

# **COMMISSION OF THE EUROPEAN COMMUNITIES**

**COM(76) 427 final**

**Brussels, 29 July 1976**

**Proposal for a Council directive concerning the placing of EEC-accepted plant protection products on the market. (submitted to the Council by the Commission)**

**COM(76) 427 final**

Proposal for a Council Directive of ..... concerning the placing of EEC-accepted plant protection products on the market.

---

Explanatory Memorandum

I. General Introduction

The use of plant protection products is essential in modern agriculture for the protection of crops and crop products from the effects of harmful organisms and weeds. They contribute thereby to the improvement of the productivity of agriculture and to assuring the availability of supplies.

Many plant protection products contain active substances whose use can also present risks to man, animals, plants and the environment and most Member States have rules governing both the marketing and use of such products. These rules differ and particularly those relating to marketing may be an obstacle to the free movement of goods within the Community and may also constitute a disincentive to innovation.

The following proposal for a Directive deals with the marketing and otherwise placing on the market of plant protection products. It is complemented by a separate proposal which the Commission is submitting at the same time and which seeks essentially to prohibit the use of certain hazardous or environmentally harmful plant protection products. The Commission departments are also studying possible extension of the scope of this present Directive to other types of pesticides.

This proposal envisages the creation of an optional "EEC-acceptance" to operate in parallel with existing national arrangements for approving plant protection products. An applicant wishing to market a plant protection product within the Community will have the choice either to apply for separate registrations under national legislation as at present or to apply for EEC-acceptance, on its own or in addition to national registrations, to one of the Member States in accordance with the provisions of this Directive. EEC-acceptance, if granted, would be recognised, subject to certain safeguards, by all Member States normally within a 1 - 2 year period.

EEC-acceptance will permit the free circulation of the product throughout the Community except in so far as Member States may be authorised, particularly because of local conditions, to prohibit its circulation in their territory or to restrict or vary its field of use.

Such a Directive was called for specifically in the Council Resolution of 22 July 1974 on the veterinary, plant health and animal feedingstuffs sectors (1). It also represents a contribution to the Communities' environmental policy as envisaged in the Programme of Action of the European Communities on the Environment (2).

This proposal complements the proposal for a Council Directive on the approximation of the laws, regulations and administrative provisions of Member States relating to the classification, packaging and labelling of pesticides (3). Together with the latter, it considerably improves the protection given to the users of plant protection products and to consumers of plants and plant products.

It will be noted that this proposal does not provide for total harmonisation. The market for plant protection products in the Community is specialised and characterised by the large number of products available. Many thousands of different commercial preparations containing several hundred active substances are in use in the Community - in France alone over 6000 products are officially approved for use in agriculture, although admittedly by no means all are of economic importance. Furthermore, a considerable proportion of nationally registered plant protection products is intended only for local or regional marketing to meet local or regional agricultural and ecological conditions and needs, which can vary significantly over a geographical area as large as the Community. Under these circumstances, it has been judged desirable at this stage to permit Member States to continue to approve for marketing in their own territory plant protection products in accordance with national provisions. In this way the proposal offers the necessary flexibility for manufacturers and distributors of products with only limited regional application.

---

(1) OJ No C 92, 6.8.1974, p. 2

(2) OJ No C 112, 20.12.1973

(3) OJ No C 40, 20.2.1975, p. 30

In this way the proposal offers the necessary flexibility for manufacturers and distributors of products with only limited regional application.

## II. Notes on individual Articles

### Article 1

This Article defines the scope of the Directive which concerns the placing on the market of EEC-accepted plant protection products.

### Article 2

This Article defines certain terms used in the Directive, notably that of "plant protection product" which is defined to include inter alia insecticides, acaricides, nematocides, molluscicides, bactericides, herbicides, fungicides, repellants, rodenticides, defoliants and growth regulators intended for use on crops, crop products and in home gardens, as well as total and aquatic herbicides.

### Article 3

This Article defines the concept of "EEC-acceptance".

### Article 4

This Article lays down the general requirements for EEC-acceptance i.e. evidence of effective and safe use for the purpose intended. It also provides that the necessary scientific principles and guidelines for checking compliance with the requirements are to be established through the procedure of the Standing Committee and that only certain active substances (listed in Annex I) may be contained in EEC-accepted plant protection products.

### Article 5

Under the provisions of this Directive, application for EEC-acceptance may be made by the manufacturer, main distributor or importer. The applicant must however have a permanent office in the Community.

Article 6

This Article places a duty on each Member State to receive and process promptly and expeditiously all applications for EEC-acceptance made to it.

Article 7

This Article provides that at least the data listed in Annex II (model application form) shall be provided at the time of application and this should normally be supported by scientific documentation.

Article 8

This Article requires satisfaction of the requirements for EEC-acceptance to be established in official trials or trials officially recognised by the competent authority.

Articles 9 and 10

These Articles deal with the records to be kept by each Member State and ensure access thereto by other Member States and the Commission.

Article 11

This Article provides that the validity of an EEC-acceptance shall be for not more than 10 years, with the possibility of renewal. It establishes certain conditions under which an acceptance, once granted, may be cancelled or amended.

Article 12

This Article requires Member States to ensure free circulation of an EEC-accepted product within normally 1-2 years of grant by the Member State in question.

Individual Member States may, however, apply before expiry of this period for authorisation to prohibit totally or partially the placing on the market of a given plant protection product within its territory or to restrict or vary its field of use. For this, it must establish that the product fails to fulfill in its territory one of the requirements for acceptance.

Article 13

This Article provides for annual publication in the Official Journal of the European Communities under the title "Common Catalogue of EEC-accepted Plant Protection Products" of all EEC-accepted plant protection products which may be freely placed on the market in the Community. It also requires Member States to maintain a national list of such products.

Article 14

This is a safeguard clause which establishes the conditions and procedure under and in accordance with which a Member State may apply to prohibit or restrict the placing on the market of a plant protection product after expiry of the 1-2 year period provided for in Article 12.

Article 15

This Article contains the detailed packaging and labelling provisions for EEC-accepted plant protection products required in addition to those provided for, where applicable, in the proposal for a Council Directive on the classification, packaging and labelling of pesticides (3).

Article 16

This Article provides that EEC-accepted plant protection products shall be subject to no packaging and labelling requirements other than those laid down in the Directive.

Articles 17 and 18

These Articles provide for official controls of EEC-accepted plant products by the Member States using Community methods of sampling and analysis.

Article 19

Under the provisions of this Article, certain technical criteria for EEC-acceptance, subsequent amendments to the Annexes as well as Community methods of sampling and analysis are to be adopted through the procedure of the Standing Committee.

Article 20

This Article lays down the procedure of the Standing Committee on Plant Health in the context of this Directive. It corresponds to earlier Commission proposals in similar cases.

III. Consultation of Interested Parties

This Proposal for a Directive has been drawn up with the assistance of government experts on agriculture, public health and the environment, and after consultation of the industrial organisations concerned. In preparing it, account has also been taken of existing international recommendations in this field.

IV. Consultation of the European Parliament and the Economic and Social Committee

The European Parliament and the Economic and Social Committee must be consulted in accordance with Article 100 of the Treaty, since the implementation of this Directive involves the amendment of legislation in one or more Member States.

Proposal for a Council Directive of ..... concerning the placing of EEC-accepted plant protection products on the market.

---

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

Having regard to the proposal from the Commission;

Having regard to the Opinion of the European Parliament;

Having regard to the Opinion of the Economic and Social Committee;

Whereas plant production has a very important place in the European Communities;

Whereas the yield from that production is continually being affected by harmful organisms and weeds and whereas it is absolutely essential to protect plants against these risks to prevent a fall in yields and thereby help to assure the availability of supplies;

Whereas one of the most important methods of protecting plants and plant products and of increasing the productivity of agriculture is to use plant protection products;

Whereas the effects of these plant protection products may not be wholly favourable for plant production and their use may involve risks for man and the environment since, in the main, they are toxic substances or preparations having dangerous effects;

Whereas, there are rules in most Member States governing approval to place plant protection products on the market and whereas these regulations contain differences which constitute an obstacle to trade and thereby directly affect the establishment and functioning of the common market;

Whereas it is therefore desirable to eliminate this obstacle by aligning the relevant provisions laid down in the Member States by law, regulation or administrative provision to create conditions permitting the free circulation of plant protection products in the Community;



Whereas a large number of plant protection products are already in circulation in the Member States and whereas a considerable proportion of these are intended only for local or regional circulation to meet local or regional agricultural and ecological conditions and needs; whereas it therefore seems desirable that Member States remain free to regulate in accordance with national provisions plant protection products intended for circulation in their own territory;

Whereas in a first stage the need for harmonisation will be satisfied by the creation of the type of an EEC-accepted plant protection product which may be placed freely on the market within the Community and whereas all EEC-accepted plant protection products are to be listed in a "Common Catalogue of EEC-accepted Plant Protection Products";

Whereas there must be uniform rules in the Member States relating to the conditions and procedure for EEC-acceptance;

Whereas it is necessary, at the time when plant protection products are EEC-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 unreasonable adverse influence on the environment in general and, in particular, no harmful effect on human or animal health;

Whereas, in a first stage, EEC-acceptance shall be limited to plant protection products containing certain active substances laid down at Community level;

Whereas EEC-accepted plant protection products shall after expiry of a certain period be subject to no restrictions on placing them on the market within the Community for reasons related to the requirements laid down in this Directive and the Annexes thereto;

Whereas it is desirable to give Member States the right through a special procedure to raise any objections they may have to a plant protection product and its inclusion in the Common Catalogue as well as to prohibit a plant protection product already included in the aforementioned Catalogue or limit its use;

Whereas it is desirable that the Commission should ensure that plant protection products to be included in the Common Catalogue of EEC-accepted Plant Protection Products be published in the Official Journal of the European Communities;

Whereas this Directive complements the Council Directive of ..... on the approximation of the laws, regulations and administrative provisions of Member States relating to the classification, packaging and labelling of pesticides in respect of the packaging and labelling of EEC-accepted plant protection products; whereas, together with the latter Directive, it considerably improves the protection given to the users of plant protection products and to the consumers of plants and plant products and whereas it also contributes to the protection of the environment;

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

Whereas official investigations of EEC-accepted plant protection products to check their compliance with the provisions of this Directive shall be carried out in accordance with Community methods of sampling and analysis;

Whereas the implementation of this Directive and the adaptation of its Annexes to the development of technical and scientific knowledge necessitates a close cooperation between the Commission and Member States; whereas the procedure of the Standing Committee on Plant Health offers a suitable basis for this;

HAS ADOPTED THIS DIRECTIVE:

#### Article 1

This Directive concerns the placing on the market within the Community of EEC-accepted plant protection products put up in commercial form.

Article 2

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

1. Plant protection products

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

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

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

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

1.4 to destroy undesired plants, or

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

2. Plant protection products put up in commercial form

Plant protection products in the form in which they are supplied to the user.

3. Residues of plant protection products

Residues of plant protection products and of their toxic metabolites or breakdown products.

4. Substances

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

5. Preparations

Mixtures or solutions composed of two or more substances, or of microorganisms or viruses used as plant protection products.

6. Active substances

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

6.1 against harmful organisms, or

6.2 on plants, parts of plants or plant products.

7. Plants

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

8. 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 7.

9. Harmful organisms

Pests of plants or of plant products, belonging to the animal or plant kingdoms and viruses.

10. Animals

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

11. Placing on the market

Any handing over whether in return for payment or free of charge.

Article 3

Member States shall provide that plant protection products may be placed on the market with the description "EEC-accepted" only if they have been officially accepted in accordance with the provisions of this Directive.

Article 4

(1) Member States shall provide that plant protection products may be "EEC-accepted" only if, in so far as can be ascertained in the light of current scientific and technical knowledge:

1.1 when properly applied for the purpose intended and having regard to all foreseeable conditions under which they will be used

1.1.1 they are sufficiently effective,

1.1.2 they have no unacceptable effect on plants or plant products,

1.1.3 they have no harmful effect on human or animal health,

1.1.4 they have no unreasonable adverse influence on the environment;

1.2 the nature and quantity of their active substances can be measured by methods in general use.

- (2) Uniform principles for checking compliance with the requirements listed in paragraph 1.1 shall be established in accordance with the procedure laid down in Article 20.
- (3) The active substances whose inclusion in EEC-accepted plant protection products is permitted are listed in Annex I.

Article 5

- (1) Application for "EEC-acceptance" of a plant protection product may be made by:
  - 1.1 the manufacturer,
  - 1.2 the distributor, if the plant protection product is to be first placed on the market within the Community by a distributor, or
  - 1.3 the importer into the Community.
- (2) Each applicant shall be required to have a permanent office within the Community.

Article 6

- (1) Each application for EEC-acceptance may be made to only one Member State.
- (2) Each Member State shall receive and decide within a reasonable period on any application for EEC-acceptance made to it.
- (3) Within one month of the receipt of each 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 or experimental designation of the plant protection product,
  - its physical nature,
  - the names and corresponding contents of all active substances contained in it,
  - the uses for which it is intended.

Article 7

- (1) The Member States shall provide that, when an application for EEC-acceptance of a plant protection product is made, at least those particulars which are set out in Annex II shall be supplied.
- (2) The applicant shall normally be required to submit scientific documentation relating to the particulars supplied.
- (3) Member States and the Commission shall ensure that information involving business or manufacturing secrets is, if the applicant so requests, treated as confidential.

Article 8

Member States shall ensure that satisfaction of the requirements for EEC-acceptance set out in Article 4 (1) is established by official or officially recognized and scientifically valid tests and analyses.

Article 9

- (1) Member States shall be responsible for compiling a file on each EEC-accepted plant protection product. Each such file shall contain at least a copy of the application, a record of the administrative actions taken by the Member State in deciding on the application and all the essential results of the tests and analyses on which acceptance was based.
- (2) Member States shall inform the other Member States and the Commission immediately in writing of each plant protection product EEC-accepted in accordance with this Directive, indicating the terms and the period of validity of such acceptance and attaching copies of each different label or draft label under which the plant protection product is to be placed on the market within the Community. It shall also inform the other Member States and the Commission immediately of any subsequent alteration, not constituting a separate acceptance, of these terms.

- (3) Any amendment of the particulars prescribed under items 12, 13 and 14 of paragraph 3.1 of Article 15 on the label of an EEC-accepted plant protection product shall be considered as a separate EEC-acceptance.

#### Article 10

Member States shall, if so requested, make available to the other Member States and to the Commission the files provided for under Article 9 (1) and shall supply to them on request and to the extent possible all information necessary for an understanding of the acceptances.

#### Article 11

- (1) Member States shall provide that EEC-acceptance shall expire not later than ten years from 31 December in the year in which it is granted. On such expiry, it may be renewed for a further period not exceeding ten years and for successive periods thereafter not exceeding ten years.
- (2) Acceptance shall be cancelled or amended if:
- 2.1 it is established that the requirements for acceptance are not or no longer satisfied;
- 2.2 false or misleading particulars were supplied concerning the facts on the basis of which acceptance was granted.
- (3) Acceptance shall be cancelled at any time on request in writing by the acceptance-holder to the Member State which granted the acceptance.

#### Article 12

- (1) With effect from 31 December of the year following the year of EEC-acceptance, the Member States may not, for reasons related to the requirements laid down in this Directive and the Annexes thereto, refuse, prohibit or restrict the placing on the market of EEC-accepted plant protection products which comply with the requirements of this Directive and the Annexes thereto.

- (2) By way of derogation from paragraph (1) a Member State may apply not less than three months before expiry of the prescribed time limit under the procedure laid down in Article 20 for authorisation to prohibit totally or partially the placing of a plant protection product on the market within its territory or to restrict or vary its field of use.
- (3) Such authorisation as provided for in paragraph (2) may be granted only if a plant protection product fails to fulfil any one of the requirements of Article 4 paragraph 1.1 in the territory of the Member State making the application. This shall be established in official or officially recognised and scientifically valid tests unless such failure is already evident from the particulars in the application.

When a Member State does not intend to make an application under the provisions of paragraph (2) in respect of a plant protection product, it shall notify the Commission or make a statement to that effect to the Standing Committee on Plant Health.
- (5) If all the Member States submit such statements or inform the Commission as provided for in paragraph (4), the time limit prescribed in paragraph (1) shall no longer apply and Article 13 paragraph (1) shall apply.
- (6) The time limit prescribed in paragraph (1) may be extended before its expiry under the procedure laid down in Article 20 if sound reasons exist.

#### Article 13

- (1) The Commission shall publish, if possible before the end of each year, a list of all the plant protection products which may be placed on the market within the Community with the description "EEC-accepted" during the following year. The list shall be published in the Official Journal of the European Communities under the title "Common Catalogue of EEC-accepted Plant Protection Products" and shall specify the year to which it relates. Should there be any discrepancy between the Catalogue and the particulars of any acceptance, the particulars given in the acceptance shall prevail.
- (2) Each Member State shall draw up an annual list of the plant protection products EEC-accepted in accordance with this Directive and of their uses provided for within its territory.



Article 14

If it is established that in the territory of a Member State an EEC-accepted plant protection product when properly applied for a use which has been provided for,

1. gives rise to harmful effects on human or animal health, or
2. gives rise to unacceptable effects on plants or plant products, or
3. has unreasonable adverse influence on the environment,

the Member State may apply under the procedure laid down in Article 20 for authorisation to prohibit totally or partially the placing of this plant protection product on the market within its territory or to restrict its use.

Article 15

(1) The Council Directive of..... on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of pesticides shall apply to the classification, packaging and labelling of EEC-accepted plant protection products.

(2) Member States shall take all necessary steps to ensure that plant protection products which have been accepted in accordance with the provisions of this Directive can not be placed on the market unless their packaging satisfies the following requirements:

- 2.1 the packages must be so constructed and sealed that their contents cannot escape; this requirement does not apply where special safety devices are prescribed;
- 2.2 the materials constituting the packages and closures must not be liable to attack by the contents or liable to form harmful or dangerous compounds with the contents;
- 2.3 the packages and closures must be sufficiently strong and solid throughout to ensure that they cannot come apart and will safely withstand the stresses and strains of normal handling.

Packages meeting these requirements shall be regarded as satisfactory.

(3) Member States shall provide that in addition to the labelling provisions of paragraph (1) the packaging of EEC-accepted plant protection products shall satisfy the following requirements as to labelling:

3.1 All packages must show clearly and indelibly the following:

3.1.1 the proprietary name or designation of the plant protection product;

3.1.2 the words "EEC-accepted" together with the abbreviation for the Member State, which has accepted the plant protection product, of the international code used for motor vehicles;

3.1.3 the name and address of the holder of the EEC-acceptance and the registration number of the plant protection product; the number shall immediately follow the abbreviation for the Member State as provided for in paragraph 3.1.2;

3.1.4 if different from 3.1.3, the name and address of the person first placing the plant protection product on the market;

3.1.5 the names and corresponding contents of all active substances contained in the plant protection product, each active substance being mentioned separately by the name or one of the names given for it in Annex I and each corresponding content being expressed in terms of pure active substance as follows:

- for plant protection products which are solids, aerosols, volatile liquids (boiling point max. 50°C) or viscous liquids (lower limit 1000 centipoises at 20°C): as a percentage by weight,
- for other liquids: as a percentage by weight and in g/l at 20°C,
- for gases: as a percentage by volume.

- 3.1.6 the weight or volume of the contents, expressed in metric units;
- 3.1.7 identification of the quantity manufactured during a specified period;
- 3.1.8 the physical nature of the preparation (e.g. wettable powder, emulsifiable concentrate etc....);
- 3.1.9 indication of the nature of special risks, if any, to the environment in general and to man and animals in particular. Indication of such risks shall normally be given in the form of standard phrases selected appropriately from those listed in Annex III of this Directive and in Annex III of the Council Directive 67/548/EEC of 27 June 1967;
- 3.1.10 advice for the protection of the environment in general and of man and animals in particular. Such safety advice shall normally be given in the form of standard phrases selected appropriately from these listed in Annex IV of this Directive and in Annex IV of the Council Directive 67/548/EEC of 27 June 1976;
- 3.1.11 the type of plant protection product (e.g. insecticide, growth regulator, herbicide etc.....)ö
- 3.1.12 the uses of the plant protection product;
- 3.1.13 directions for use and timing of application;
- 3.1.14 the dose rate, expressed in metric units, for each use;
- 3.1.15 where necessary, the safety interval between application and
  - a) sowing or planting,
  - b) harvesting,
  - c) use or consumption, or
  - d) sowing or planting succeeding cropsfor each use.
- 3.1.16 warnings concerning 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

- a) the crop in question, or
- b) succeeding crops.

3.1.17 if accompanied by a leaflet as provided for in paragraph 3.5 the sentence "Read accompanying instructions before use".

In no case may wording on the label on plant protection products accepted in accordance with the provisions of this Directive bear such indications as "non-toxic" or "harmless". However, labels may state that a plant protection product, for example, is harmless to bees or to any other specified organisms (pests, fish, game, beneficial species etc....) provided that such indications refer to the normal use of the plant protection product.

3.2 The label required in accordance with the provisions of paragraph 3.1 must be so affixed to one or more surfaces of the package that it can be read horizontally when the package is set down normally. The dimensions of the label must be as follows:

<u>Package contents</u>	<u>Dimensions</u>
- less than or equal to 3 l	if possible at least 52 x 74 mm
- greater than 3 l, and not exceeding 50 l,	at least 74 x 105 mm
- greater than 50 l, and not exceeding 500 l	at least 105 x 148 mm
- greater than 500 l	at least 148 x 210 mm

The entire surface of the label must adhere to the immediate packaging of the plant protection product.

3.3 A label shall not be required where the particulars are clearly shown on the package itself in a manner satisfying the requirements of paragraph 3.2.

3.4 Member States may make the placing on the market in their territories of plant protection products accepted in accordance with the provisions of this Directive subject to the requirement that such plant protection products be labelled in at least one of their official languages.

3.5 Member States may permit the particulars required under items 13 and 16 of paragraph 3.1 be indicated on a separate leaflet accompanying the package if the space available on the package is too small to allow labelling in accordance with the provisions of paragraph 3.2. Such a leaflet shall be regarded as part of the label for the purpose of this Directive.

- (4) Member States shall provide that toxic EEC-accepted plant protection products must be strikingly coloured.

#### Article 16

(1) The Member States may not, for reasons related to colour, packaging or labelling, prohibit, restrict or impede the placing on the market of plant protection products which comply with the requirements of this Directive and the Annexes thereto.

(2) The provisions of paragraph 1 shall be without prejudice to the right of Member States to require:

2.1 reference to be made on the label that EEC-accepted plant protection products are subject to additional national provisions relating to the protection of the user or to the persons permitted to place them on the market;

2.2 a statement on the label that EEC-accepted plant protection products may not be used for purposes, or in a manner, not provided for on the label.

(3) Member States shall inform the other Member States and the Commission of any implementation of paragraph 2.

#### Article 17

Member States shall make suitable arrangements for EEC-accepted plant protection products, which have been placed on the market, to be officially controlled, at least by check sampling, as regards their compliance with the requirements of this Directive.

#### Article 18

Member States shall take all steps necessary to ensure that official controls of EEC-accepted plant protection products to check their compliance with the requirements laid down by law, regulation or administrative provision are carried out in accordance with Community methods of sampling and analysis.

Article 19

- (1) The following shall be established, having regard to current scientific and technical knowledge, in accordance with the procedure laid down in Article 20;
  - 1.1 criteria for the composition, purity and condition, where these are found necessary, of the active substances listed in Annex I;
  - 1.2 explanatory notes covering the particulars set out in Annex II;
  - 1.3 any necessary amendments to Annexes I,II,III and IV;
  - 1.4 the methods of sampling and analysis referred to in Article 18.
- (2) Active substances shall be included in Annex I only if
  - 2.1 on the basis of the results presented it may be expected that plant protection products manufactured from them will meet the requirements of Article 4, paragraph (1);
  - 2.2 their residues, if constituting a danger to human or animal health, can be measured by methods in general use.

Article 20

- (1) Where the procedure laid down in this Article is to be followed, matters shall be referred without delay by the Chairman, either on his own initiative or at the request of a Member State, to the Standing Committee on Plant Health set up by the Council Decision of.... hereinafter called the "Committee".
- (2) Within the Committee, the votes of the Member States shall be weighted as provided in Article 148 (2) of the Treaty. The Chairman shall not vote.
- (3) The representative of the Commission shall submit a draft of the measures to be adopted. The Committee shall deliver its Opinion on such measures within a time limit set by the Chairman according to the urgency of the matters. Opinions shall be delivered by a majority of forty-one votes.

- (4) The Commission shall adopt the measures and implement them forthwith where they are in accordance with the Opinion of the Committee. Where they are not in accordance with the Opinion of the Committee, or if no Opinion is delivered, the Commission shall without delay propose to the Council the measures to be adopted. The Council shall adopt the measures by a qualified majority.
- If the Council has not adopted any measures within three months of the proposal being submitted to it, the Commission shall adopt the proposed measures and implement them forthwith.

Article 21

- (1) The Member States shall bring into force the provisions necessary to comply with this Directive within 18 months of its notification and shall forthwith inform the Commission thereof.
- (2) On notification of this Directive Member States shall inform the Commission, in time to enable it to put forward its comments, of all draft laws, regulations or administrative provisions which they contemplate adopting in the field covered by this Directive.

Article 22

This Directive is addressed to the Member States.

ANNEX I

Active substances permitted in EEC-accepted plant protection products



alachlor  
alachlore  
alaclor  
alachloor

aldicarb  
aldicarbe

aluminiumphosphid  
aluminium phosphide  
phosphure d'aluminium  
fosfuro di alluminio  
aluminiumfosfide

anthraquinon  
anthraquinone  
antrachinone  
anthrachinon

asulam  
asulame

atrazin  
atrazine  
atrazina

azinhos-methyl  
azinhos-méthyl  
azinfos-metile  
azinfos-methyl

barban  
barbane

benomyl  
bénomyl  
benomil

bentazon  
bentazone

benzoylprop-ethyl  
Benzoylprop-äthyl  
benzoylprop-éthyl  
benzoilprop-etile

binapacryl  
binapacril

bromacil  
bromacile

bromophos  
bromofos

captafol

captan  
captane  
captano

carbaryl  
carbaril

carbophenothion  
carbophénothion  
carbofenotion  
carbofenothion

chloraniformethan  
chloraniforméthane  
cloraniformetano  
chloraniformethaan

chlorbufam  
chlorbufame  
clorbufam  
chloorbufam

chlorodimeform  
chlordimeform  
chlordiméforme  
clordimeform  
chloordimeform

chlorfenvinphos  
clorfenvinfos  
chloorfenvinfos

chloroxuron  
cloroxuron

chlorpropham  
chlorprophame  
clorprofam  
chloorprofam

chlorpyrifos  
chlorpyriphos  
clorpirifos  
chloorpyrifos

chlorthiamid  
chlorthiamide  
clortiamid  
chloorthiamide

chlortoluron  
clortoluron  
chloortoluron

coumatetralyl  
coumatétralyl  
cumatetralil  
cumatetralyl

crimidin  
crimidine  
crimidina

cycluron  
cicluron

cyhexatin  
ciexatin

2,4-D (x)

desmetryn  
desmetryne  
desmétryne  
desmetrina

---

(x) Kun tilladt som salte og estere  
nur als Salze und Ester zugelassen  
admis seulement comme sels et esters  
permitted only as salts and esters  
ammesso solo come sali e esteri  
enkel toegelaten als zouten en esters

dalapon Na-salt  
Dalapon-Natriumsalz  
dalapon-sodium  
dalapon sale di sodio  
dalapon-natrium

dazomet

demeton-S-methylsulfon  
demeton-S-methylsulphone  
déméton-S-méthylsulphone  
demeton-S-metilsulfone

diazinon  
diazinone

dicamba (x)

dichlobenil  
dichlobénil  
diclobenil

dichlofluanid  
dichlofluanide  
diclofluanide

dichlorprop (x)  
diclorprop  
dichloorprop

dichlorpropan  
dichloropropane  
dicloropropano  
dichloorpropaan

---

(x) kun tilladt som salte  
nur als salze zugelassen  
permitted only as salts  
admis seulement comme sels  
ammesso solo come sali  
enkel toegelaten als zouten

dichlorvos  
diclorvos  
dichloorvos

dicofol

dimethirimol  
diméthirimol  
dimetirimol

dimethoat  
dimethoate  
diméthoate  
dimetoato  
dimethoat

dinocap

dinoseb og dets ammonium og amin salte  
Dinoseb und seine Ammonium und Aminsalze  
dinoseb and its ammonium and amine salts  
dinosèbe et ses sels d'ammonium et sels  
d'amine  
dinoseb e suri sali d'ammonio e d'amine  
dinoseb en zijn ammonium - en amine  
zouten

dinoseb acetat  
Dinosebacetat  
dinoseb acetate  
dinosèbe : ester acétique  
dinoseb acetato  
dinosebacetaat

diquat dibromid  
Deiquat dibromid  
diquat dibromide  
diquat dibromuro

diuron

DNOC

dodemorph  
dodémorph  
dodemorf

dodih  
dodine  
doguadine  
dodina

endosulfen

EPTC

fenazaflor  
fénazaflor  
fenazafloor

fenitrothion  
fénitrothion  
fenitrotion

fenthion  
fention

ferbam  
ferbame

ferrosulfat  
Eisen-II-sulfat  
ferrous sulphate  
sulfate de fer  
ferro solfato  
ferrosulfaat

folpet  
folpel

fonofos

formetanat  
formetanate  
formétanate  
formetanato  
formetanaat

ioxynil (x)  
doxynil

kobberoxychlorid  
Kupferoxychlorid  
copper oxychloride  
oxychlorure de cuivre  
ossicloruro di rame  
koper oxychloride

lenacil  
lénacile

lindan  
lindane  
lindano  
lindaan

linuron

malathion  
malation

mancozeb  
mancozèbe

maneb  
manèbe

---

(x) kun tilladt som alkali salte og octansyre-ester  
nur als Alkalisalze und Octanoat zugelassen  
permitted only as alkali metal salts and octanoic ester  
admis seulement comme sels alcalins et ester octanoïque  
ammesso solo come sali alcalini ed estere ottanoico  
enkel toegelaten als alkalimetaalzouten en octanoaat

MCPA (x)

mehlorprop (x)  
mecoprop  
mécoprop

metaldehyd  
metaldehyde  
métaldéhyde  
metaldeide

methabenzthiazuron  
méthabenzthiazuron  
metabenzthiazuron

methidathion  
méthidathion  
metidation

methomyl  
méthomyl  
métomil

methoprotryn  
methoprotryne  
métoprotryne  
metoprotrin  
méthoprotryne

methoxychlor  
méthoxychlore  
metossiclore  
methoxychlor

methylbromid  
Methylbromid (Brom-methan)  
bromomethane (methyl bromide)  
bromure de méthyle (bromométhane)  
bromuro di metile (bromometano)  
methylbromide (broommethaan)

metiram  
métirame  
metirame-zinc

---

(x) kun tilladt som salte  
nur als Salze zugelassen  
permitted only as salts  
admis seulement comme sels  
ammesso solo come sali  
enkel toegelaten als zouten



metobromuron  
métobromuron

metoxuron  
métoxuron

metribuzin  
métribuzin

mercaptodimethur  
methiocarb  
méthiocarbe  
metiocarb

mevinphos  
mévinphos  
mevinfos

monolinuron

monuron

natrium chlorat  
Natriumchlorat  
sodium chlorate  
chlorate de soude  
sodio clorato  
natrium chloraat

nicotin  
Nikotin  
nicotine  
nicotina  
nikotine

nicotinsulfat  
Nikotinsulfat  
nicotine sulphate  
sulphate de nicotine  
solfato di nicotina  
nicotinsulfaat

nitrofen  
nitrofène  
nitrofeen

omethoat  
omethoate  
ométhoate  
ometoate  
omethoat

oxydemeton-methyl  
oxydéméton-méthyl  
essidemeton-metile

paraquat dichlorid og di-(methylsulfat)  
Paraquat dichlorid und di-(methylsulfat)  
paraquat dichloride and di-(methylsulphate)  
paraquat dichloride et di-(méthylsulfate)  
paraquat dicloro e di-(metilsolfato)  
paraquat dichloride en di-(methylsulfaat)

parathion  
paration

pentachlorphenol  
pentachlorophenol  
pentachlorophénol  
pentaclorofenolo  
pentachloorphenol  
pentachloorfenol

pentachlorphenol Na-salt  
Natrium-pentachlorphenolat  
sodium pentachlorphenate  
pentachlorophénate de sodium  
pentaclorofenato di sodio  
natrium pentachloorfenolaat

phenmedipham  
phenmédiphame  
fenmedifam

phosalon  
phosalone  
fosalone

phosmet  
fosmet

phosphamidon  
fosfamidone  
fosfamidon

pirimicarb  
pirimicarbe

prometryn  
prometryne  
prométryne  
prometrina

propachlor  
propachlore  
propaclor  
propachloor

propham  
prophame  
profam

propineb  
propinèbe

propyzamid  
propyzamide  
propizamide

pyrazon  
pyrazone  
pirazon

pyrethriner (x)  
Pyrethrine  
pyrethrins  
pyrèthrines  
pirethrine  
pyrethrinen

chinomethionat  
quinomethionate  
chinométhionate  
chinometionato  
chinomethionaat

rotenon  
rotenone  
roténone

simazin  
simazine  
simazina

svovl  
Schwefel  
sulphur  
soufre  
zolfo  
zwavel

---

(x) kun sammen med piperonyl butoxyd  
nur zusammen mit iperonylbutoxid  
only together with piperonyl butoxide  
seulement avec piperonyl butoxide  
solo con piperonilbutossido  
enkel met piperonylbutoxide

sulfotep

TCA

TCA sodium

terbuthylazin  
terbuthylazine  
terbutylazine  
terbutilazina  
terbutylazin

terbutryn  
terbutryne  
terbutrin

tetradifon  
tétradifon

thallium sulfat  
Thalliumsulfat  
thallium sulphate  
sulfate de thallium  
tallio solfato  
thallium sulfaat

thiometon  
thiométon  
tiometon

thiophanat  
Thiophanat-éthyl  
thiophanate-ethyl  
thiophanate-éthyl  
thiophanate  
tiofanato  
thiofanaat-ethyl

thiophanaat-methyl  
thiophanate-methyl  
thiophanate-méthyl  
méthylthiophanate  
tiofanate metile  
thiofanaat-methyl

thiram  
thirame  
tiram

tri-allat  
Triallat  
tri-allate  
triallate  
tri-allaat

trichlorfon  
triclорfon  
trichlorphon  
trichloorfon

trichloronat  
trichloronate  
triclорonato  
trichloronaat

tridemorph  
tridémorphe  
tridémorph  
tridemorf

triforin  
triforine

vamidothion  
vamidotion

warfarin  
warfarine  
coumafène

zineb  
zinèbe

zinkphosphid  
zinc phosphide  
zinc (phosphure de ...)  
zinco (fosfuro di ...)  
zinkfosfide

ziram  
zirame

---

ANNEX II

MODEL

Application form for the EEC-acceptance of a plant protection product (hereinafter referred to as "the product")

Name of responsible authority: .....
.....
Date received: .....
Ref. No .....

N.B. If there is insufficient space under any heading, the particulars may be supplied in a separate numbered document attached to the form. In such cases, a summary of the particulars must be given under the heading in question on the form together with the reference to the numbered document.

1. (a) Name of applicant: (b) Address and telephone number of permanent office in the Community:	
2. (a) Proprietary name of the product: (b) Experimental designation:	
3. Name and address of manufacturer:	
4. Physical condition and nature of the product (e.g. wettable powder, emulsifiable concentrate, granules etc....):	



3. Detailed composition of the product:

5.1

Names of all ingredients (1)	Contents (2)	Equivalent content of each active substance on pure basis

- (1) Each ingredient must be indicated by its ISO common name or, if not available, by its chemical designation according to IUPAC nomenclature and, in the case of an active substance, by its empirical and structural formula ; In the case of an ingredient not chemically definable, it should be indicated by other appropriate characterisation.
- (2) For products which are solids, aerosols, volatile liquids (b.p.  $\leq 50^{\circ}\text{C}$ ), or viscous liquids ( $\geq 1000$  centipoises at  $20^{\circ}\text{C}$ ), as a percentage by weight; for other liquids, as a percentage by weight and in g/l at  $20^{\circ}\text{C}$ ; for gases, as a percentage by volume.

<p>5.2 Indicate any active substance not listed in Annex I:</p> <p>5.3 For each distinct source of each technical active substance used in manufacture, its composition (i.e. purity in percentage, nature and percentages of impurities, isomers, secondary products).</p>	
<p>6. Chemical properties of each active substance:</p>	
<p>7. Physical properties of</p> <p>7.1 each active substance:</p> <p>7.2 the product:</p>	
<p>8. Method(s) of analysis for the composition of the product</p> <p>8.1 Method(s) for qualitative and quantitative determination of the active substance(s) in the product:</p> <p>8.2 Other:</p>	

---

9. Application (3)

9.1 Mode of action:

9.2 Types of pest controlled and types of crops protected or other purpose of application:

9.3 Application rate(s):

9.4 Number and timing of applications:

9.5 Methods of application:

---

10. Specific phytotoxicity, including necessary waiting periods to avoid phytotoxic effects, e.g. with soil fumigants, persistent herbicides:

---

(3) The applicant must attach copies of each different label or draft label, including leaflets forming part of the label as provided for in Article 15 paragraph 3.5, under which the product will be placed on the market within the Community.

---

11. Experimental data to demonstrate efficacy of the product for the uses proposed and under the conditions of use envisaged:

---

12. Residues

12.1 Method(s) for residue analysis:

12.2 Proposed method for the official control of residues in named edible crops/animal products of each active substance:

12.3 Residue data:

12.4 Proposed maximum permissible residue of each active substance in named edible crops/animal products:

12.5 Proposed safety interval(s), including necessary waiting periods following fumigation of edible crops:

---

---

13. Nature of packaging in which the product will be placed on the market and the size range of packages:

---

14. Stability of the product in the packaging in which it will be placed on the market:

---

15. Experimental data on toxicity in animals:

---

---

16. Proposed classification of the products according to risk (4):

---

17. Medical data:

---

18. Environment

18.1 Information giving all the data permitting an assessment to be made of the foreseeable risks, whether immediate or delayed, that the product may present for the environment as a function, in particular, of its toxicological characteristics, biodegradability, potential for bioaccumulation and volume of production envisaged:

18.2 Production envisaged:

---

19. Has application for EEC-acceptance been made to another Member State?

---

Place ..... Signature .....  
Date .....

(4) In accordance with the provisions of the Council Directive of..... on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of pesticides (OJ.....)

ANNEX III

Standard phrases of nature of special risks

1. Dangerous to livestock/game/wild birds/ wild animals/ wild flowers/  
bees/ fish.
2. Harmful to livestock/ game/ wild birds/ wild animals/ wild flowers/  
bees/ fish.
3. (Active substance) is one of the more persistent constituents of  
plant protection products and its repeated application may lead  
to the contamination of the environment with possible detrimental  
effects.

ANNEX IV

Standard phrases of safety advice

1. Not to be used on any edible crop.
2. May only be used on (named crops or foodstuffs).
3. Not to be applied to (named crops or foodstuffs) at a rate in excess of (dosage rate in terms of active substances) per application.
4. Not more than (number) application(s) to be made on (crops or foodstuffs) per season.
5. Not to be used later than (date).
6. Allow at least (days/weeks) between (last) application and harvesting.
7. Wear (state item or items) if handling (crop or crops) within (interval) of treatment.
8. Post warning telling unprotected persons to keep out of treated areas for (state period).
9. Keep all livestock out of treated areas for at least (interval).
10. Keep all livestock away from treated water for at least (interval).
11. Do not apply at flowering stage. Keep down flowering weeds.
12. Do not contaminate ponds, waterways and ditches with product or used container.
13. Keep tightly closed/in a cool place/locked up/out of reach of children/away from foodstuffs/away from feedingstuffs/away from heat/away from flame.
14. Neutralise waste material with.... / wash out container thoroughly/ and dispose of safely by...../burying.
15. Empty container completely and burn.
16. Dispose of rinsings from/container/equipment away from ponds, waterways, ditches and wells.
17. Do not enter/greenhouse/glasshouse/mushroom house/warehouse/ship's hold within (interval) of treatment unless wearing/full protective clothing/respirator.