, no harmful effect on human or animal health; and whereas it is necessary, after plant health preparations have been authorized, to monitor the quality and evolution of pesticides put on sale;

(Amendment No. 9)  
Tenth recital

Whereas acceptance should be limited to plant protection products containing certain active substances specified at Community level on the basis of their toxicological and ecotoxicological properties;

Whereas authorization should also be limited to plant health preparations containing certain active substances specified at Community level on the basis of their toxicological and ecotoxicological properties which guarantee that they have no harmful effect on human health or the environment;

(Amendment No. 10)  
Thirteenth recital

Whereas the Community procedure should not prevent Member States from authorizing for use in their territory for a limited period of time plant protection products containing an active substance not yet entered on the Community list, provided that the interested party has submitted a dossier meeting Community requirements and the Member State has concluded that the active substance and the plant protection products satisfy the Community conditions set in regard to them;

Whereas the Community procedure should not prevent Member States from granting or withdrawing authorization in their own territory for plant health preparations which do not comply with the provisions of this Directive in order to deal with cases of force majeure, provided that the Commission is notified immediately in accordance with the prescribed procedures and informed of the reasons for the decision and the procedure followed;

Commission text

Amendments

(Amendment No. 11)  
Fourteenth recital

Whereas, in the interest of safety, substances on the list should be reviewed periodically;

Whereas, in the interest of safety, substances on the list should be reviewed periodically to take account of scientific and technological developments and of impact studies based on actual use of the authorized substances;

(Amendment No. 12)  
Fourteenth recital a (new)

Whereas resources devoted to the conduct of tests should not be squandered by the unnecessary repetition of tests as a result of different regulations in the Member States; whereas considerations of public interest militate against the undue repetition of tests on animals;

(Amendment No. 13)  
Fifteenth recital

Whereas it is in the interest of free movement of plant products as well as plant protection products that acceptance granted by one Member State, and tests carried out with a view to acceptance, should be recognized by other Member States, unless certain agricultural, plant health and environmental conditions relevant to the use of the products concerned are not comparable;

Whereas it is in the interest of free movement of plant products as well as plant health preparations that authorization granted by one Member State, and tests carried out with a view to authorization, should be recognized by other Member States, unless certain agricultural, plant health and environmental conditions relevant to the use of the preparations concerned are not comparable; whereas to this end there is a need to harmonize the methods of experimentation and control applied by the Member States for the purpose of granting authorization;

Commission text

Amendments

(Amendment 14)  
Seventeenth recital

Whereas, however, Member States must be enabled to accept plant protection products not complying with the above-mentioned conditions when it is necessary to do so because of an unforeseeable danger threatening plant production which cannot be contained by other means; whereas such acceptance should be reviewed by the Commission in close cooperation with the Member States in the framework of the Standing Committee on Plant Health;

Deleted

(Amendment No. 15)  
Eighteenth recital

Whereas this Directive complements the Community provisions on the classification, packaging and labelling of pesticides; whereas together with the latter provisions it considerably improves the protection of users of plant protection products and consumers of plants and plant products, and whereas it also contributes to the protection of the environment;

Whereas this Directive complements the Community provisions on the classification, packaging and labelling of pesticides; whereas together with the latter provisions it must considerably improve the protection of users of plant health preparations and consumers of plants and plant products, and whereas it also contributes to the protection of the environment; whereas, in this respect, there is a need to ensure that the packaging of such preparations contains an explicit indication of the agricultural conditions under which they are to be used;

(Amendment No. 16)  
Eighteenth recital a (new)

Whereas Community standards in relation to plant health preparations accord with internationally recognized principles; whereas there is a need to promote greater international cooperation as regards the protection of health and the environment;



Commission text

Amendments

(Amendment No. 17)  
Eighteenth recital b (new)

Whereas, in order to facilitate the free movement of plant health preparations and to avoid the controls already carried out in one Member State being repeated in another, it is desirable to lay down standard conditions for the manufacture and, in respect of third countries, the importation of preparations and the granting of authorization in respect thereof;

(Amendment No. 18)  
Eighteenth recital c (new)

Whereas it is important that, within the Member States, the monitoring and control of the manufacture, distribution and application of plant health preparations should be effected by persons with appropriate professional qualifications;

(Amendment No. 19)  
Nineteenth recital

Whereas, in order to ensure that the requirements laid down in respect of accepted plant protection products are satisfied when they are placed on the market, Member States must make provision for appropriate inspection arrangements;

Whereas, in order to ensure that the requirements laid down are satisfied, Member States must make provision for appropriate control and inspection arrangements with regard to the quality, purpose and method of using plant health preparations;

Commission text

Amendments

(Amendment No. 20)  
Nineteenth recital a (new)

Whereas, in order to achieve the objectives set out above, there is a need substantially to strengthen the means available to the competent authorities of the Member States and the Standing Committee on Plant Health by enabling them to call on the help of technical assistance and monitoring services to ensure compliance with good manufacturing practices, good agricultural practices and the requirements in relation to packaging;

(Amendment No. 21)  
Twentieth recital

Whereas the procedures provided by this Directive are not appropriate for evaluation of the risks to the environment presented by plant protection products containing or composed of genetically modified organisms, but whereas, in future, specific procedures will be introduced by amendment to this Directive for the evaluation of such products;

Whereas this Directive and Directives 90/220/EEC on the voluntary dissemination of genetically modified organisms and .../.../EEC on the confined utilization of genetically modified micro-organisms shall apply to plant health preparations containing or composed of genetically modified organisms; whereas provision should also be made for a global directive on the whole system of GMO;

(Amendment No. 22)  
Article 1(1)

1. This Directive concerns the acceptance and placing on the market within the Community of plant protection products put up in commercial form, and the placing on the market within the Community of active substances intended for a use as specified in Article 2(1).

1. This Directive concerns the authorization, placing on the market, use and control within the Community of plant health preparations put up in commercial form, and the placing on the market and control within the Community of active substances intended for a use as specified in Article 2(1).

Commission text

Amendments

(Amendment No. 23)  
Article 1(2)a (new)

2a. This Directive shall apply without prejudice to Council Directive 80/778/EEC of 15 July 1980 relating to the quality of water intended for human consumption, Council Directive 75/440/EEC concerning the quality required of surface water intended for the abstraction of drinking water in the Member States and Council Directive 80/68/EEC concerning the protection of groundwater against pollution by certain dangerous substances.

(Amendment No. 24)  
Article 1(2)b (new)

2b. This Directive shall apply without prejudice to national provisions which have not yet been harmonized and which concern other measures, compatible with Community legislation, regarding the sale and use of plant health preparations, promote the safe sale and use thereof and preclude any danger to the environment, health or groundwater.

(Amendment No. 25)  
Article 1(3) (new)

3. This Directive shall also apply to the genetically modified micro-organisms covered by Directives .../.../EEC on the confined utilization of GMO and 90/220/EEC on the voluntary dissemination of GMO.

(Amendment No. 26)  
Article 2, title (new)

Definitions

Commission text

Amendments

(Amendment No. 27)  
Article 2

For the purposes of this Directive the following definitions shall apply:

For the purposes of this Directive the following definitions shall apply:

1. Plant protection products

1. Plant health preparations

Active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to:

Active substances and preparations containing one or more active substances intended to:

1.1 destroy organisms harmful to plants or plant products or to prevent the action of such organisms, in so far as such substances or preparations are not otherwise defined below;

1.1 destroy organisms harmful to plants or plant products or to prevent the action of such organisms, in so far as such substances or preparations are not defined in the following provisions;

1.2 influence the life processes of plants, other than as a nutrient;

1.2 influence the life processes of plants, other than as a nutrient;

1.3 preserve plant products, in so far as such substances or products are not subject to special Council or Commission provisions on preservatives;

1.3 preserve plant products, in so far as such substances or preparations are not subject to special Council or Commission provisions on preservatives;

1.4 destroy undesirable plants, or

1.4 destroy undesired plants, or

1.5 destroy parts of plants or prevent undesired growth of plants.

1.5 destroy parts of plants or prevent undesired growth of plants.

2. Residues of plant protection products

2. Residues of plant health preparations

### Commission text

One or more substances present in or on plants or plant products, or elsewhere in the environment, and resulting from the use of a plant protection product.

#### 3. Substances

Chemical elements and their compounds, as they occur naturally or by manufacture, including any impurity inevitably resulting from the manufacturing process.

#### 4. Active substances

Substances, micro-organisms and viruses having general or specific action:

4.1 against harmful organisms, or

4.2 on plants, parts of plants or plant products.

#### 5. Preparations

Mixtures or solutions composed of two or more substances of which at least one is an active substance, intended for use as plant protection products.

#### 6. Plants

Live plants and live parts of plants, including fresh fruit and seeds.

### Amendments

Specific substances left by a pesticide in food, agricultural products or animal feed. The term includes all pesticide derivatives, such as by-products of conversion, metabolites and the by-products of reaction, and impurities which are deemed toxicologically significant; the expression 'pesticide residues' includes residues from unknown or unavoidable sources (such as the environment), as well as those from known use of a chemical preparation.

#### 3. Substances

Chemical elements and their compounds, as they occur naturally in manufacture.

#### 4. Active substances

Substances, micro-organisms and viruses having general or specific action:

4.1 against harmful organisms, or

4.2 on plants, parts of plants or plant products.

#### 5. Preparations

Mixtures or solutions composed of two or more substances, or of micro-organisms or viruses used as plant health preparations.

deleted

## Commission text

### 7. Plant products

Products in the unprocessed state or having undergone only simple preparation such as milling, drying or pressing, derived from plants, but excluding plants themselves as defined in point 6.

### 8. Harmful organisms

Pests of plants or plant products belonging to the animal or plant kingdom, and also viruses, mycoplasmas and other pathogens.

### 9. Animals

Animals belonging to species normally fed and kept or consumed by man.

### 10. Placing on the market

Any handing over, whether in return for payment or free of charge, other than for storage followed by consignment from the territory of the Community. Importation into the territory of the Community shall be deemed to be placing on the market for the purposes of this Directive.

### 11. Environment

Water, air and land and any inter-relationship between them, as well as any relationship with living organisms.

### 12. Integrated pest control

The rational application of a combination of biological, chemical, cultural or plant breeding measures whereby the use of chemical plant protection products is limited to the necessary minimum.

## Amendments

### 7. Plant products

Products in the unprocessed state or having undergone only simple preparation such as milling, drying or pressing, derived from plants, but excluding plants themselves.

### 8. Harmful organisms

Pests of plants or plant products belonging to the animal or plant kingdom, and also bacteria, viruses, mycoplasmas and other pathogens.

deleted

### 10. Placing on the market

Any transfer of possession, whether in return for payment or free of charge.

deleted

### 12. Integrated plant protection

The rational application of a combination of biological, chemical, physical, cultural or plant breeding measures whereby the use of chemical plant health preparations is limited to the necessary minimum.

Commission text

Amendments

(Amendment No. 28)  
Article 3, title (new)

Authorization of preparations by the  
Member States

(Amendment No. 29)  
Article 3(1)

1. Member States shall prescribe that plant protection products may be placed on the market for use in their territory only if they have accepted the product in accordance with this Directive.

1. Plant health preparations may be placed on the market in the Community only if they have been authorized in at least one Member State in accordance with this Directive.

Such authorization shall be valid for five years, renewable for further periods of five years provided that the holder requests an extension at least six months before the expiry of the current authorization.

(Amendment No. 30)  
Article 3(2)

2. Member States shall not, on the grounds that a plant protection product is not accepted for use in their territory, impede the storage or movement of such products intended for use in another Member State, provided that:

deleted

- the product is accepted in another Member State, and
- the operators in question satisfy the inspection requirements laid down by the Member States in order to ensure compliance with paragraph 1.

Commission text

Amendments

(Amendment No. 31)  
Article 3(3)

3. Member States shall prescribe that plant protection products must be used properly and in accordance with any conditions laid down pursuant to this Directive. Proper use shall include application of the principles of integrated pest control.

2. Member States shall prescribe that plant health preparations must be used properly and in accordance with any conditions laid down pursuant to this Directive. Proper use shall include:

1. the application of the principles of integrated plant protection; To this end, Member States shall establish technical assistance and monitoring services to train farmers and product distributors in good agricultural practices, to provide on-the-spot information and advice on the preparation quantities to be used (according to the place, season and climatic or other conditions) and to monitor compliance with the good practices recommended;

2. the use of officially licensed and regularly serviced spraying equipment; the application of pesticides from aircraft shall be prohibited;

3. the effective monitoring of the restrictions on use laid down at the time of authorization or at a later date;

4. good specialist knowledge of pests and the means of combating them;

5. restrictions on use in officially designated feeder areas for groundwater and spring-water production plants, medicinal springs, drinking water reservoirs and rivers whose water is used for drinking and in other areas where the groundwater is susceptible to contamination;



Commission text

Amendments

6. restrictions on use in open spaces used for agricultural or market-gardening purposes.

(Amendment No. 32)  
Article 3(4)a (new)

4a. Member States shall prescribe that plant health preparations may be exported to countries outside the Community only if they have been authorized in accordance with this Directive.

(Amendment No. 33)  
Article 4, title (new)

Conditions governing the authorization of preparations

(Amendment No. 34)  
Article 4(1)

1. Member States shall provide that a plant protection product may be accepted only if:

(a) its active substances are listed in Annex I and any conditions laid down therein are fulfilled;

(b) it is established, in the light of current scientific and technical knowledge that, when properly applied for the purpose intended, and having regard to all foreseeable conditions under which it may be used:

(i) it is sufficiently effective;

(ii) it has no unacceptable effect on plants or plant products;

1. Only those plant health preparations whose active substances are listed in Annex I and comply with any conditions laid down therein shall be authorized, provided that they comply with the criteria set out in Article 5(1) of this Directive.

(a) if it is established, in the light of current scientific and technical knowledge that, when properly applied for the purpose intended, and having regard to all foreseeable conditions under which they may be used:

(i) they are sufficiently effective;

(ii) they have no unacceptable effect on plants or plant products;

Commission text

(iii) it has no harmful effect on human or animal health;

(iv) it has no unacceptable adverse influence on the environment;

Amendments

(iii) they have no harmful effect on human or animal health or on the groundwater, whether directly or indirectly;

(iv) they have no unacceptable adverse influence on the environment;

These conditions shall be deemed to have been met in so far as they accord with a set of uniform principles applicable in all the Member States as set out in Annex IIIa.

(Amendment No. 35)

Article 4(1)(c)

(c) the nature and quantity of its active substances and, where appropriate, their toxic impurities can be determined by methods in general use.

(b) the nature and quantity of their active substances and, where appropriate, their impurities, and of the other components included in the preparation, can be determined by methods recognized by the authorities responsible for authorization and harmonized in accordance with Article 19.

(Amendment No. 36)

Article 4(1)(c)a (new)

(c)a requirements regarding the protection of human and animal health in connection with the transport of hazardous substances do not preclude them.

Commission text

Amendments

(Amendment No. 37)  
Article 4(2)

2. Member States shall ensure that compliance with the requirements set out in paragraph 1 is established by official or officially recognized tests and analyses carried out under agricultural, plant health and environmental conditions relevant to use of the plant protection product in question and representative of those prevailing where the product is intended to be used within the territory of the Member State concerned.

2. The tests referred to in Article 12 shall be carried out in accordance with the methods described in Directive 67/548/EEC and the criteria set out in this Directive. Reports on these tests shall be submitted by properly qualified experts and shall give reasons for the use of alternative methods in the event of those referred to above being inadequate or inappropriate. The trials should take account of the agricultural, plant health and environmental conditions under which the preparation is intended to be used.

The Member States shall ensure that reports on trials and analyses state specifically the crop or crops to which, and the ecological area within which, the pesticide may be applied.

As well as requiring authorization, plant health preparations must be manufactured in accordance with good manufacturing practices and under the supervision of a properly qualified expert. A code of good manufacturing practices shall be drawn up under the procedure laid down in Article 19.

The Member States shall establish monitoring services to ensure compliance with the principles of good manufacturing practice.

(Amendment No. 38)  
Article 4(2)a (new)

2a. The following shall be grounds for refusing, suspending or revoking authorization, according to whichever is appropriate:

Commission text

Amendments

1. the grounds set out in paragraph 1 of this Article;
2. repeated failure to comply with Good Manufacturing Practices or to ensure supervision by the properly qualified expert referred to in Article 3(2);
3. failure to bring manufacturing processes up to date in the light of the current state of technical knowledge;
4. the placing on the market of plant protection preparations under conditions other than those stipulated in the summary of characteristics of the approved preparation;
5. failure to comply with any particular rules and conditions as regards packaging stipulated in the authorization.

(Amendment No. 39)  
Article 5, title (new)

Community authorization of  
active substances

(Amendment No. 40)  
Article 5(1)

1. An active substance shall be included in Annex I for an initial period not exceeding ten years and only if:

(a) its residues in edible plant products, edible livestock products or the environment do not have any harmful effects on human or animal health or on the environment and, if constituting a potential hazard, can be measured by methods in general use;

1. An active substance shall be included in Annex I for an initial period not exceeding five years if it is known that the plant health preparations containing the active substances fulfil the following conditions:

(a) its residues in edible plant products, edible livestock products or the environment do not have any harmful effects on human or animal health or on the environment and can be measured by methods in general use;

Commission text

Amendments

(b) it may be expected, on the basis of scientific and technical data, that preparations manufactured from it will meet the requirements of Article 4(1)(b)(iii) and (iv).

(b) it may be expected, on the basis of scientific and technical data, that preparations manufactured from it will meet the requirements of Article 4(1)(b)(iii) and (iv).

The criteria for approving active substances are set out in Annex Ia.

(Amendment No. 41)  
Article 5(2)

2. The inclusion of a substance in Annex I may be renewed on one or more occasions for periods not exceeding five years in each case.

2. The inclusion of a substance in Annex I may be renewed on one or more occasions for periods not exceeding five years in each case at the request of the interested party.

(Amendment No. 42)  
Article 6, title (new)

The procedure for authorizing active substances

(Amendment No. 43)  
Article 6(1)

1. A Member State or the Commission shall, in order to obtain the inclusion of an active substance in Annex I, ensure that a dossier satisfying the requirements of Annex II is transmitted by the interested party to the other Member States and to the Commission.

1. The Commission shall, in order to obtain the inclusion of an active substance in Annex I, ensure that a dossier satisfying the requirements of Annex II is transmitted by the interested party to the other Member States and to the Commission.

The Commission shall refer the dossier for examination by the Standing Committee on Plant Health.

The Commission shall without delay refer the dossier for examination by the Standing Committee on Plant Health.

Commission text

Amendments

(Amendment No. 44)  
Article 6(3)

3. As part of the procedure for assessing the dossier the interested party may be invited by the Commission to:

- provide any further information deemed necessary for the purpose of assessing whether the active substance satisfies the requirements indicated in Article 5(1),
- appear before the Committee.

3. As part of the procedure for assessing the dossier the interested party may be invited by the Commission or upon that party's request shall be entitled to:

- provide any further information deemed necessary for the purpose of assessing whether the active substance satisfies the requirements indicated in Article 5(1),
- appear before the Committee.

The interested party shall have the right to appear before the Committee if that party so requests.

(Amendment No. 45)  
Article 6(4)

4. The procedure laid down in Article 18 shall be followed for taking a decision to include an active substance in Annex I and for setting any conditions in connection therewith.

4. The procedure laid down in Article 18 shall be followed for taking a decision to include an active substance in Annex I and for setting any conditions in connection therewith.

Within one month following notification of a decision concerning the inclusion of an active substance in Annex I, the applicant may appeal against the decision. This appeal shall give rise to a new assessment during which the applicant may be heard by the Committee or by members designated by the Committee. Final notification shall be issued to the interested party within three months following the appeal.

Commission text

Amendments

(Amendment No. 46)  
Article 7, title (new)

Procedures for withdrawing  
an active substance

(Amendment No. 47)  
Article 7

Member States shall prescribe that the holder of an acceptance must notify to the competent authority all information on the harmful effects of any substance listed in Annex I or of its residues on human or animal health or on unacceptable adverse effects on the environment. Member States shall notify this information to the other Member States and to the Commission, which shall refer the information to the Standing Committee on Plant Health.

1. Each Member State shall lay down rules for the proper distribution and use of plant protection preparations in accordance with the recommendations of the FAO and the Council of Europe.

2. Member States shall prescribe that the holder of an authorization or any one else possessing relevant information (in particular the technical assistance and monitoring services referred to in Articles 3(3) and 4(2)) must notify to the competent authority all information on the harmful effects of any substance listed in Annex I or of its residues on human or animal health or on unacceptable adverse effects on the environment. Member States shall notify this information to the other Member States and to the Commission, which shall refer the information to the Standing Committee on Plant Health.

The Member States shall take the necessary steps to ensure that the information referred to in the previous paragraph is communicated to the FAO.

3. The Commission or a Member State may consult the Committee on its own initiative.

Commission text

Amendments

4. The Committee may, in such cases, re-assess the dossier on the active substance. Producers of preparations which use the substance in question may at their own request be heard by the Committee.

5. In accordance with the procedure set out in Article 18, the active substance may be withdrawn from Annex I.

(Amendment No. 48)  
Article 8, title (new)

Transitional measures and derogations

(Amendment No. 49)  
Article 8(1)

By way of derogation from Article 4, a Member State may:

1. in very special circumstances, authorize for a period not exceeding 120 days the placing on the market of plant protection products not complying with Article 4 if such a measure appears necessary because of an unforeseeable danger threatening plant production which cannot be contained by other means. In this case, the Member State concerned shall immediately inform the other Member States and the Commission of its action. It shall be decided without delay, in accordance with the procedure laid down in Article 18, whether and, if so, under what conditions the action taken by the Member State may be continued or repeated;

By way of derogation from Article 4(1)(a), a Member State may:

1. in very special circumstances, authorize for a period not exceeding 120 days the placing on the market of plant health preparations not complying with Article 4(1)(a) if such a measure appears necessary because of a case of force majeure. In this case, the Member State concerned shall immediately inform the other Member States and the Commission of its action. It shall be decided without delay, in accordance with the procedure laid down in Article 18, whether and, if so, under what conditions the action taken by the Member State may be continued or repeated;



Commission text

Amendments

(Amendment No. 50)  
After Article 8(1), new paragraph

The criteria for determining what constitutes an unforeseeable danger are set out in Annex IIa.

(Amendment No. 51)  
Article 8(2)

2. permit, for a period not exceeding three years, the placing on the market of plant protection products containing an active substance not listed in Annex I and not yet available on the market on the date of implementation of this Directive, provided that:

2. ~~Provisional authorizations to place on the market shall not be permitted.~~

(a) following application of Article 6(1) and (2) it is found that the dossier on the active substance satisfies the requirements of Annex II.

deleted

(b) the Member State establishes that the active substance satisfies the requirements of Article 5(1) and that the plant protection product satisfies the requirements of Article 4(1)(b) and (c).

deleted

In such cases the Member State shall immediately inform the other Member State and the Commission of its assessment of the dossier and of the terms of acceptance.

deleted

If, on assessment of the dossier as provided for in Article 6(3), it is found that the active substance does not satisfy the requirements of Article 5(1), a decision may be taken by the procedure laid down in Article 18 requiring the Member State to withdraw the acceptance.

deleted

Commission text

Amendments

(Amendment No. 52)

Article 8(3), first subparagraph

3. For a period of 10 years from the date of implementation of this Directive, without prejudice to Directive 79/117/EEC, authorize the placing on the market in its territory of plant protection products containing active substances not listed in Annex I that were already on the market before that date.

3. For a period of five years from the date of implementation of this Directive, without prejudice to Directive 79/117/EEC, authorize the placing on the market in its territory of plant health preparations containing active substances not listed in Annex I that were already on the market before that date.

(Amendment No. 53)

Article 8(3), second subparagraph

The Commission shall draw up a programme of work for the gradual examination of these active substances during that period. In implementing this programme the Commission may require interested parties to submit all requisite data to the Commission and the Member States within a prescribed period.

The Commission shall draw up a programme of work with a view to the inclusion in Annex I, by 1 January 1993, of those substances which are authorized by a majority of the Member States. The remaining substances shall be subject to a gradual examination, which must be concluded within the above-mentioned period of five years. In implementing this programme the Commission may require interested parties to submit all requisite data to the Commission and the Member States within a prescribed period.

(Amendment No. 54)

Article 8(3), at end of second subparagraph

Two years after the date of implementation of this Directive, the Commission shall forward to the Council and the European Parliament a report on the progress achieved with the programme.

(Amendment No. 55)

Article 9, title (new)

Procedure for authorizing plant health preparations

Commission text

Amendments

(Amendment No. 56)  
Article 9

1. Application for acceptance of a plant protection product may be made by the manufacturer, the importer or the distributor, if the plant protection product is to be placed on the market in the first instance by a distributor.

2. Every applicant shall be required to have a permanent office within the Community.

3. Member States may require that applications for acceptance be submitted in their national or official languages or one of those languages.

4. Each Member State shall agree to consider any application for acceptance made to it and shall decide thereon within a reasonable period.

5. Within 45 days of the receipt of an application the Member State concerned shall inform the other Member States and the Commission thereof and shall at the same time provide the following particulars of the application:

- the name and address of the applicant;
- the name and address of the manufacturer, if different from the applicant;
- the designation or trade name or code number of the plant protection product;
- the type of preparation;

1. Applications for authorization of a plant health preparation shall be submitted to the competent health authority of a Member State, in accordance with the requirements set out in Annex III, by the manufacturer or those responsible for placing the preparation on the market.

The reports referred to in Annex III shall be assessed by properly qualified experts.

2. Every applicant shall be required to have a permanent office within the Community.

3. Member States may require that applications for authorization be submitted in their national or official languages or one of those languages.

4. Within 45 days of the receipt of the application or applications the competent authority referred to in paragraph 1 shall forward a copy of the complete dossier or dossiers to the Standing Committee on Plant Health Preparations and shall notify the other Member States by forwarding to them a summary of the dossier or dossiers, to include:

- the name and address of the applicant;
- the name and address of the manufacturer, if different from the applicant;
- the designation or trade name of the plant health preparation;
- the type of preparation;

Commission text

- the name and amount of each active substance contained in it;
  - the use for which it is intended and the directions for using it.
6. Member States shall ensure that a dossier is compiled on each application. Each dossier shall contain at least a copy of the application, a record of the administrative decisions taken by the Member State concerning the application and the particulars and technical documentation laid down in Article 12(1), together with a summary of the latter. Member States shall on request make available to the other Member States and to the Commission the dossiers provided for in this paragraph; they shall supply to them on request all information necessary for full comprehension of applications.

Amendments

- the name and amount of each active substance contained in it;
  - the use for which it is intended and the directions for using it.
5. Member States shall ensure that a dossier is compiled on each application. Each dossier shall contain at least a copy of the application, a record of the administrative decisions taken by the Member State concerning the application and the particulars and technical documentation laid down in Article 12(1), together with a summary of the latter. Member States shall on request make available to the other Member States and to the Commission the dossiers provided for in this paragraph; they shall supply to them on request all information necessary for full comprehension of applications.

6. On receipt of the notification referred to in paragraph 4, the Committee shall acknowledge receipt thereof and assign a provisional registration number to the plant health preparation which is the subject of the application for authorization.

7. In order to ensure proper assessment and to expedite the procedure, the Member State may have recourse to more than one properly equipped technical centre located in the Community.

8. During the processing of the application the competent authorities in the other Member States shall forward the information available to them to the Member State handling the application. The interested party may be called upon to submit additional reports, in which case the deadlines shall be extended accordingly.
9. The Member State handling the application shall draw up an assessment report and shall, within a period of 100 days which may, if there is good cause, be extended for a further 90 days, approve the summary of the preparation's characteristics and the information to be included on the packaging. The assessment report shall be forwarded to the other Member States, the Commission and the Committee, together with the summary of the preparation's characteristics and a model of the approved packaging.
- The Member States may, within 60 days of receipt of the assessment report, submit to the Committee any objections which it has not been possible to resolve by direct communication with the Member State responsible for dealing with the application.
10. Provided no objections have been received by the end of the 60 days referred to in the previous paragraph, the Member State may authorize the plant health preparation and shall assign it, as its European registration number, the provisional number granted pursuant to paragraph 6 of this Article. This number must appear on the preparation's packaging.

Commission text

Amendments

In the event of a negative opinion, the interested party may, within 60 days, apply to the Standing Committee on Plant Health Preparations for the decision to be reviewed.

11. The Member State shall notify the authorizations it has granted in accordance with the procedure laid down in the previous paragraph to the Standing Committee on Plant Health Preparations, which shall register the new plant health preparation under the provisional number assigned to it.

12. In the event of reasoned objections, the Standing Committee on Plant Health Preparations shall notify the other Member States and the interested party, enclosing a copy of the document setting out the objections in question, and shall set a date for deciding on the issues raised.

Prior to the Committee taking a decision, the interested party may if necessary be required, or, at his own request, allowed, to submit in person or in writing his comments on the objections raised. The interested party may also submit, or be asked to submit, additional information, in which case the deadlines shall be extended accordingly.

13. The Committee shall deliver its opinion as soon as possible, and shall notify it to the interested party and to the Member States.

Commission text

Amendments

An appeal may be lodged within 30 days by either the interested party or a Member State, with a view to the issue being reconsidered by the Committee. In such cases the Committee shall seek additional studies or reports from the Scientific Committee on Pesticides. Such reports shall be submitted within 120 days. The Standing Committee on Plant Health Preparations shall deliver its opinion on the disputed issues.

The party seeking a review shall bear the costs thereof where the final decision is not in his favour. The same shall apply in the case of objections if the Commission deems them to have been imprudence or if they are lodged without first having exhausted the other possibilities referred to in paragraph 6.

14. When the Committee has delivered its final opinion, the Commission shall take the utmost account thereof. It shall inform the Committee of the manner in which it has taken the opinion into account and shall notify its decision to the interested party.

15. The Committee shall be responsible for maintaining a General Register of Plant Health Preparations in which all authorized preparations shall be entered. The Commission shall publish an annual list of plant health preparations which are banned in the Community.

(Amendment No. 57)  
Article 10

Compulsory mutual recognition of authorized preparations

(Amendment No. 58)  
Article 10

1. At the request of the applicant, a Member State to which an application is made for the acceptance of a plant protection product already accepted in another Member State must:
- unless certain agricultural, plant health or environmental conditions relevant to the use of the product are not comparable in the regions concerned, refrain from requiring the repetition of tests and analyses already carried out in connection with the acceptance of the product in that Member State; and
  - unless certain agricultural, plant health or environmental conditions relevant to the use of the product are not comparable in the regions concerned, authorize placing on the market in its territory.

1. The applications for authorization to place plant health preparations on the market referred to in the previous Article shall be accompanied by a draft summary of the preparation's characteristics containing the following information:
- 1.1 the name and address of the applicant and, where different, of the manufacturer;
  - 1.2 the designation and trade name of the plant health preparation;
  - 1.3 the nature and number of the active substances which the preparation contains and the composition of the excipient in so far as this information is necessary for the correct application of the preparation;
  - 1.4 physico-chemical data concerning the active substance and plant health preparation;
  - 1.5 the means of rendering the active substance or plant health preparation harmless;
  - 1.6 the interpretation of the results of the tests to establish efficacy and harmlessness to animals, plants and the environment, and the names of the centres responsible for carrying out the tests;
  - 1.7 recommended methods and precautions to reduce the handling, storage, transport, fire or other hazards;
  - 1.8 decontamination procedures to be adopted in the event of accidental spillage or leakage.



Commission text

2. Member States shall inform the Commission of cases where they have required repetition of a test and of cases where they have refused to accept a plant protection product already accepted in another Member State, in respect of which the applicant had claimed that the agricultural, plant health and environmental conditions relevant to use of the product in the regions concerned in the Member State where the test was carried out or for which acceptance was granted were comparable to those in their own territory. They shall notify the Commission of the ground on which repetition of the test was required or acceptance was refused.

3. In accordance with the procedure laid down in Article 18, it may be decided that a Member State which has refused to recognize comparability should accept the tests and analyses or should authorize the placing on the market of the product in the regions concerned in its territory.

(Amendment No. 59)  
Article 10(3)a (new)

Amendments

2. When forwarding the summary of the preparation's characteristics proposed by the applicant, the competent authority shall include a copy of the experts' reports and the proposed indications for inclusion on the packaging.

3. Authorization to place a plant health preparation on the market shall also entail approval of the summary of the preparation's characteristics, on the basis of which it is to be marketed.

3a. Where the applicant is a person other than the first applicant, the data supplied by the latter may not, for a period of fifteen years after first authorization - for first use - or fifteen years after authorization for subsequent use, be used in support of a request for authorization in any Member State by a second applicant, unless the latter has the agreement of the first applicant concerning use of data.

(Amendment No. 60)  
Article 11, title (new)

Withdrawal of authorization  
of preparations

Commission text

Amendments

(Amendment No. 61)  
Article 11

1. Member States shall inform the other Member States and the Commission immediately in writing of each plant protection product accepted in accordance with this Directive, indicating the conditions and the period of validity of such acceptance and attaching a copy of the label under which the plant protection product is to be placed on the market. They shall also inform the other Member States and the Commission immediately of any subsequent revocation or non-renewal of the acceptance or alteration of the conditions of an acceptance.

deleted

2. Each Member State shall draw up an annual list of the plant protection products accepted in its territory and shall communicate that list to the other Member States and the Commission.

deleted

3. By means of the procedure laid down in Article 19 a standardized information system shall be set up to facilitate the application of paragraphs 1 and 2 and also of Article 9(5).

deleted

4. Acceptance shall be cancelled or modified if it is established that:

1. Member States may revoke authorization for a plant health preparation authorized in accordance with this Directive if it is established that:

(a) the requirements for acceptance are not or are no longer satisfied;

(a) the requirements for authorization are not or are no longer satisfied;

(b) false or misleading particulars were supplied concerning the facts on the basis of which authorization was granted.

(b) false or misleading particulars were supplied concerning the facts on the basis of which authorization was granted;

Commission text

Amendments

- (c) there has been repeated failure to comply with good manufacturing practices or to ensure supervision by qualified experts;
- (d) the manufacturing process has not been brought up to date in the light of the current state of technical knowledge;
- (e) the plant health preparations have been placed on the market under conditions other than those stipulated in the summary of characteristics of the approved preparation;
- (f) there has been failure to comply with any particular rules and conditions as regards packaging stipulated in the authorization.

(Amendment No. 62)  
Article 12, title (new)

Documents required for an  
application for authorization  
- Data protection

(Amendment No. 63)  
Article 13, title (new)

Confidentiality of information

(Amendment No. 64)  
Article 13, first paragraph

Member States and the Commission shall ensure that information involving industrial and commercial secrets is, if the party wishing to have an active substance included in Annex I or the applicant for acceptance of a plant protection product so requests, treated as confidential.

deleted

Commission text

Amendments

(Amendment No. 65)  
Article 13, second paragraph

Industrial and commercial secrecy shall not apply to:

- the names and composition of the active substance or plant protection product;
- physico-chemical data concerning the active substance or plant protection product;
- any ways of rendering the active substance or plant protection product harmless;
- the interpretation of the results of the tests to establish efficacy and harmlessness to animals, plants and the environment, and the name of the body responsible for the tests;
- recommended methods and precautions to reduce handling, storage, transport, fire or other hazards;
- decontamination procedures to be followed in the case of accidental spillage or leakage;
- first aid and medical treatment to be given in the case of injury to persons.

If the interested party or applicant himself subsequently discloses previously confidential information, he shall be required to inform the competent authority accordingly.

Industrial and commercial secrecy shall not apply to:

- the names and composition of the active substance or plant health preparation;
- physico-chemical data concerning the active substance or plant health preparation;
- any ways of rendering the active substance or plant health preparation harmless;
- the interpretation of the results of the tests to establish efficacy and harmlessness to animals, plants and the environment, and the name of the body responsible for the tests;
- recommended methods and precautions to reduce handling, storage, transport, fire or other hazards;
- decontamination procedures to be followed in the case of accidental spillage or leakage;
- first aid and medical treatment to be given in the case of injury to persons;
- data concerning the toxicological and environmental effects of the plant health preparation.

If the interested party or applicant himself subsequently discloses previously confidential information, he shall be required to inform the competent authority accordingly.

(Amendment No. 66)  
Article 15, title (new)

Packaging of  
plant health preparations

Commission text

Amendments

(Amendment No. 67)  
Article 15(1)

Member States shall take the necessary measures to ensure that the packaging of plant protection products satisfies the following requirements as to labelling:

1. All packages must show clearly and indelibly the following:
  - (a) the trade name or designation of the plant protection product;
  - (b) the name and address of the holder of the acceptance and the registration number of the plant protection product and, if different, the name and address of the person placing the plant protection product on the market;
  - (c) the name and amount of each active substance expressed:
    - for plant protection products which are solids, aerosols, volatile liquids (maximum boiling point 50°C) or viscous liquids (lower limit 1 Pa at 20°C): as a percentage by weight;
    - for other liquids: as a percentage by weight and in grams per litre at 20°C;
    - for gases: as a percentage by volume.

Member States shall take the necessary measures to ensure that the packaging of plant health preparations satisfies the following requirements as to labelling:

1. All packages must show clearly and indelibly the following:
  - (a) the trade name or designation of the plant health preparation;
  - (b) the name and address of the holder of the authorization and the registration number of the plant health preparation and, if different, the name and address of the person placing the plant health preparation on the market;
  - (c) the name and amount of each active substance expressed:
    - for plant health preparations which are solids, aerosols, volatile liquids (maximum boiling point 50°C) or viscous liquids (lower limit 1 Pa at 20°C): as a percentage by weight;
    - for other liquids: as a percentage by weight and in grams per litre at 20°C;
    - for gases: as a percentage by volume.

### Commission text

The name must be as given in the list contained in Annex I to Directive 67/548/EEC or, if not included therein, its ISO common name. If the latter is not available, the active substance shall be designated by its chemical designation according to IUPAC or the nomenclature published by the journal 'Chemical Abstracts';

- (d) the net quantity of the plant protection product given in legal units of measurement;
- (e) the batch number;
- (f) the indications required under Article 6 of Directive 78/631/EEC, in particular those mentioned in paragraphs 2(d), (g), (h), and (i), 3 and 4 of that Article;
- (g) the nature of any special risks by means of standard phrases selected appropriately from those listed in Annex IV;

### Amendments

The name must be as given in the list contained in Annex I to Directive 67/548/EEC or, if not included therein, its ISO common name. If the latter is not available, the active substance shall be designated by its chemical designation according to IUPAC or the nomenclature published by the journal 'Chemical Abstracts';

- (d) the net quantity of the plant health preparation given in legal units of measurement;
- (e) the batch number;
- (ea) the number of the preparation in the European Register of Plant Health Preparations;
- (eb) the name of the qualified person who supervised the batch;
- (f) the indications required under Article 6 of Directive 78/631/EEC, in particular those mentioned in paragraphs 2(d), (g), (h), and (i), 3 and 4 of that Article;
- (g) the nature of any special risks by means of standard phrases selected appropriately from those listed in Annex IV;
- (ga) where applicable, the special agricultural, plant health and environmental conditions under which the preparation is intended to be used or under which its use is excluded;

Commission text

- (h) safety precautions in the form of standard phrases selected appropriately from those listed in Annex V;
- (i) the type of action of the plant protection product (e.g. insecticide, growth regulator, weedkiller, etc.);
- (j) the type of preparation (e.g. wettable powder, emulsifiable concentrate, etc.);
- (k) the uses for which the plant protection product has been accepted;
- (l) directions for use and the dose rate, expressed in metric units, for each use provided for under the terms of the acceptance;
- (m) where necessary, the safety interval for each use between application and:
- sowing or planting of the crop to be protected,
  - sowing or planting of succeeding crops,
  - harvesting,
  - use or consumption;
- (n) particulars of possible phytotoxicity, varietal susceptibility, tainting of produce and any other adverse side effects, together with the intervals to be observed between application and sowing or planting of
- the crop in question, or
  - subsequent crops;

Amendments

- (h) safety precautions in the form of standard phrases selected appropriately from those listed in Annex V;
- (i) the type of action of the plant health preparation (e.g. insecticide, growth regulator, weedkiller, etc.);
- (j) the type of preparation (e.g. wettable powder, emulsifiable concentrate, etc.);
- (k) the uses for which the plant health preparation has been authorized and the specific agricultural, plant health and environmental conditions under which the preparation may or should not be used;
- (l) directions for use and the dose rate, expressed in metric units, for each use provided for under the terms of the authorization;
- (m) where necessary, the safety interval for each use between application and:
- sowing or planting of the crop to be protected,
  - sowing or planting of succeeding crops,
  - harvesting,
  - use or consumption;
- (n) particulars of possible phytotoxicity, varietal susceptibility, tainting of produce and any other adverse side effects, together with the intervals to be observed between application and sowing or planting of
- the crop in question, or
  - subsequent crops;

Commission text

(o) if accompanied by a leaflet, as provided for in paragraph 2, the sentence 'Read accompanying instructions before use'.

Amendments

(o) if accompanied by a leaflet, as provided for in paragraph 2, the sentence 'Read accompanying instructions before use'.

(Amendment No. 68)  
Article 16, title (new)

Control measures

(Amendment No. 69)  
Article 16

Member States shall make suitable arrangements for plant protection products which have been placed on the market to be officially checked by sampling to see whether they comply with the requirements of this Directive.

The competent authority in the Member State concerned shall ensure by repeated inspections, carried out by the technical assistance and control services referred to in Articles 3(3) and 4(2), that the legal provisions relating to plant health preparations are being complied with.

These inspections shall concern both the plant health preparation itself and the use to which it is put (checks on compliance with good agricultural practices).

On completion of each such inspection the agents of the competent authority shall draw up a report on compliance by the manufacturer with the principles and guidelines of good manufacturing practices as laid down in Community law. The contents of this report shall be communicated to the manufacturer concerned.

The Member States shall notify the other Member States and the Commission of the results of such inspections.



Commission text

Amendments

(Amendment No. 70)

Article 17(1)

1. The following shall be established, having regard to current scientific and technical knowledge, in accordance with the procedure laid down in Article 18:

- any standards for the composition, purity and characteristics of active substances listed in Annex I found to be necessary;
- any necessary amendments to Annex I;
- uniform principles for checking compliance with the requirements set out in Article 4(1)(b).

1. The following shall be established, having regard to current scientific and technical knowledge, in accordance with the procedure laid down in Article 18:

- deleted
- any necessary amendments to Annex I.

deleted

(Amendment No. 71)

Article 17(2)

2. The following shall be established, having regard to current scientific and technical knowledge, in accordance with the procedure laid down in Article 19:

- any necessary amendments to Annexes II, III, IV and V;
- explanatory notes covering the particulars set out in Annexes II and III;

2. The following shall be established, having regard to current scientific and technical knowledge, in accordance with the procedure laid down in Article 19:

- any necessary amendments to Annexes II, III, IV and V;
- explanatory notes covering the particulars set out in Annexes II and III;
- uniform principles for checking compliance with the requirements set out in Article 4(1)(b);
- harmonized methods of testing and analyzing the active substances in accordance with Articles 4(1)(b) and 5(1)(c).

Commission text

Amendments

(Amendment No. 72)  
Article 18 (at end)

The Commission shall report annually to the European Parliament on the activities of the Standing Committee on Plant Health.

(Amendment No. 73)  
Article 20(2)

2. Member States shall require any person intending to conduct in their territory any research, experiment or test involving the release into the environment of a plant protection product containing as an active substance a living micro-organism or virus to notify their competent authorities at least 45 days before the start of the proposed research, experiment or test. Those authorities shall be given with the notification any information necessary to enable them to evaluate the safety of the proposed research, experiment or test. This provision shall not apply to genetically modified organisms covered by Directive / /EEC on the deliberate release to the environment of genetically modified organisms.

2. Member States shall require any person intending to conduct in their territory any research, experiment or test involving the release into the environment of a plant health preparation containing as an active substance a living micro-organism or virus to notify their competent authorities at least 45 days before the start of the proposed research, experiment or test. Those authorities shall be given with the notification any information necessary to enable them to evaluate the safety of the proposed research, experiment or test.

(Amendment No. 74)  
Article 20 a (new)

20a. At the request of a manufacturer, an exporter or the authorities of an importing third country, the Member States shall certify that a manufacturer of plant health preparations is in possession of an authorization to manufacture. The issue of such certificates shall be subject to the following rules:

1. the Member States shall comply with FAO and Council of Europe rules on pesticides;

Commission text

Amendments

2. in the case of authorized preparations a summary of characteristics shall be included with the preparation;
3. where the manufacturer is not in possession of an authorization to place the preparation on the market within the Community, he shall, for the purposes of obtaining the certificate referred to above, submit to the competent authorities a declaration stating why he is not in possession of such authorization.

(Amendment No. 75)

Annex I

**ACTIVE SUBSTANCES  
AUTHORIZED FOR INCORPORATION IN  
PLANT PROTECTION PRODUCTS**

To be established according to the procedure of Article 6(4) and Article 8, point 3, third indent.

**ACTIVE SUBSTANCES  
AUTHORIZED FOR INCORPORATION IN  
PLANT HEALTH PREPARATIONS**

To be established according to the procedure of Article 6(4), Article 7(4) and Article 8, point 3, including, in the latter case, the identity of the first person whose application led to the substance in question being included on the list.

(Amendment No. 76)

Annex Ia (new)

**ANNEX Ia  
CRITERIA FOR THE ACCEPTANCE  
OF ACTIVE SUBSTANCES  
(to be established by the Commission)**

Commission text

Amendments

(Amendment No. 77)

Annex II, introduction, final paragraph

Tests must be conducted according to the methods described in Annex V of Directive 79/831/EEC<sup>1</sup> or in the event of a method being inappropriate or not described, other methods used must be justified. Tests must be conducted in accordance with the provisions provided for in Directive 86/609/EEC<sup>2</sup>.

Tests must be conducted in accordance with the methods described in Directive 67/548/EEC<sup>2</sup> and the criteria set out in this Directive. Reports on these tests shall be submitted by properly qualified experts and shall give reasons for the use of alternative methods in the event of those referred to above being inadequate or inappropriate. The tests shall take account of the agricultural, plant health and environmental conditions under which the preparation is intended to be used.

The adoption of rules governing trials shall be in accordance with the procedure set out in Article 18.

(Amendment No. 78)

Annex II, Part A, point 2.11

2.11 Stability in acidic and alkaline environments

2.11 Biodegradability

(Amendment No. 79)

Annex II, Part A, point 5.3.1a (new)

5.3.1a The toxic effects on children under five

(Amendment No. 80)

Annex II, Part A, point 7.2.7a (new)

7.2.7a Where necessary, the agricultural, plant health and environmental conditions under which, in the light of results of the trials, the substance is intended to be used.

Commission text

Amendments

(Amendment No. 81)  
Annex II, Part B, point 5.4a (new)

5.4a Where necessary in the light of the test results, the agricultural, plant health and environmental conditions under which the organisms are intended to be used.

(Amendment No. 82)  
Annex IIa (new)

ANNEX IIa  
CRITERIA FOR DEFINING A  
CASE OF FORCE MAJEURE  
(to be established by the Commission)

(Amendment No. 83)  
Annex III, Part A, point 5.9a (new)

5.9a specific agricultural, plant health and environmental conditions under which the preparation is intended to be used

(Amendment No. 84)  
Annex III, Part A, points 6.1.5a (new) and 6.1.5b (new)

6.1.5a chronic toxicity

6.1.5b synergetic effects

(Amendment No. 85)  
Annex III, Part B, point 4.8a (new)

4.8a the agricultural, plant health and environmental conditions under which the preparation is to be used.

(Amendment No. 86)  
Annex III, Part B, points 5.1.5a (new) and 5.1.5b (new)

5.1.5a chronic toxicity

5.1.5b synergetic effects

(Amendment No. 87)  
Annex IIIa (new)

ANNEX IIIa  
UNIFORM PRINCIPLES FOR THE  
AUTHORIZATION OF PREPARATIONS  
(to be established by the Commission)

## DRAFT LEGISLATIVE RESOLUTION

embodying the opinion of the European Parliament  
on the Commission's amended proposal for a Council directive  
concerning the placing of EEC-accepted plant protection products  
on the market

### The European Parliament,

- having regard to the Commission's amended proposal to the Council (COM(89) 34 final<sup>1</sup>),
  - having been consulted by the Council pursuant to Rule 43 of the EEC Treaty (C3-0064/89),
  - having regard to the second report of the Committee on the Environment, Public Health and Consumer Protection and the opinions of the Committee on Economic and Monetary Affairs and Industrial Policy, the Committee on Legal Affairs and Citizens' Rights and the Committee on Agriculture, Fisheries and Rural Development (A3-0302/90),
1. Approves the Commission proposal subject to Parliament's amendments and in accordance with the vote thereon;
  2. Calls on the Council to notify Parliament should it intend to depart from the text approved by Parliament;
  3. Instructs its President to forward this opinion to the Council and Commission.

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<sup>1</sup> OJ No. C 89, 10.4.1989, p. 22

OPINION

pursuant to Rule 120 of the Rules of Procedure  
of the Committee on Economic and Monetary Affairs and Industrial Policy

Draftsman: Mr Lataillade

At its meeting of 30 August 1989, the Committee on Economic and Monetary Affairs and Industrial Policy appointed Mr Lataillade draftsman of this opinion.

The committee considered the draft opinion at its meetings of 8-10 November and 18-20 December 1989. On 20 December 1989, it adopted its conclusions unanimously.

The following took part in the vote: Beumer, Chairman; de Montesquiou, Vice-Chairman; Lataillade, draftsman; Barton, P. Beazley, Bofill Abeilhe, de Donnea, Herman, Hoppenstedt, Metten, Rogalla, Siso Cruellas and von Wogau.

## I. FREE MOVEMENT OF PLANT PROTECTION PRODUCTS

### 1. Economic impact of the system advocated

Plant protection products comprise all the active substances and preparations (micro-organisms, viruses, chemical substances) used to destroy organisms harmful to plants, influence plant development, or preserve plant products. They are generally known as pesticides.

The purpose of this proposal for a directive is to facilitate the free movement of these products in the EEC. It is one of the measures included in the White Paper on the completion of the single market. The free movement of plant protection products that comply with environmental protection standards cannot but help to increase agricultural yields and the availability of supplies.

The Commission presented a proposal on the subject as early as 1976 but it was blocked owing to reservations expressed by the Member States concerning the complexity of the Community procedure selected for the mutual recognition and granting of derogations. It has therefore submitted this amended proposal.

### 2. Field of application

The directive applies to all existing or future plant protection products, whether chemical substances, micro-organisms or viruses, intended for application to plants.

However, genetically modified organisms (GMOs) require a separate directive and are excluded from the field of application of this one.

### 3. Acceptance

Acceptance comprises two procedures, inclusion on the list of active substances authorized for incorporation in plant protection products and acceptance proper - inclusion on the list of active substances (Annex II).

There is no problem if the active substance under consideration already features on the Community list of active substances. This is a so-called positive list of substances whose use is considered to have no adverse effects on human or animal health or the environment.

However, if the substance contained in the product is not on the list, the manufacturer must apply to the Standing Committee on Plant Health for its inclusion (Article 6 and Annex II).

### 4. Derogations

The directive contains a number of derogations from the free movement of accepted plant protection products (Articles 8 and 10).

#### - derogation for unforeseeable danger

In certain unforeseeable circumstances (such as an unknown disease which suddenly ravages certain types of plants or abnormally high rainfall in a



particular region, increasing the risk of spreading plant protection residues) a Member State may, if necessary, allow a plant protection product which does not comply with Article 4 to be placed on the market for a period not exceeding 120 days.

- derogation for products containing an active substance not listed in Annex I

A Member State may also allow a product whose active substance is the subject of an application for inclusion in the list but has not yet been entered on it to be placed on the market. This option is designed to avoid excessive restrictions on the industries concerned and to ensure that demand can be met. However, it is subject to a time limit (three years) and is strictly controlled.

- derogation for products containing active substances not listed in Annex I but already on the market before the date of implementation of the directive

This derogation concerns the existing active substances (about 400) which have to be examined by the Committee on Plant Health for inclusion on the list. This derogation is limited to a maximum period of ten years.

- derogation based on degree of comparability (Article 10)

While the above derogations concern non-accepted products this one limits the impact of acceptance.

A Member State may consider that certain agricultural, plant health or environmental conditions for the use of a product are not comparable in the regions concerned. In this case, it is entitled to demand the repetition of tests and analyses or to refuse to allow the product to be placed on the market.

## 5. Management of the system

Management of the system is assigned, at Community level, to the Standing Committee on Plant Health.

However, this committee, set up by Council Decision 76/894/EEC, will operate in two ways.

It will operate as a Regulatory Committee empowered to make decisions on, for example, the inclusion of substances on the list, the establishment of acceptance criteria and the assessment of requests for derogations.

The other management activities required for the implementation of the directive will be performed by the same committee acting as an advisory committee.

## II. ASSESSMENT OF THE PROPOSAL FOR A DIRECTIVE

### 1. Advisability of the proposal

Plant production plays an important part in the Community. The free movement of plant protection products is likely to enhance productivity and yields in this sector of the economy. EEC acceptance will result in the free use as

well as the free movement of these products. Essentially, therefore, this proposal, which is included in the White Paper, is welcome.

## 2. Derogations

The number of derogations might at first sight give cause for concern. They might appear to water down the directive.

In fact, the specific characteristics of this category of product need to be borne in mind. Plant health products or pesticides differ from pharmaceutical products, for example, in that they are as essential to agriculture as they are harmful both to users and to the environment in general. This accounts for the need to retain the option of derogations for certain, unforeseeable circumstances, taking into account the complexity of the field. It was also essential to introduce the concept of comparability in a Community as large as the EEC, with such diverse geographical and climatic conditions.

However, the time limits for some of the derogations are perhaps excessively generous.

## 3. Management of the system

The Standing Committee on Plant Health is faced with considerable tasks. Competent and quick inspections of dossiers, appropriate use of derogations and compilation of the 'positive' list of active substances as quickly as possible will depend to a large extent on the committee's efficiency. It must therefore be given all the resources it needs.

### PROPOSED AMENDMENTS

#### Amendment No. 1

##### Article 6

Paragraph 4: add the following subparagraph:

'Within one month following the amendment of a decision concerning the inclusion of an active substance in Annex I, the applicant may appeal against the decision. This appeal shall give rise to a new assessment during which the applicant may be heard by the Committee or by members designated by the Committee. Final notification shall be issued to the interested party within a period of three months.'

#### Amendment No. 2

##### Article 6

Add a new paragraph 7 to read:

'The Committee on Plant Health shall reach a decision within six months of submission of the dossier. An additional period of three months shall be allowed where paragraph 3 is applied.'

Amendment No. 3

Article 8

Paragraph 2 to read: 'permit during the period of assessment by the Committee on Plant Health ...' (rest unchanged)

Amendment No. 4

Article 9

End of paragraph 4 to read: '... shall decide thereon within a period of 120 days'.

Amendment No. 5

Article 12

Paragraph 2, second subparagraph to read:

'Such exemption may not, however, be granted in respect of data from toxicological, metabolic, ecotoxicological and residue studies submitted with a view to the inclusion of the active substance in Annex I, or its renewal or the acceptance of the plant protection product by a person other than the applicant for acceptance, unless ...'

CONCLUSIONS

1. Plant protection products include all substances and preparations used for the protection, development and preservation of plants.
2. This proposal, included in the White Paper, should, while complying with environmental protection standards, help to increase the productivity and quality of agriculture. Its impact, in the context of the completion of the internal market, is therefore far from insignificant.
3. The procedure selected for bringing about the free movement of plant protection products takes into account their complex and ambivalent characteristics. These products, which are essential to agriculture, also present hazards to users and the environment in general.
4. The acceptance procedure therefore comprises the two aspects of prior inclusion of the substances on the positive list and acceptance as such, both aspects being strictly controlled. It also allows for a number of derogations.
5. These derogations from the acceptance procedure and its effects are justified in particular by the diversity of climatic and geographical conditions in the EEC (comparability criteria) and by the complexity of the assessment procedures. However, some of the periods of derogation may be considered excessively long.
6. The Commission should also submit the specific proposal it is considering concerning genetically modified organisms as soon as possible.

7. Finally, successful application of the directive will depend largely on the ability of the Standing Committee on Plant Health to perform its numerous tasks relating to control and the management of the system. This presupposes a substantial increase in its resources.
8. Subject to these observations and amendments, which the Committee on the Environment, Public Health and Consumer Protection is requested to take into account, this proposal for a directive may be approved.

OPINION

(pursuant to Rule 120 of the Rules of Procedure)

of the Committee on Agriculture, Fisheries and Rural Development

Draftsman: Mr V. Garcia

At its meeting of 18/19 September 1989 the Committee on Agriculture, Fisheries and Rural Development appointed Mr Garcia draftsman of this opinion.

The committee considered the draft opinion at its meetings of 6/7 November 1989 and 20/21 February 1990. At the latter meeting it adopted its conclusions unopposed, with two abstentions.

The following took part in the vote: Colino Salamanca, Chairman; Graefe zu Baringdorf, Vice-Chairman; Garcia, draftsman; Blaney, Carvalho Cardoso, da Cunha Oliveira, Fernex (for Falqui), McCartin, Mendes Bola (for Martin), Navarro, Nicholson (for Pisoni), Ortiz Climent, Saridakis, Sierra Bardaji, Sonneveld, Spencer, Stevenson, Vazquez Fouz and Vohrer.

The approach of 1 January 1993 and the completion of the single market make it necessary to introduce, as a matter of urgency, a number of measures to facilitate the circulation of goods and services. In the context of the agri-foodstuffs sector and of environmental protection, the rules governing the application of plant health products are especially in need of harmonization.

The Commission's attempts, since 1976, to achieve this goal have been blocked by the reservations expressed by certain Member States. The present proposal concerning the placing of EEC-accepted plant protection products on the market is therefore regarded as a courageous step on the Commission's part.

This analysis of the amended proposal for a directive has been guided by the following:

- the need to ensure compatibility between the different conditions prevailing in the Member States, with the somewhat difficult objective of achieving harmonization;
- the attempt to devise means of providing the plant protecting product industry and the consumers of the products with the capacity for response, within the proposed overall framework.

In the first place, the approach adopted is not felt to be the most suitable. Rather than drawing up an 'approved list' of accepted products, followed by mutual recognition and then implementation by the Member States, the reverse order would have been preferable - that is, approval at national level should precede mutual recognition, which should then be followed by inclusion in the Community-approved list. The pyramid would thus be built from the base up, rather than from the top down.

Nonetheless, a number of amendments are proposed which it is believed could fill some major gaps. Greater coordination between this directive and the regulation on the fixing of maximum levels for pesticide residues in and on products of plant origin would also have been preferable. These levels should be fixed in parallel with the 'approved list', which would thus be more clearly defined. This would provide an excellent framework for the producers and users of plant health products and for the consumer.

Finally, the system of requirements, tests and other checks laid down in Annexes II and III is excessively cumbersome and complicated; these rules appear to be so difficult to implement that they might in practice obstruct what they are in theory intended to improve.

This directive is in general an extremely positive measure, subject to acceptance of the amendments which are considered essential to ensure it is more in line with present-day conditions.

The Committee on Agriculture, Fisheries and Rural Development calls on the Committee on the Environment, Public Health and Consumer Protection, as the committee responsible, to incorporate the following amendments into its report:

Text proposed by the Commission

Amendments proposed by the Committee on Agriculture, Fisheries and Rural Development

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THE COUNCIL OF THE EUROPEAN COMMUNITIES

Having regard to the Treaty establishing the European Economic 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,

First to seventh recitals unchanged

Eighth recital

Whereas such rules should provide that plant protection products should not be put on the market unless they have been officially accepted and should be used properly having regard to the principles of integrated pest control;

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AMENDMENT No. 1

THE COUNCIL OF THE EUROPEAN COMMUNITIES

Having regard to the Treaty establishing the European Economic Community, and in particular Articles 43 and 100a 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,

AMENDMENT No. 2

Eighth recital

Whereas such rules should provide that plant protection products should not be put on the market unless they have been officially accepted and should be used properly having regard to the principles of integrated plant protection;

Ninth recital

Whereas it is necessary, at the time when plant protection products are accepted, to make sure that, when properly applied for the purpose intended, they are sufficiently effective and have no unacceptable effect on plants or plant products, no unacceptable adverse influence on the environment in general and, in particular, no harmful effect on human or animal health;

AMENDMENT No. 3

Ninth recital

Whereas it is necessary, at the time when plant protection products are accepted, to make sure that, when properly applied for the purpose intended, they are sufficiently effective and have no unacceptable effect on plants or plant products or on the biological balance of the agricultural ecosystem, no unacceptable adverse influence on the environment in general and, in particular, no harmful effect on human or animal health;

Remaining recitals unchanged  
Article 1 unchanged

Article 2

Paragraphs 1 to 4 unchanged

5. Preparations

Mixtures or solutions composed of two or more substances of which at least one is an active substance, intended for use as plant protection products.

Paragraphs 6 to 11 unchanged

12. Integrated pest control

The rational application of a combination of biological, chemical, cultural or plant breeding measures whereby the use of chemical plant protection products is limited to the necessary minimum.

AMENDMENT No. 4

Article 2

Paragraphs 1 to 4 unchanged

5. Preparations

Mixtures or solutions composed of two or more substances of which at least one is an active substance or organic preparations, intended for use as plant protection products.

Paragraphs 6 to 11 unchanged

12. Integrated plant protection

The rational application of a combination of biological, chemical, physical, cultural or plant breeding measures whereby the use of chemical plant protection products is limited to the necessary minimum.



Text proposed by the Commission

Amendments proposed by the Committee  
on Agriculture, Fisheries and Rural  
Development

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Article 3

Paragraphs 1 and 2 unchanged

3. Member States shall prescribe that plant protection products must be used properly and in accordance with any conditions laid down pursuant to this Directive. Proper use shall include application of the principles of integrated pest control.

Paragraph 4 unchanged

Article 4 unchanged

Article 5

Paragraphs 1 and 2 unchanged

Article 6

1. A Member State or the Commission shall, in order to obtain the inclusion of an active substance in Annex I, ensure that a dossier satisfying the requirements of Annex II is transmitted by the interested party of the other Member States and to the Commission.

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AMENDMENT No. 5

Article 3

Paragraphs 1 and 2 unchanged

3. Member States shall prescribe that plant protection products must be used properly and in accordance with any conditions laid down pursuant to this Directive. Proper use shall include application of the principles of integrated plant protection.

Paragraph 4 unchanged

AMENDMENT No. 6

Article 5

2a (new) For the first inclusion of a new active substance in Annex I, the requirements relating to the environment and human health shall be considered to have been satisfied only where the data concerned have been obtained on the basis of at least one existing preparation.

AMENDMENT No. 7

Article 6

1. A Member State or the Commission shall, in order to obtain the inclusion of an active substance in Annex I, ensure that a dossier satisfying the requirements of Annex II is transmitted by the interested party of the other Member States and to the Commission.

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The Commission shall refer the dossier for examination by the Standing Committee on Plant Health.

Paragraph 2 unchanged

3. As part of the procedure for assessing the dossier the interested party may be invited by the Commission to:

- provide any further information deemed necessary for the purpose of assessing whether the active substance satisfies the requirements indicated in Article 5(1),
- appear before the committee.

4. The procedure laid down in Article 18 shall be followed for taking a decision to include an active substance in Annex I and for setting any conditions in connection therewith.

Paragraphs 5 and 6 unchanged

AMENDMENT No. 7 (continued)

The Commission shall refer the dossier without delay for examination by the Standing Committee on Plant Health.

Paragraph 2 unchanged

3. As part of the procedure for assessing the dossier the interested party may, on the invitation of the Commission or at his own request:

(remainder unchanged)

4. The procedure laid down in Article 18 shall be followed for taking a decision to include an active substance in Annex I and for setting any conditions in connection therewith. The decision shall be taken no later than one year after the date of the first transmission of the dossier by the interested party to the Member State concerned and to the Commission. The interested party may appeal within one month of notification of the decision, thus initiating a second review of the dossier, during which the interested party shall be entitled to appear before the committee. The final decision must be taken no later than three months after the date of the appeal.

Paragraphs 5 and 6 unchanged

Article 8

By way of derogation from Article 4,  
a Member State may:

1. in very special circumstances,  
authorize for a period not  
exceeding 120 days the placing on  
the market of plant protection  
products not complying with  
Article 4 if such a measure  
appears necessary because of an  
unforeseeable danger threatening  
plant production which cannot be  
contained by other means. In this  
case, the Member State concerned  
shall immediately inform the other  
Member States and the Commission  
of its action. It shall be  
decided without delay, in  
accordance with the procedure laid  
down in Article 18, whether and,  
if so, under what conditions the  
action taken by the Member State  
may be continued or repeated;
2. permit, for a period not exceeding  
three years, the placing on the  
market of plant protection  
products containing an active  
substance not listed in Annex I  
and not yet available on the  
market on the date of  
implementation of this Directive,  
provided that:

AMENDMENT No. 8

NOT APPLICABLE TO THE ENGLISH  
VERSION

AMENDMENT No. 9

Article 8

By way of derogation from Article 4,  
a Member State may:

1. in very special circumstances,  
authorize for a period not  
exceeding 120 days the placing  
on the market of plant  
protection products not  
complying with Article 4 if such  
a measure appears necessary  
because of an unforeseeable  
danger threatening plant  
production or products in storage  
which cannot be contained by  
other means ... (remainder  
unchanged)
2. permit, for a period which shall  
not exceed three years but which  
may be extended until the active  
substance is included in Annex I,  
the placing on the market of  
plant protection products  
containing an active substance  
not listed in Annex I and not yet  
available on the market on the  
date of implementation of this  
Directive, provided that:

AMENDMENT No. 9 (continued)

(a) following application of Article 6(1) and (2) it is found that the dossier on the active substance satisfies the requirements of Annex II;

(a) the Member State has (9 words deleted) found that the dossier on the active substance satisfies the requirements of Annex II, except in the case of data concerning long-term chronic toxicity, which may be supplied by the applicant in the form of full or partial reports, at the discretion of the Member State;

(b) the Member State establishes that the active substance satisfies the requirements of Article 5(1) and that the plant protection product satisfies the requirements of Article 4(1)(b) and (c).

(b) (unchanged)

In such cases the Member State shall immediately inform the other Member State and the Commission of its assessment of the dossier and of the terms of acceptance.

In such cases the Member State shall immediately inform the other Member State and the Commission of its assessment of the dossier and of the terms of acceptance.

If, on assessment of the dossier as provided for in Article 6(3), it is found that the active substance does not satisfy the requirements of Article 5(1), a decision may be taken by the procedure laid down in Article 18 requiring the Member State to withdraw the acceptance;

If, on assessment of the dossier as provided for in Article 6(3), it is found that the active substance does not satisfy the requirements of Article 5(1), a decision may be taken by the procedure laid down in Article 18 requiring the Member State to withdraw the acceptance. The derogation referred to in Article 8(2) must also apply to plant protection products which are under assessment by the Member States or which are already on the market on the date of entry into force of this Directive on the basis of a provisional authorization of sale.

3. for a period of 10 years from the date of implementation of this Directive, without prejudice to Directive 79/117/EEC, authorize the placing on the market in its territory of plant protection products containing active substances not listed in Annex I that were already on the market before that date.

The Commission shall draw up a programme of work for the gradual examination of these active substances during that period. In implementing this programme the Commission may require interested parties to submit all requisite data to the Commission and the Member States within a prescribed period.

During this period it may, following examination by the Standing Committee on Plant Health of such an active substance, be decided, by the procedure laid down in Article 18, that the substance can be included in Annex I or that the Member State must withdraw the authorization referred to above within a prescribed period.

AMENDMENT No. 9 (continued)

3. for a period of 10 years from the date of implementation of this Directive, without prejudice to Directive 79/117/EEC, authorize the placing on the market in its territory of plant protection products containing active substances not listed in Annex I that were already on the market before that date.

The Commission shall draw up a programme of work with a view to the inclusion in Annex I, by 1 January 1993, of those substances which are accepted by a majority of the Member States. The remaining substances shall be subject to a gradual examination, which must be concluded within the above-mentioned period of 10 years. In implementing this programme ... (remainder unchanged).

Article 9

Paragraphs 1 to 3 unchanged

4. Each Member State shall agree to consider any application for acceptance made to it and shall decide thereon within a reasonable period.

Paragraphs 5 and 6 unchanged

Article 10

1. At the request of the applicant, a Member State to which an application is made for the acceptance of a plant protection product already accepted in another Member State must:

- unless certain agricultural, plant health or environmental conditions relevant to the use of the product are not comparable in the regions concerned, refrain from requiring the petition of tests and analyses already carried out in connection with the acceptance of the product in that Member State, and

AMENDMENT No. 10

Article 9

Paragraphs 1 to 3 unchanged

4. Each Member State shall agree to consider any application for acceptance made to it and shall decide thereon within one year at the latest.

Paragraphs 5 and 6 unchanged

AMENDMENT No. 11

Article 10

1. At the request of the applicant, a Member State to which an application is made for the acceptance of a plant protection product already accepted in another Member State must, taking into account that mutual recognition must not be utilized to the detriment of the first applicant:

- unless certain agricultural, plant health or environmental conditions relevant to the use of the product are not comparable in the regions concerned, refrain from requiring the petition of tests and analyses already carried out in connection with the acceptance of the product in that Member State, and also refrain from requiring supplementary studies, and
- (unchanged)

AMENDMENT No. 11 (continued)

1a (new)

Where the applicant is a person other than the first applicant, the data supplied by the latter may not, for a period of fifteen years after first authorization - for first use - or fifteen years after acceptance for subsequent use, be used in support of a request for authorization in any Member State by a second applicant, unless the latter has the agreement of the first applicant concerning use of data.

Paragraphs 2 and 3 unchanged

Paragraphs 2 and 3 unchanged

Article 11 unchanged

AMENDMENT No. 12

Article 12

Article 12

Paragraph 1 unchanged

Paragraph 1 unchanged

2. By way of derogation from paragraph 1, applicants may, if the active substance is already listed in Annex I and does not differ substantially in degree of purity and nature of impurities, be exempted from supplying the information required under paragraph 1(b), except for that identifying the active substance.

2. By way of derogation from paragraph 1, .... (unchanged) ... active substance.

Such exemption may not, however, be granted in respect of data from toxicological, metabolic, ecotoxicological and residue studies submitted with a view to the inclusion of the active substance in Annex I by a person other than the applicant for acceptance, unless:

Such exemption may not, however, be granted in respect of data from toxicological, metabolic, ecotoxicological and residue studies submitted for the following purposes:

- either the applicant has agreed with the other person that recourse may be had to these data,
- or the application for acceptance is made at least 15 years after the first acceptance in a Member State of a plant protection product containing the active substance in question;

AMENDMENT No. 12 (continued)

- with a view to inclusion of the active substance in Annex I and, in relation to the data submitted for consideration, to the continuation or renewal of such inclusion;
- as part of a review by the Standing Committee on Plant Health of active substances not included in Annex I but already on the market at the date of entry into force of this Directive;
- in support of acceptance of a plant protection product by a Member State;
- to extend the use of a plant protection product which is already accepted in a Member State;
- in support of acceptance by a Member State of a new formulation of an active substance which is already authorized;
- in support of the renewal of the authorization of a plant protection product by the Member States, by a person other than the first applicant,

unless

- either the applicant has agreed with the other person that recourse may be had to these data,
- or the application for acceptance is made at least 15 years after the first inclusion in Annex I (10 words deleted) of the active substance in question.



AMENDMENT No. 12 (continued)

3. unchanged

3. unchanged

Articles 13 and 14 unchanged

AMENDMENT No. 13

Article 15

Article 15

1(a) to 1(m) unchanged

1(a) to 1(m) unchanged

(n) particulars of possible phytotoxicity, varietal susceptibility, tainting of produce and any other adverse side effects, together with the intervals to be observed between application and sowing or planting of:

(n) particulars of possible phytotoxicity, varietal susceptibility, tainting of produce and any other adverse side effects, especially the effects on benign organisms, together with the intervals to be observed ... (remainder unchanged)

- the crop in question, or

- subsequent crops;

(o) unchanged

(o) unchanged

2. unchanged

2. unchanged

3. Member States shall stipulate that the labels of accepted plant protection products which are not intended for domestic use shall also bear the statement 'unsuitable for domestic use'.

3. Member States shall stipulate that the labels of accepted plant protection products which are not intended for domestic use shall also bear the statement 'reserved for agricultural use'.

Paragraphs 4 and 5 unchanged

Paragraphs 4 and 5 unchanged

Articles 16 and following unchanged

Text proposed by the Commission

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Amendments proposed by the Committee  
on Agriculture, Fisheries and Rural  
Development

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ANNEX I

ACTIVE SUBSTANCES AUTHORIZED FOR  
INCORPORATION IN PLANT PROTECTION  
PRODUCTS

(remainder unchanged)

AMENDMENT No. 14

ANNEX I

ACTIVE SUBSTANCES AUTHORIZED FOR  
INCORPORATION IN PLANT PROTECTION  
PRODUCTS WITH IDENTIFICATION OF THE  
FIRST APPLICANT NAMED IN THE DOSSIER  
FOR THE RELEVANT AUTHORIZATION

(remainder unchanged)

ANNEXES II, III, IV and V unchanged

OPINION OF THE COMMITTEE ON LEGAL AFFAIRS AND CITIZENS' RIGHTS

Letter from the Chairman to Mr Collins, Chairman of the Committee on the Environment, Public Health and Consumer Protection

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Brussels, 20 December 1989

Dear Mr Collins,

At its meeting of 19 and 20 December 1989 the Committee on Legal Affairs and Citizens' Rights considered the question of the appropriate legal basis for the amended proposal for a Council directive concerning the placing of EEC-accepted plant protection products on the market (COM(89) 34 final).

After hearing the proposal by Mr Marinho, member responsible for questions of legal basis, the Committee on Legal Affairs and Citizens' Rights decided<sup>2</sup> that the correct legal basis was Article 100a of the EEC Treaty and not Article 43 of this Treaty as proposed by the Commission. It was considered that the aim of the above proposal for a directive was the harmonization of the rules concerning the approval of plant protection products with a view to preventing barriers to intra-Community trade.

Yours sincerely,

(sgd) Graf Stauffenberg

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<sup>2</sup> The following were present at the time of the vote: Stauffenberg, Chairman; Vayssade, first Vice-Chairman; Speroni, third Vice-Chairman; Marinho, rapporteur; Bandres Molet, Bontempi, Elliott, Fontaine, Inglewood, Mazzone, Medina Ortega, Oddy, Price, Simpson, Tazdait.

