Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market

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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 (1) ,
Having regard to the opinion of the European Parliament (2) ,
Having regard to the opinion of the Economic and Social Committee (3) ,
Whereas plant production has a very important place in the Community;
Whereas plant production yields are continually affected by harmful organisms including weeds; whereas it is absolutely essential to protect plants against these risks to prevent a decline in yields and to help to ensure security of supplies;
Whereas one of the most important ways of protecting plants and plant products and of improving agricultural production is to use plant protection products;
Whereas these plant protection products can have non-beneficial effects upon plant production; whereas their use may involve risks and hazards for humans, animals and the environment, especially if placed on the market without having been officially tested and authorized and if incorrectly used;
Whereas, in view of the hazards, there are rules in most Member States governing the authorization of plant health products; whereas these rules present differences which constitute barriers not only to trade in plant protection products but also to trade in plant products, and thereby directly affect the establishment and operation of the internal market;
Whereas it is therefore desirable to eliminate such barriers by harmonizing the provisions laid down in the Member States;
Whereas uniform rules on the conditions and procedures for the authorization of plant protection products must be applied by the Member States;
Whereas such rules should provide that plant protection products should not be put on the market or used unless they habe been officially authorized and should be used properly having regard to the principles of good plant protection practice and of integrated pest control;
Whereas the provisions governing authorization must ensure a high standard of protection, which, in particular, must prevent the authorization of plant protection products whose risks to health, groundwater and the environment and human and animal health should take priority over the objective of improving plant production;
Whereas it is necessary, at the time when plant protection products are authorized, 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 influence on the environment in general and, in particular, no harmful effect on human or animal health or on groundwater;
Whereas authorization 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 it is therefore necessary to establish a Community list of authorized active substances;
Whereas a Community procedure must be laid down for assessing whether an active substance can be entered on the Community list; whereas the information that interested parties must submit with a view to admission of a substance to the list should be specified;
Whereas the Community procedure should not prevent Member States from authorizing for use in their territory for a limited period 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 can be expected to satisfy the Community conditions set in regard to them;
Whereas, in the interests of safety, substances on the Community list should be reviewed periodically, to take account of developments in science and technology and of impact studies based on the actual use of plant protection products containing the said substances;
Whereas it is in the interests of free movement of plant products as well as of plant protection products 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 (including climatic) conditions relevant to the use of the products concerned are not comparable in the regions concerned; 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;
Whereas it is therefore desirable that a system for the mutual supply of information should be established and that Member States should make available to each other on request the particulars and scientific documentation submitted in connection with applications for authorization of plant protection products;
Whereas, however, Member States must be enabled to authorize plant protection products not complying with the abovementioned conditions when it is necessary to do so because of an unforeseeable danger threatening plant production which cannot be countered by other means; whereas such authorization should be reviewed by the Community in close cooperation with the Member States in the framework of the Standing Committee on Plant Health;
Whereas this Directive complements Community provisions on the classification, packaging and labelling of pesticides; whereas together with these provisions it considerably
improves the protection of users of plant protection products and consumers of plants and plant products; whereas it also contributes to the protection of the environment;
Whereas it is necessary to maintain consistency between this Directive and Community rules on the residues of plant protection products in agricultural products and the free movement of the latter in the Community; whereas this Directive complements Community provisions relating to maximum permissible levels for pesticide residues and will facilitate the adoption of such levels in the Commission; whereas together with the latter provisions it considerably improves the protection of consumers of plants and plant products;
Whereas resources devoted to the conduct of tests on vertebrate animals should not be dissipated as a result of the differences in the laws of the Member States and whereas considerations of public interest and Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes (4) militate against needless repetition of tests on animals;
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 marketing and use of plant protection products;
Whereas the procedures provided for by this Directive for the evaluation of the risks to the environment presented by plant protection products containing or composed of genetically modified organisms correspond in principle to those laid down in Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms (5) ; whereas in future however the supply of data in accordance with Part B of Annexes II and III is likely to be subject to specific requirements, provision should be made to amend this Directive accordingly;
Whereas the implementation of this Directive and the adaptation of its Annexes to advances in technical and scientific knowledge necessitate close cooperation between the Commission and the Member States, and whereas the procedure of the Standing Committee on Plant Health offers a suitable basis for this cooperation,

HAS ADOPTED THIS DIRECTIVE:

Scope

Article 1

1. This Directive concerns the authorization, placing on the market, use and control within the Community of plant protection products in commercial form and the placing on

(;) OJ No L 358, 18. 12. 1986, p. 1.

($) OJ No L 117, 8. 5. 1990, p. 15.

the market and control within the Community of active substances intended for a use specified in Article 2 (1) .

2. This Directive shall apply without prejudice to Council Directive 78/631/EEC of 26 June 1978 on the approximation of the laws of the Member States relating to the classification, packaging and labelling of dangerous preparations (pesticides) (;) , as last amended by Directive 84/291/EEC ($) and, where active substances are concerned, without prejudice to the provisions concerning classification, packaging and labelling of Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (=) , as last amended by Directive 90/517/EEC (%) .

3. This Directive applies to the authorization to place on the market plant protection products containing or composed of genetically modified organisms, provided that authorization to release them into the environment has been granted after the risk to the environment has been assessed in accordance with the provisions of Parts A, B and D and the relevant provisions of Part C of Directive 90/220/EEC.

The Commission shall submit to the Council, in sufficient time for the latter to be able to act not later than two years after the date of notification of this Directive, a proposal for an amendment with a view to including in this Directive (&) a specific procedure for evaluating the risk to the environment analogous to that provided for the Directive 90/220/EEC, and enabling this Directive to be placed on the list provided for in Article 10 (3) of Directive 90/220/EEC in accordance with the procedure laid down in the said Article 10.

Within five years of the date of notification of this Directive, the Commission, on the basis of experience gained, shall provide the European Parliament and the Council with a report on the operation of the arrangements described in the first and second subparagraphs.

4. This Directive shall apply without prejudice to Council Regulation (EEC) No 1734/88 of 16 June 1988 concerning export from and import into the Community of certain dangerous chemicals (() .

Definitions

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, put up in the form in which they are supplied to the user, intended to:

(;) OJ No L 206, 29. 7. 1978, p. 13.

($) OJ No L 144, 30. 5. 1984, p. 1.

(=) OJ No 196, 16. 8. 1967, p. 1.

(%) OJ No L 287, 19. 10. 1990, p. 37.

(&) This Directive was notified to the Member States on 26 July 1991.

(() OJ No L 155, 22. 6. 1988, p. 2.

1.1.

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

1.2.
influence the life processes of plants, other than as a nutrient, (e.g. growth regulators) ;
1.3.
preserve plant products, in so far as such substances or products are not subject to special Council of Commission provisions on preservatives;
1.4.
destroy undesired plants; or
1.5.
destroy parts of plants, check or prevent undesired growth of plants;
2.
' residues of plant protection products'
one or more substances present in or on plants or products of plant origin, edible animal products or elsewhere in the environment and resulting from the use of a plant protection product, including their metabolites and products resulting from their degradation or reaction;
3.
' substances'
chemical elements and their compounds, as they occur naturally or by manufacture, including any impurity inevitable resulting from the manufacturing process;
4.
' active substances'
substances or micro-organisms including 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;
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, bacteria and mycoplasmas and other pathogens;
9.
' animals'
animals belonging to species normally fed and kept or consumed by man;
10.
' placing on the market'
any supply, whether in return for payment or free of charge, other than for storage followed by consignment from the territory of the Community or disposal. Importation of a plant protection product into the territory of the Community shall be deemed to constitute placing on the market for the purposes of this Directive;
11.
' authorization of a plant protection product'

administrative act by which the competent authority of a Member State authorizes, following an application submitted by an applicant, the placing on the market of a plant protection product in its territory or in a part thereof;
12.
' environment'
water, air, land, wild species of fauna and flora, and any interrelationship between them, as well as any relationship with living organisms;
13.
' integrated control'
the rational application of a combination of biological, biotechnological, chemical, cultural or plant-breeding measures whereby the use of chemical plant protection products is limited to the strict minimum necessary to maintain the pest population at levels below those causing economically unacceptable damage or loss.

General provisions
Article 3
1. Member States shall prescribe that plant protection products may not be placed on the market and used in their territory unless they have authorized the product in accordance with this Directive, except where the intended use is covered by Article 22.
2. Member States shall not, on the grounds that a plant protection product is not authorized for use in their territory, impede the production, storage or movement of such products intended for use in another Member State, provided that:
- the product is authorized in another Member State, and
- the inspection requirements laid down by the Member States in order to ensure compliance with paragraph 1 are satisfied.
3. Member States shall prescribe that plant protection products must be used properly. Proper use shall include compliance with the conditions established in accordance with Article 4 and specified on the labelling, and the application of the principles of good plant protection practice as well as, whenever possible, the principles of integrated control.
4. Member States shall prescribe that active substances may not be placed on the market unless:
- they are classified, packaged and labelled in accordance with Directive 67/548/EEC, and
- where the active substance was not on the market two years after notification of this Directive, a dossier has been forwarded to the Member States and to the Commission, in accordance with Article 6, with the declaration that the active substance is intended for a use specified in Article 2 (1) . This condition shall not apply to active substances intended for a use under Article 22.

Granting, review and withdrawal of authorizations of plant protection products
Article 4
1. Member States shall ensure that a plant protection product is not authorized unless:
(a) its active substances are listed in Annex I and any conditions laid down therein are fulfilled, and, with regard to the following points (b) , (c) , (d) and (e) , pursuant to the uniform principles provided for in Annex VI, unless:
(b)
it is established, in the light of current scientific and technical kowledge and shown from appraisal of the dossier provided for in Annex III, that when used in accordance with Article 3 (3) , and having regard to all normal conditions under which it may be used, and to the consequences of its use:
ii(i) it is sufficiently effective;
i(ii)
it has no unacceptable effect on plants or plant products;
(iii)

it does not cause unnecessary suffering and pain to vertebrates to be controlled;
(iv)
it has no harmful effect on human or animal health, directly or indirectly (e.g. through drinking water, food or feed) or on groundwater;
i(v)
it has no unacceptable influence on the environment, having particular regard to the following considerations:
- its fate and distribution in the environment, particularly contamination of water including drinking water and groundwater,
- its impact on non-target species;
(c)
the nature and quantity of its active substances
and, where appropriate, any toxicologically or ecotoxicologically significant impurities and co-formulants can be determined by appropriate methods, harmonized according to the procedure provided in Article 21, or, if not, agreed by the authorities responsible for the authorization;
(d)
its residues, resulting from authorized uses, and which are of toxicological or environmental significance, can be determined by appropriate methods in general use;
(e)
its physical and chemical properties have been determined and deemed acceptable for the purposes of the appropriate use and storage of the product;
(f)
maximum residue levels in the agricultural products referred to in the authorization have been provisionally established by the Member State and notified to the Commission in accordance with Article 12; within three months of the said notification, the Commission shall consider whether the provisional maximum levels established by the Member State are acceptable, and in accordance with the procedure laid down in Article 19 it shall establish provisional maximum levels throughout the Community and these shall remain in force until the corresponding maximum levels are adopted pursuant to the procedure provided for in the second subparagraph of Article 1 (1) of Directive 90/462/EEC (;) and in Article 11 of Directive 86/362/EEC ($) , as amended by Directive 88/298/EEC (=) .
In particular:
i(i) Member States may not prohibit or impede the introduction into their territory of products containing pesticide residues provided the residue level does not exceed the provisional maximum levels set in accordance with the first subparagraph;
(ii)
Member States must ensure that the conditions for approval are applied in such a way that the provisional maximum levels are not exceeded.
2. The authorization must stipulate the requirements relating to the placing on the market and use of the product or at least those aimed at ensuring compliance with the provisions of paragraph 1 (b) .
3. Member States shall ensure that compliance with the requirements set out in paragraph 1 (b) to (f) is established by
(;) OJ No L 350, 14. 12. 1990, p. 71.
($) OJ No L 221, 7. 8. 1986, p. 36.
(=) OJ No L 126, 20. 5. 1988, p. 53.
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 these prevailing where the product is intended to be used, within the territory of the Member State concerned.
4. Without prejudice to paragraphs 5 and 6, authorizations shall be granted for a fixed period of

up to 10 years only, determined by the Member States; they may be renewed after verification that the conditions imposed in paragraph 1 are still satisfied. Renewal may be granted for the period necessary to the competent authorities of the Member States, for such verification, where an application for renewal has been made.
5. Authorizations may be reviewed at any time if there are indications that any of the requirements referred to in paragraph 1 are no longer satisfied. In such instances the Member States may require the applicant for authorization or party to whom an extension of the field of application was granted in accordance with Article 9 to submit further information necessary for the review. The authorization may, where necessary, be extended for the period necessary to complete a review and provide such further information.
6. Without prejudice to Decisions already taken pursuant to Article 10, an authorization shall be cancelled if it is established that:
(a) the requirements for obtaining the authorization are not or are no longer satisfied;
(b)
false or misleading particulars were supplied concerning the facts on the basis of which the authorization was granted;
or modified if it is established that:
(c)
on the basis of developments in scientific and technical knowledge the manner of use and amounts used can be modified.
It may also be cancelled or modified at the request of the holder of the authorization, who shall state the reasons therefor; amendments can be granted only if it is established that the requirements of Article 4 (1) continue to be satisfied.
Where a Member State withdraws an authorization, it shall immediately inform the holder of the authorization; moreover, it may grant a period of grace for the disposal, storage, placing on the market and use of existing stocks, of a length in accordance with the reason for the withdrawal, without prejudice to any period provided for by decision taken under Council Directive 79/117/EEC of 21 December 1978 prohibiting the placing on the market and use of plant protection products containing certain active substances (%) , as last amended by Directive 90/335/EEC (&) , or Article 6 (1) or Article 8 (1) or (2) of this Directive.
(%) OJ No L 33, 8. 2. 1979, p. 36.
(&) OJ No L 162, 28. 6. 1990, p. 37.
Inclusion of active substances in Annex I
Article 5
1. In the light of current scientific and technical knowledge, an active substance shall be included in Annex I for an initial period not exceeding 10 years, if it may be expected that plant protection products containing the active substance will fulfil the following conditions:
(a) their residues, consequent on application consistent with good plant protection practice, do not have any harmful effects on human or animal health or on groundwater or any unacceptable influence on the environment, and the said residues, in so far as they are of toxicological or environmental significance, can be measured by methods in general use;
(b) their use, consequent on application consistent with good plant protection practice, does not have any harmful effects on human or animal health or any anacceptable influence on the environment as provided for in Article 4 (1) (b) (iv) and (v) .
2. For inclusion of an active substance in Annex I, the following shall be taken into particular account:
(a) where relevant, an acceptable daily intake (ADI) for man;
(b)
an acceptable operator exposure level if necessary;
(c)
where relevant, an estimate of its fate and distribution in the environment as well as its impact on

non-target species.
3. For the first inclusion of an active substance which was not yet on the market two years after notification of this Directive, the requirements shall be deemed to be satisfied where this has been established for at least one preparation containging the said active substance.
4. Inclusion of an active substance in Annex I may be subject to requirements such as:
- the minimum degree of purity of the active substance,
- the nature and maximum content of certain impurities,
- restrictions arising from evaluation of the information referred to in Article 6, taking account of the agricultural, plant health and environmental (including climatic) conditions in question,
- type of preparation,
- manner of use.
5. On request, the inclusion of a substance in Annex I may be renewed once or more for periods not exceeding 10 years; such inclusion may be reviewed at any time if there are indications that the criteria referred to in paragraphs 1 and 2 are no longer satisfied. Renewal shall be granted for the period necessary to complete a review, where an application has been made for such renewal in sufficient time, and in any case not less than two years before the entry is due to lapse, and shall be granted for the period necessary to provide information requested in accordance with Article 6 (4) .

Article 6
1. Inclusion of an active substance in Annex I shall be decided in accordance with the procedure laid down in Article 19.
The following shall also be decided in accordance with that procedure:
- any conditions for inclusion,
- amendements to Annex I, where necessary,
- removal of an active substance form Annex I if it no longer satisfies the requirements of Article 5 (1) and (2) .
2. A Member State receiving an application for the inclusion of an active substance in Annex I shall without undue delay ensure that a dossier which is believed to satisfy the requirements of Annex II is forwarded by the applicant to the other Member States and to the Commission together with a dossier complying with Annex III on at least one preparation containing that active substance. The Commission shall refer the dossier to the Standing Committee on Plant Health referred to in Article 19 for examination.
3. Without prejudice to the provisions of paragraph 4, at the request of a Member State, and within three to six months after the date of referral to the committee mentioned in Article 19, it shall be established by the procedure laid down in Article 20 whether the dossier has been submitted in accordance with the requirements of Annexes II and III.
4. If the assessment of the dossier referred to in paragraph 2 shows that further information is necessary, the Commission may ask the applicant to submit such information. The applicant or his authorized representative may be asked by the Commission to submit his remarks to it, in particular whenever an unfavourable decision is envisaged.
These provisions shall also apply if, after inclusion of an active substance in Annex I, facts emerge that cast doubt on its conformity with the requirements indicated in Article 5 (1) and (2) , or if renewal in accordance with Article 5 (5) is being considered.
5. The procedure concerning the submission and appraisal of applications for inclusion in Annex I and setting or varying any conditions for inclusion shall be adopted in accordance with the procedure laid down in Article 21.
Information on potentially harmful effects
Article 7
Member States shall prescribe that the holder of an authorization or those to whom an extension of the field of application has been granted in accordance with Article 9 (1) must immediately

notify the competent authority of all new information on the potentially dangerous effects of any plant protection product, or of residues of an active substance on human or animal health or on groundwater, or their potentially dangerous effects on the environment. Member States shall ensure that the parties concerned immediately notify this information to the other Member States and to the Commission, which shall refer the information to the committee referred to in Article 19.

Transitional measures and derogations

Article 8

1. By way of derogation from Article 4, a Member State may, to enable a gradual assessment to be made of the properties of new active substances and to make it easier for new preparations to be made available for use in agriculture, authorize, for a provisional 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 two years after notification of this Directive, provided that:

(a) following application of Article 6 (2) and (3) it is found that the dossier on the active substance satisfies the requirements of Annexes II and III in relation to the projected uses;

(b) the Member State establishes that the active substance can satisfy the requirements of Article 5 (1) and that the plant protection product may be expected to satisfy the requirements of Article 4 (1) (b) to (f) .

In such cases the Member State shall immediately inform the other Member States and the Commission of its assessment of the dossier and of the terms of the authorization, giving at least the information provided for in Article 12 (1) .

Following the evaluation of the dossier as provided for in Article 6 (3) , it may be decided, in accordance with the procedure laid down in Article 19, that the active substance does not satisfy the requirements specified in Article 5 (1) . In such cases the Member States shall ensure that the authorizations must be withdrawn.

By way of derogation from Article 6, if, on expiry of the three-year period, a decision has not been taken concerning the inclusion of an active substance in Annex I, a further period may be ordered by the procedure referred to in Article 19 to enable a full examination to be made of the dossier and, where appropriate, of any additional information requested in accordance with Article 6 (3) and (4) .

The provisions of Article 4 (2) , (3) , (5) and (6) shall apply to authorizations granted under the terms of this paragraph without prejudice to the foregoing subparagraphs.

2. By way of derogation from Article 4 and without prejudice to paragraph 3 or to Directive 79/117/EEC, a Member State may, during a period of 12 years following the notification of this Directive, authorize the placing on the market in its territory of plant protection products containing active substances not listed in Annex I that are already on the market two years after the date of notification of this Directive.

After the adoption of this Directive, the Commission
shall commence a programme of work for the gradual examination of these active substances within the 12-year period referred to in the foregoing subparagraph. This programme may require interested parties to submit all requisite data to the Commission and the Member States within a period provided for in the programme. A Regulation, adopted according to the procedure laid down in Article 19, will set out all the provisions necessary for the implementation of the programme.

Ten years following notification of this Directive the Commission shall present to the European Parliament and the Council a progress report on the programme. Depending upon the conclusions of the report, it may be decided, according to the procedure laid down in Article 19, whether, for certain substances, the 12-year period referred to in the first subparagraph is to be extended for a period to be determined.

During the 12-year period referred to in the first subparagraph it may, following examination by the Committee referred to in Article 19 of such active substance, be decided by the procedure laid down in that Article that the substance can be included in Annex I and under which conditions, or, in cases where the requirements of Article 5 are not satisfied or the requisite information and data have not been submitted within the prescribed period, that such active substance will not be included in Annex I. The Member States shall ensure that the relevant authorizations are granted, withdrawn or varied, as appropriate, within a prescribed period.
3. Where they review plant protection products containing an active substance in accordance with paragraph 2, and before such review has taken place, Member States shall apply the requirements laid down in Article 4 (1) (b) (i) to (v) , and (c) to (f) in accordance with national provisions concerning the data to be provided.
4. By way of further derogation from Article 4, in special circumstances a Member State may authorize for a period not exceeding 120 days the placing on the market of plant protection products not complying with Article 4 for a limited and controlled use if such a measure appears necessary because of an unforeseeable danger 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 19, whether and under which conditions the action taken by the Member State may be extended for a given period, repeated, or revoked.

Application for authorization
Article 9
1. Application for authorization of a plant protection product shall be made by or on behalf of the person responsible for first placing it on the market in a Member State to the competent authorities of each Member State where the plant protection product is intended to be placed on the market.
Official or scientific bodies involved in agricultural activities or professional agricultural organizations and professional users may request that the field of application of a plant protection product already authorized in the Member State in question be extended to purposes other than those covered by this authorization.
Member States shall grant an extension of the field of application of an authorized plant protection product and shall be obliged to grant such an extension when it is in the public interest to the extent that:
- the documentation and information to support an extension of the field of application has been submitted by the applicant,
- they have established that the conditions referred to in Article 4 (1) (b) (iii) , (iv) and (v) are satisfied,
- the intended use is minor in nature,
- users are fully and specifically informed as to instructions for use, by means of an addition to the labelling or, failing that, by means of an official publication.
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. They may also require that samples of the preparation and of its ingredients be provided.
4. Each Member State shall agree to consider any application for authorization made to it and shall decide thereon within a reasonable period, provided that it has the necessary scientific and technical structures at its disposal.
5. Member States shall ensure that a file is compiled on each application. Each file shall contain at least a copy of the application, a record of the administrative decisions taken by the Member State concerning the application and concerning the particulars and documentation laid down in Article 13 (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 files provided for in this paragraph; they shall supply to them on request all information necessary for full comprehension of applications, and shall where requested ensure that applicants provide a copy of the technical documentation laid down in Article 13 (1) (a) .

Mutual recognition of authorizations

Article 10

1. At the request of the applicant, who must substantiate the claim to comparability with documentary evidence, a Member State to which an application is made for the authorization of a plant protection product already authorized in another Member State must:

- refrain from requiring the repetition of tests and analyses already carried out in connection with the authorization of the product in that Member State, and to the extent that agricultural, plant health and environmental (including climatic) conditions relevant to the use of the product are comparable in the regions concerned, and
- to the extent that the uniform principles have been adopted in accordance with Article 23, where the product contains only active substances listed in Annex I, also authorize the placing of that product on the market in its territory, to the extent that agricultural, plant health and environmental (including climatic) conditions relevant to the use of the product are comparable in the regions concerned.

Authorization may be subject to conditions resulting from the implementation of other measures in accordance with Community law, relating to the conditions for distribution and use of plant protection products intended to protect the health of the distributors, users and workers concerned.

Subject to compliance with the Treaty, authorization may also be accompanied by restrictions on use arising from differences in dietary patterns and necessary in order to avoid exposure of consumers of treated products to the risks of dietary contamination in excess of the acceptable daily intake of the residues concerned.

Authorization may be subject, with the agreement of the applicant, to changes in the conditions of use in order to render, in the regions concerned, any non-comparable agricultural, plant health or environmental (including climatic) conditions irrelevant for the purpose of comparability.

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 authorize a plant protection product already authorized in another Member State, in respect of which the applicant had claimed that the agricultural, plant health and environmental (including climatic) conditions relevant to use of the product in the regions concerned in the Member State where the test was carried out or for which authorization was granted were comparable to those in their own territory. They shall notify the Commission of the grounds on which repetition of the test was required or authorization was refused.

3. Without prejudice to Article 23, in cases where a Member State refuses to recognize comparability and accept tests and analyses or authorize the placing on the market of a plant protection product in the relevant regions of its territory, the decision as to whether or not comparability exists shall be taken in accordance with the procedure laid down in Article 19 and, if the decision is negative, it shall also specify the conditions of use under which the non-comparability may be deemed irrelevant. In this procedure account shall be taken, inter alia, of the serious ecological vulnerability problems that may arise in certain Community regions or zones thereby requiring, if they do arise, specific protection measures. The Member State shall without delay accept the tests and analyses or authorize the placing of the plant protection product on the market, subject in the latter case to any terms which the above decision may set.

Article 11

1. Where a Member State has valid reasons to consider that a product which it has authorized or is bound to authorize under Article 10 constitutes a risk to human or animal health or the environment, it may provisionally restrict or prohibit the use and/or sale of that product on its territory. It shall immediately inform the Commission and the other Member States of such action and give reasons for its decision.
2. A decision shall be taken on the matter within three months in accordance with theprocedure laid down in Article 19.

Exchange of information
Article 12
1. Within a period of one month at the end of each quarter at least, Member States shall inform each other and the Commission in writing of any plant protection products
authorized or withdrawn, in accordance with the provisions of this Directive, indicating at least:
- the name or business name of the holder of the authorization,
- the trade name of the plant protection product,
- the type of preparation,
- the name and amount of each active substance which it contains,
- the use or uses for which it is intended,
- the maximum residue levels provisionally established where they have not already been set by Community rules,
- where relevant, the reasons for withdrawal of an authorization,
- the dossier needed for the evaluation of the maximum residue levels provisionally established.
2. Each Member State shall draw up an annual list of the plant protection products authorized in its territory and shall communicate that list to the other Member States and the Commission.
In accordance with the procedure laid down in Article 21 a standardized information system shall be set up to facilitate the application of paragraphs 1 and 2.

Data requirements, data protection and confidentiality
Article 13
1. Without prejudice to Article 10, Member States shall require that applicants for authorization of a plant protection product submit with their application:
(a) a dossier satisfying, in the light of current scientific and technical knowledge, the requirements set out in Annex III; and
(b) for each active substance in the plant protection product, a dossier satisfying, in the light of current scientific and technical knowledge, the requirements set out in Annex II.
2. By way of derogation from paragraph 1, and without prejudice to the provisions of paragraphs 3 and 4, applicants shall be exempted from supplying the information required under paragraph 1 (b) except for that identifying the active substance if the active substance is already listed in Annex I, taking into account the conditions of inclusion in Annex I, and does not differ significantly in degree of purity and nature of impurities, from the composition registered in the dossier accompanying the original application.
3. In granting authorizations, Member States shall not make use of the information referred to in Annex II for the benefit of other applicants:
(a) unless the applicant has agreed with the first applicant that use may be made of such information; or
(b)
for a period of 10 years from first inclusion in Annex I of an active substance not on the market two years after the date of notification of this Directive; or
(c)
for periods not exceeding 10 years from the date of the decision in each Member State and provided for in existing national rules, concerning an active substance on the market two years

after the date of notification of this Directive; and
(d)
for a period of five years from the date of a decision, following receipt of further information necessary for first inclusion in Annex I, which has been taken either to vary the conditions for, or to maintain, the inclusion of an active substance in Annex I, unless the five-year period expires before the period provided for in paragraphs 3 (b) and (c) , in which case the period of five years shall be extended so as to expire on the same date as those periods.
4. In granting authorizations, Member States shall not make use of the information referred to in Annex III to the benefit of other applicants:
(a) unless the applicant has agreed with the first applicant that use may be made of such information; or
(b)
for a period of 10 years from first authorization of the plant protection product in any Member State, where authorization follows the inclusion in Annex I of any active substance contained in the product; or
(c)
for periods not exceeding 10 years and provided for in existing national rules after the first authorization of the plant protection product in each Member State, where that authorization precedes inclusion in Annex I of any active substance contained in the product.
5. Member States, on examination of an application for authorization, shall inform the Commission of instances where they consider an active substance to be listed in Annex I, which has been produced by a person or manufacturing process other than those specified in the dossier on the basis of which the active substance was first included in Annex I. They shall transmit to it all data regarding the identify and impurities of the active substance.
6. By way of derogation from paragraph 1, for active substances already on the market two years after notification of this Directive, Member States may, with due regard for the provisions of the Treaty, continue to apply previous national rules concerning data requirements as long as such substances are not included in Annex I.
7. Notwithstanding paragraph 1, and without prejudice to Article 10, where the active substance is listed in Annex I:
(a) applicants for authorization of plant protection products shall, before carrying out experiments involving vertebrate animals, enquire of the competent authority of the Member State to which they intend making application:
- whether the plant protection product for which an application is to be made is the same as a plant protection product for which authorization has been granted, and
- as to the name and address of the holder or holders of the authorization or authorizations.
The enquiry shall be supported by evidence that the prospective applicant intends to apply for authorization on his own behalf and that the other information specified in paragraph 1 is available;
(b) the competent authority of the Member State, if satisfied that the applicant intends to apply, shall provide the name and address of the holder or holders of previous relevant authorizations and shall at the time inform the holders of the authorizations of the name and address of the applicant.
The holder or holders of previous authorizations and the applicant shall take all reasonable steps to reach agreement on the sharing of information so as to avoid the duplication of testing on vertebrate animals.
Where data is requested with a view to inclusion in Annex I of an active substance already on the market two years after notification of this Directive, the competent authorities of the Member State shall encourage data holders to cooperate in the provision of the requested data, with a view to limiting the duplication of testing on vertebrate animals.
If, nevertheless, the applicant and holders of previous authorizations of the same product can still

not reach an agreement on the sharing of data, Member States may introduce national measures obliging the applicant and holders of previous authorizations located within their territory to share the data with a view to avoiding duplicative testing on vertebrate animals and determine both the procedure for utilizing information, and the reasonable balance of the interests of the parties concerned.

Article 14
Member States and the Commission shall, without prejudice to Council Directive 90/313/EEC of 7 June 1990 on the freedom of access to information on the environment (6) , ensure that information submitted by applicants involving industrial and commercial secrets is treated as confidential if the applicant wishing to have an active substance included in Annex I or the applicant for authorization of a plant protection product so requests, and if the Member State or the Commission accepts that the applicant' s request is warranted.
Confidentiality shall not apply to:
- the names and content of the active substance or substances and the name of the plant protection product,
- the name of other substances which are regarded as dangerous under Directives 67/548/EEC and 78/631/EEC,
- physico-chemical data concerning the active substance and plant protection product,
- any ways of rendering the active substance or plant protection product harmless,
- a summary of the results of the tests to establish the substance' s or product' s efficacy and harmlessness to humans, animals, plants and the environment,
- recommended methods and precautions to reduce handling, storage, transport, fire or other hazards,
- methods of analysis referred to in Articles 4 (1) (c) and (d) and 5 (1) ,
- methods of disposal of the product and of its packaging,
- decontamination procedures to be followed in the case of accidential spillage or leakage,
- first aid and medical treatment to be given in the case of injury to persons.
If the applicant subsequently discloses previously confidential information, he shall be required to inform the competent authority accordingly.

Packaging and labelling of plant protection products
Article 15

Article 5
(1) of Directive 78/631/EEC shall apply to all plant protection products not covered by Directive 78/631/EEC.

Article 16
Member States shall take all necessary measures to ensure that the packaging of plant protection products satisfies the following requirements as to labelling.
1. All packaging 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 authorization and the authorization number of the plant protection product and, if different, the name
and address of the person responsible for the final packaging and labelling or for the final labelling of the plant protection product on the market;
(c)
the name and amount of each active substance expressed as provided for in Article 6 of Directive 67/548/EEC and in particular paragraph (2) (d) of that Article.

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 rules;
(d)
the net quantity of plant protection product given in legal units of measurement;
(e)
the formulation batch number or some means of identifying it;
(f)
the particulars required under Article 6 of Directive 78/631/EEC, in particular those mentioned in paragraph 2 (d) , (g) , (h) and (i) , and paragraphs 3 and 4 of that Article and information on first aid;
(g)
the nature of any special risks for humans, animals or the environment, by means of standard phrases selected as appropriate from those given in Annex IV;
(h)
safety precautions for the protection of humans, animals or the environment, in the form of standard phrases selected as appropriate from those given 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 authorized and any specific agricultural, plant health and environmental conditions under which the product may be used 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,
- access by humans or animals,
- harvesting,
- use or consumption;
(n)
particulars of possible phytotoxicity, varietal susceptibility, and any other direct or indirect adverse side effects on plants or products of plant origin together with the intervals to be observed between application and sowing or planting of:
- the crop in question, or
- subsequent crops;
(o)
if accompanied by a leaflet, as provided for in paragraph 2, the sentence ' Read accompanying instructions before use' ;
(p)
directions for safe disposal of the plant protection product and of the packaging; and
(q)
the expiry date relevant to normal conditions of storage where the shelf life of the product is limited to less than two years.
2. Member States may permit the requirements in paragraph 1 (l) , (m) and (n) to be indicated on

a separate leaflet accompanying the package if the space available on the package is too small. Such a leaflet shall be regarded as part of the label for the purposes of this Directive.
3. Taking account of the rules in force within their territories regarding the supply of certain plant protection products to certain categories of users, pending Community harmonization, the Member States shall require that it be indicated on the label whether a product is restricted to certain categories of users.
4. In no circumstances may the label of the packaging of a plant protection product bear the indications ' non-toxic' , ' harmless' , or similar indications. However, information to the effect that the plant protection product may be used when bees or other non-target species are active, or when crops or weeds are in flower or other such phrases to protect bees or other non-target species may be given on the label, if the authorization relates explicitly to use during the season for bees or other specified organisms and presents minimal hazard to them.
5. Member States may make the placing of plant protection products on the market in their territories subject to their being labelled in their national language or languages, and may require that samples, models or drafts of the packaging, labelling and leaflets referred to in this Article be submitted.
By way of derogation from paragraph 1 (g) and (h) , Member States may require additional phrases to be clearly and indelibly marked on packaging where they are deemed to be necessary for the protection of human beings, animals or the environment; in that event they shall notify the other Member States and the
Commission forthwith of each derogation granted and shall forward the additional phrase or phrases and the reasons for these requirements.
In accordance with the procedure laid down in Article 19, a decision shall be taken that the additional phrase or phrases is or are justified and hence that Annexes IV and V must be amended accordingly, or that the Member States concerned must no longer require such phrase(s) . The Member State shall be entitled to maintain its requirement until such time as a decision has been taken.

Control measures
Article 17
Member States shall make the necessary arrangements for plant protection products which have been placed on the market and for their use to be officially checked to see whether they comply with the requirements of this Directive and in particular with the requirements of the authorization and information appearing on the label.
The Member States shall report annually before 1 August to the other Member States and the Commission on the results of the inspection measures taken in the previous year.

Administrative provisions
Article 18
1. The Council, acting by a qualified majority on a proposal from the Commission, shall adopt the ' uniform principles' referred to in Annex VI.
2. In accordance with the procedure laid down in Article 19 and having regard to current scientific and technical knowledge, the necessary amendments to Annexes II, III, IV, V and VI shall be adopted.

Article 19
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 Decision 76/894/EEC (7) , herinafter referred to as ' the Committee' .
The representative of the Commission shall submit to the committee a draft of the measures to be

taken. The committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the
majority laid down in Article 148 (2) of the Treaty. The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in that Article. The chairman shall not vote.
The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the committee.
If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.
If, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission.

Article 20
Where the procedure laid down in this Article is to be followed, matters shall be referred by the chairman, either on his own initiative or at the request of a Member State, to the committee.
The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft, within a time limit which the chairman may lay down according to the urgency of the matter, if necessary by taking a vote.
The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the committee.
If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.
If, on the expiry of a period of 15 days from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission.

Article 21
Where the procedure laid down in this Article is to be followed, matters shall be referred by the Chairman, either on his own initiative or at the request of a Member State, to the committee.
The representative of the Commission shall submit to the committee a draft of the measures to be taken. The
committee shall deliver its opinion on the draft, within a time limit which the chairman may lay down according to the urgency of the matter, if necessary by taking a vote.
The opinion shall be recorded in the minutes; in addition, each Member State shall have the right to ask to have its position recorded in the minutes.
The Commission shall take the utmost account of the opinion delivered by the committee. It shall inform the committee of the manner in which its opinion has been taken into account.

Research and development
Article 22
1. The Member States shall prescribe that any experiment or test for research or development purposes involving the release into the environment of an unauthorized plant protection product may only be carried out after authorization for trial purposes has been granted and under controlled conditions and for limited quantities and areas.
2. The persons concerned shall submit an application to the competent authority of the Member State in whose territory the experiment or test is to be conducted, within time periods prescribed by the Member State before the commencement of the experiment or test, together with a dossier containing all the available data to permit an assessment to be made of possible effects on human or animal health or the possible impact on the environment.

If the proposed experiments or tests referred to in paragraph 1 are liable to have harmful effects on human or animal health or to have an unacceptable adverse influence on the environment, the Member State concerned may either prohibit them or permit them subject to such conditions as it considers necessary to prevent those consequences.
3. Paragraph 2 shall not apply if the Member State has granted the person concerned the right to undertake certain experiments and tests and has determined the conditions under which the experiments and tests have to be undertaken.
4. Common conditions for the application of this Article, in particular the maximum quantities of pesticides that may be released during experiments covered by paragraph 1, and the minimum data to be submitted in accordance with paragraph 2, shall be adopted in accordance with the procedure laid down in Article 19.
5. This Article shall not apply to experiments or tests covered by Part B of Directive 90/220/EEC.
Implementation of the Directive
Article 23
1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive within two years following notification thereof. They shall immediately inform the Commission thereof. The uniform principles shall be adopted one year after the date of notification.
When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.
2. Paragraph 1 notwithstanding, Member States need not bring into force laws, regulations and administrative
provisions implementing Article 10 (1) , second indent, until one year at the latest following adoption of the uniform principles, and only in relation to the requirements of Article 4 (1) (b) to (e) which are covered by the uniform principles thus adopted.

Article 24
This Directive is addressed to the Member States.
Done at Brussels, 15 July 1991.
For the Council
The President
P. BUKMAN
ANNEX I
ACTIVE SUBSTANCES AUTHORIZED FOR INCORPORATION IN PLANT PROTECTION PRODUCTS
ANNEX II
REQUIREMENTS FOR THE DOSSIER TO BE SUBMITTED FOR THE INCLUSION OF AN ACTIVE SUBSTANCE IN ANNEX I INTRODUCTION The information shall include:
- a technical dossier supplying the information necessary for evaluating the foreseeable risks, whether immediate or delayed, which the substance may entail for humans and the environment and containing at least the information and results of the studies referred to below, together with a detailed and full description of the studies conducted and of the methods used or a bibliographical reference to them,
- the proposed classification and labelling of the substance in accordance with Directive 67/548/EEC.
However, certain pieces of information which would not be necessary owing to the nature of the substance or of its proposed uses need not be supplied. In such cases, or where it is not scientifically necessary or technically possible to supply information, a justification which is acceptable to the Commission in accordance with Article 6 must be submitted.

Tests must be conducted according to the methods described in Annex V to Directive 79/831/EEC 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 requirements of Directive 86/609/EEC and the principles laid down in Directive 87/18/EEC (;) .

PART A
Chemical substances ($)
1.
Identity of the active substance
1.1.
Applicant (name, address, etc.)
1.2.
Manufacturer (name, address, including location of plant)
1.3.
Common name proposed or ISO-accepted, and synonyms
1.4.
Chemical name (IUPAC nomenclature)
1.5.
Manufacturer' s development code number(s)
1.6.
CAS and EEC numbers (if available)
1.7.
Empirical and structural formula, molecular mass
1.8.
Method of manufacture (synthesis pathway) of the active substance
1.9.
Specification of purity of the active substance in g/kg or g/l as appropriate
1.10.
Identity of isomers, impurities and additives (e.g. stabilizers) , together with the structural formula and the possible range expressed as g/kg or g/l as appropriate
(;) OJ No L 15, 17. 1. 1987, p. 29.
($) Substance within the meaning of the definition of Article 2, point 3.
2.
Physical and chemical properties of the active substance
2.1.
Melting point, boiling point, relative density (;)
2.2.
Vapour pressure (in Pa) at 20 oC, volatility (e.g. Henry' s law constant) (;)
2.3.
Appearance (physical state, colour and odour; if appropriate, threshold concentrations for substances with intense odour or taste in water) ($)
2.4.
Absorption spectra (UV/VIS, IR, NMR, MS) , molecular extinction at relevant wavelengths (;)
2.5.
Solubility in water including effect of pH (5 to 9) and temperature on solubility (;)
2.6.
Solubility in organic solvents including effect of temperature on solubility (;)
2.7.
Partition coefficient N-octanol/water including effect of pH (5 to 9) and temperature (;)
2.8.
Stability in water, hydrolysis rate, photochemical degradation, quantum yield and identity of

breakdown product(s) , dissociation constant including effect of pH (5 to 9) (;)
2.9.
Stability in air, photochemical degradation, identity of breakdown product(s) ($)
2.10.
Stability in organic solvents used in preparations ($)
2.11.
Thermal stability, identity of breakdown products
2.12.
Flammability including auto-flammability and identity of combustion products
2.13.
Flash point
2.14.
Surface tension
2.15.
Explosive properties
2.16.
Oxidizing properties
2.17.
Reactivity towards container material
3.
Further information on the active substance
3.1.
Function, e.g. fungicide, herbicide, insecticide, repellant, growth regulator
3.2.
Effects on harmful organisms, e.g. contact poison, inhalation poison, stomach poison, fungitoxic or fungistatic, etc., systemic or not in plants
3.3.
Field of use envisaged, e.g. field, glasshouse, food or feed storage, home garden
3.4.
Where necessary, in the light of the test results, any specific agricultural, plant health or environmental conditions under which the active substance may or may not be used.
3.5.
Harmful organisms controlled and crops or products protected or treated
3.6.
Mode of action
3.7.
Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies
3.8.
Recommended methods and precautions concerning handling, storage, transport or fire
3.9.
In case of fire, nature of reaction product, combustion gases, etc.
(;) These data must be submitted for the purified active substance of stated specification.
($) These data must be submitted for the active substance and the purified active substance of stated specification.
3.10.
Emergency measures in the case of an accident
3.10.1.
Procedures for destruction or decontamination of the active substance
3.10.2.
Possibility of recovery

3.10.3.
Possibility of neutralization
3.10.4.
Controlled discharge
3.10.5.
Controlled incineration
3.10.6.
Water purification
3.10.7.
Others
4.
Analytical methods
4.1.
Analytical methods for the determination of pure active substance and, where appropriate, for relevant breakdown products, isomers and impurities of the active substance and additives (e.g. stabilizers)
4.2.
Analytical methods including recovery rates and the limits of determination for residues in, and where relevant on, the following:
4.2.1.
Treated plants, plant products, foodstuffs, feedingstuffs
4.2.2.
Soil
4.2.3.
Water (including drinking water)
4.2.4.
Air
4.2.5.
Animal and human body fluids and tissues
5.
Toxicological and metabolism studies on the active substance
5.1.
Acute toxicity
5.1.1.
Oral
5.1.2.
Percutaneous
5.1.3.
Inhalation
5.1.4.
Intraperitoneal
5.1.5.
Skin and where appropriate eye irritation
5.1.6.
Skin sensitization
5.2.
Short-term toxicity
5.2.1.
Oral cumulative toxicity (28-day study)
5.2.2.
Oral administration - two species, one rodent (preferably rat) and one non-rodent, usually 90-day

study
5.2.3.
Other routes (inhalation, percutaneous as appropriate)
5.3.
Chronic toxicity
5.3.1.
Oral long-term toxicity and carcinogenicity (rat and other mammalian species) - other routes as appropriate
5.4.
Mutagenicity - test battery to assess gene mutations, chromosomal aberrations and DNA perturbations
5.5.
Reproductive toxicity
5.5.1.
Teratogenicity studies - rabbit and one rodent species, oral and when appropriate percutaneous
5.5.2.
Multigeneration studies in mammals (at least two generations)
5.6.
Metabolism studies in mammals
5.6.1.
Absorption, distribution and excretion studies - following both oral and percutaneous administration
5.6.2.
Elucidation of metabolic pathways
5.7.
Neurotoxicity studies - including where appropriate delayed neurotoxicity tests in adult hens
5.8.
Supplementary studies
5.8.1.
Toxic effects of metabolites from treated plants in cases where different from those identified in animal studies
5.8.2.
Any mechanistic studies needed to clarify effects reported in toxicity studies
5.9.
Toxic effects on livestock and pets
5.10.
Medical data
5.10.1.
Medical surveillance on manufacturing plant personnel
5.10.2.
Direct observation, e.g. clinical cases and poisoning incidents
5.10.3.
Health records, both from industry and agriculture
5.10.4.
Observations on exposure of the general population and epidemiological studies if appropriate
5.10.5.
Diagnosis of poisoning (determination of active substance, metabolites) , specific signs of poisoning, clinical tests
5.10.6.
Sensitization/allergenicity observations
5.10.7.

Proposed treatment: first aid measures, antidotes, medical treatment
5.10.8.
Prognosis of expected effects of poisoning
5.11.
Summary of mammalian toxicology and conclusions (including no observable adverse effect level (NOAEL) , no observable effect level (NOEL) , acceptable daily intake (ADI) . Overall evaluation with regard to all toxicological data, and other information concerning the active substance
6.
Residues in or on treated products, food and feed
6.1.
Identification of breakdown and reaction products and of metabolites in treated plants or products
6.2.
Behaviour of residue of the active substance and its metabolites from the time of application until harvest or outloading of stored products - uptake and distribution in, and where relevant on, plants, kinetics of disappearance, binding to plant constituents, etc.
6.3.
Overall material balance for the active substance. Sufficient residue data from supervised trials to demonstrate that residues likely to arise from the proposed treatments would not be of concern for human and animal health
6.4.
Estimation of the potential and actual exposure through diet and other means, such as residue monitoring data for products in the distribution chain, or such as data concerning exposure via air, water, etc.
6.5.
Feeding and metabolism studies in livestock (if residues remain in or on crops or parts of crops used for feed) to permit evaluation of residues in foodstuffs of animal origin
6.6.
Effects of industrial processing and/or household preparation on the nature and magnitude of residues
6.7.
Summary and evaluation of residue behaviour resulting from data submitted pursuant to points 6.1 to 6.6
7.
Fate and behaviour in the environment
7.1.
Fate and behavoir in soil
7.1.1.
Rate and route of degradation (to 90 per cent degradation) including identification of the processes involved and identification of metabolites and breakdown products in at least three soil types under appropriate conditions.
7.1.2.
Adsorption and desorption in at least three soil types and where relevant adsorption and desorption of metabolites and breakdown products
7.1.3.
Mobility in at least three soil types and where relevant mobility of metabolites and breakdown products
7.1.4.
Extent and nature of bound residues
7.2.

fate and behaviour in water and air
7.2.1.
Rate and route of degradation in aquatic systems - biodegradation, hydrolysis, photolysis (as far as not covered by point 2.8) , including identification of metabolites and breakdown products
7.2.2.
Adsorption and desorption in water (sedimentation) and where relevant adsorption and desorption of metabolites and breakdown products
7.2.3.
Rate and route of degradation in air (for fumigants and other volatile active substances) (as far as not covered by point 2.9)
8.
Ecotoxicological studies on the active substance
8.1.
Effects on birds
8.1.1.
Acute oral toxicity
8.1.2.
Short-term toxicity - eight-day dietary study in at least one species (other than chicken)
8.1.3.
Effects on reproduction
8.2.
Effects on aquatic organisms
8.2.1.
Acute toxicity to fish
8.2.2.
Chronic toxicity to fish
8.2.3.
Effects on fish reproduction and growth rate
8.2.4.
Bioaccumulation in fish
8.2.5.
Acute toxicity for Daphnia magna
8.2.6.
Daphnia magna reproduction and growth rate
8.2.7.
Effects on algal growth
8.3.
Effects on other non-target organisms
8.3.1.
Acute toxicity to honeybees and other beneficial arthropods (e.g. predators)
8.3.2.
Toxicity to earthworms and to other soil non-target macro-organisms
8.3.3.
Effects on soil non-target micro organisms
8.3.4.
Effects on other non-target organisms (flora and fauna) believed to be at risk
8.3.5.
Effects on biological methods for sewage treatment
9.
Summary and evaluation of points 7 and 8
10.

Proposals including justification for the proposals for the classification and labelling of the active substance according to Council Directive 67/548/EEC
- Hazard symbol(s)
- Indications of danger
- Risk phrases
- Safety phrases

11.
A dossier as referred to in Annex III, part A, for a representative plant protection product
PART B Micro-organisms and viruses (this part does not apply to GMOs where points come under Directive 90/220/EEC)
1.
Identity of the organism
1.1.
Applicant (name, address, etc.)
1.2.
Manufacturer (name, address, including location of plant)
1.3.
Common name or alternative and superseded names
1.4.
Taxonomic name and strain for bacteria, protozoa and fungi, indication whether it is a stock variant or a mutant strain; for viruses the taxonomic designation of the agent, serotype, strain or mutant
1.5.
Collection and culture reference number where the culture is deposited
1.6.
The appropriate test procedures and criteria used for identification (e.g. morphology, biochemistry, serology)
1.7.
Composition - microbiological purity, nature, identity, properties, content of any impurities and extraneous organisms
2.
Biological properties of the organism
2.1.
Target organism. Pathogenicity or kind of antagonism to host, infective dose, transmissibility and information on mode of action
2.2.
History of the organism and its uses. Natural occurrence and geographical distribution
2.3.
Host specificity range and effects on species other than the target harmful organism including species most closely related to the target species - to include infectivity, pathogenicity and transmissibility
2.4.
Infectivity and physical stability when used according to the proposed method. Effect of temperature, exposure to air radiation, etc. Persistence under the likely environmental conditions of use
2.5.
Whether the organism is closely related to a plant pathogen or to a pathogen of a vertebrate species or a non-target invertebrate species
2.6.
Laboratory evidence of genetic stability (i.e. mutation rate) under environmental conditions of proposed use

2.7.
Presence, absence or production of toxins as well as their nature, identity, chemical structure (if appropriate) and stability
3.
Further information on the organism
3.1.
Function, e.g. fungicide, herbicide, insecticide, repellant, growth regulator
3.2.
Effects on harmful organisms, e.g. contact poison, inhalation poison, stomach poison, fungitoxic or fungistatic, etc., systemic or not in plants
3.3.
Field of use envisaged, e.g. field, glasshouse, food or feed storage, home garden
3.4.
Where necessary, in the light of the test results, any specific agricultural, plant health or environmental conditions under which the active substance may or may not be used
3.5.
Harmful organisms controlled and crops or products protected or treated
3.6.
Method of production with descriptions of the techniques used to ensure a uniform product and of assay methods for its standardization. In the case of a mutant, detailed information should be provided on its production and isolation, together with all known differences between the mutant and the parent wild strains
3.7.
Methods to prevent loss of virulence of seed stock
3.8.
Recommended methods and precautions concerning handling, storage, transport or fire
3.9.
Possibility of rendering the organism uninfective
4.
Analytical methods
4.1.
Methods for establishing the identity and purity of seed stock from which batches are produced and results obtained, including information on variability
4.2.
Methods to show microbiological purity of the final product and showing that contaminants have been controlled to an acceptable level, results obtained and information on variability
4.3.
Methods used to show that there are no human or other mammalian pathogens as contaminants in the active agent, including in the case of protozoa and fungi, the effects of temperature (35 oC and other relevant temperatures)
4.4.
Methods to determine viable and non-viable (e.g. toxins) residues in or on treated products, foodstuffs, feedingstuffs, animal and human body fluids and tissues, soil, water and air, where relevant
5.
Toxicological, pathogenicity and infectivity studies
5.1.
Bacteria, fungi, protozoa and mycoplasma
5.1.1.
Toxicity and/or pathogenicity and infectivity
5.1.1.1.

Oral single dose
5.1.1.2.
In cases where a single dose is not appropriate to assess pathogenicity, a set of range-finding texts must be carried out to reveal highly toxic agents and infectivity
5.1.1.3.
Percutaneous single dose
5.1.1.4.
Inhalation single dose
5.1.1.5.
Intraperitoneal single dose
5.1.1.6.
Skin and, where necessary, eye irritation
5.1.1.7.
Skin sensitization
5.1.2.
Short-term toxicity (90 days exposure)
5.1.2.1.
Oral administration
5.1.2.2.
Other routes (inhalation, percutaneous as appropriate)
5.1.3.
Supplementary toxicological and/or pathogenicity and infectivity studies
5.1.3.1.
Oral long-term toxicity and carcinogenicity
5.1.3.2.
Mutagenicity - (tests as referred to under point 5.4 of part A)
5.1.3.3.
Teratogenicity studies
5.1.3.4.
Multigeneration study in mammals (at least two generations)
5.1.3.5.
Metabolic studies - absorption, distribution and excretion in mammals including elucidation of metabolic pathways
5.1.3.6.
Neurotoxicity studies, including where appropriate delayed neurotoxicity tests in adult hens
5.1.3.7.
Immunotoxicity, e.g. allergenicity
5.1.3.8.
Pathogenicity and infectivity under immunosuppression
5.2.
Viruses, viroids
5.2.1.
Acute toxicity and/or pathogenicity and infectivity. Data as outlined under point 5.1.1 and cell culture studies using purified infective virus and primary cell cultures of mammalian, avian and fish cells
5.2.2.
Short-term toxicity
Data as outlined under point 5.1.2 and tests for infectivity carried out by bio-assay or on a suitable cell culture at least seven days after the last administration to the test animals
5.2.3.
Supplementary toxicological and/or pathogenicity and infectivity studies as outlined under point

5.1.3
5.3.
Toxic effects on livestock and pets
5.4.
Medical data
5.4.1.
Medical surveillance on manufacturing plant personnel
5.4.2.
Health records, both from industry and agriculture
5.4.3.
Observations on exposure of the general population and epidemiological data, if appropriate
5.4.4.
Diagnosis of poisoning, specific signs of poisoning, clinical tests, if appropriate
5.4.5.
Sensitization/allergenicity observations, if appropriate
5.4.6.
Proposed treatment: first aid measures, antidotes, medical treatment, if appropriate
5.4.7.
Prognosis of expected effects of poisoning, if appropriate
5.5.
Summary of mammalian toxicology and conclusions (including NOAEL, NOEL and ADI, if appropriate) . Overall evaluation with regard to all toxicological pathogenicity and infectivity data, and infectivity and other information concerning the active substance
6.
Residues in or on treated products, food and feed
6.1.
Identification of viable and non-viable (e.g. toxins) residues in or on treated plants or products, the viable residue by culture or bio-assay and the non-viable by appropriate techniques
6.2.
Likelihood of multiplication of the active substance in or on crops or food together with a report on any effect on food quality
6.3.
In cases where residues of toxins remain in or on an edible plant product, data as outlined under points 4.2.1 and 6 of part A are required
6.4.
Summary and evaluation of residue behaviour resulting from data submitted under points 6.1 to 6.3
7.
Fate and behaviour in the environment
7.1.
Spread, mobility, multiplication and persistence in air, water, soil
7.2.
Information concerning possible fate in food chains
7.3.
In cases where toxins are produced, data as outlined under part A, point 7 are required, where relevant
8.
Ecotoxicological studies
8.1.
Birds - acute oral toxicity and/or pathogenicity and infectivity
8.2.

Fish - acute toxicity and/or pathogenicity and infectivity
8.3.
Toxicity - Daphnia magna (if appropriate)
8.4.
Effects on algal growth
8.5.
Important parasites and predators of target species; acute toxicity and/or pathogenicity and infectivity
8.6.
Honey-bees: acute toxicity and/or pathogenicity and infectivity
8.7.
Earthworms: acute toxicity and/or pathogenicity and infectivity
8.8.
Other non-target organisms believed to be at risk: acute toxicity and/or pathogenicity and infectivity
8.9.
Extent of indirect contamination on adjacent non-target crops, wild plants, soil and water
8.10.
Effects on other flora and fauna
8.11.
In cases where toxins are produced, data as outlined under Part A, points 8.1.2, 8.1.3, 8.2.2, 8.2.3, 8.2.4, 8.2.5, 8.2.6, 8.2.7 and 8.3.3 are required, where relevant
9.
Summary and evaluation of points 7 and 8
10.
Proposals including justification of the proposals for the classification and labelling of the active substance in accordance with Directive 67/548/EEC
- Hazard symbol(s)
- Indications of danger
- Risk phrases
- Safety phrases
11.
A dossier as referred to in Annex III, part B, for a representative plant protection product.

ANNEX III
REQUIREMENTS FOR THE DOSSIER TO BE SUBMITTED FOR THE AUTHORIZATION OF A PLANT PROTECTION PRODUCT INTRODUCTION
The information required shall include:
- a technical dossier supplying the information necessary for evaluating efficacy and the foreseeable risks, whether immediate or delayed, which the plant protection product may entail for humans and the environment and containing at least the information and results of the studies referred to below, together with a detailed and full description of the studies conducted and of the methods used or a bibliographical reference to them,
- the proposed classification and labelling of the plant protection product in accordance with relevant Community Directives.
In individual cases it may be necessary to require information as provided for in Annex II, Part A, for formulants (e.g. solvents and synergists) .
However, certain pieces of information which would not be necessary owing to the nature of the product or of its proposed uses need not be supplied. In such cases, or where it is not scientifically necessary, or technically possible to supply information, a justification which is acceptable to the competent authorities must be submitted.

Tests must be conducted according to the methods described in Annex V to Directive 79/831/EEC 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 requirements of Directive 86/609/EEC and the principles laid down in Directive 87/18/EEC.

PART A Chemical preparations 1.
Identity of the plant protection product
1.1.
Applicant (name and address, etc.)
1.2.
Manufacturer of the preparation and the active substance(s) (names and addresses, etc. including location of plants)
1.3.
Trade name or proposed trade name, and manufacturer' s development code number for the preparation, if appropriate
1.4.
Detailed quantitative and qualitative information on the composition of the preparation (active substance(s)) , impurities, adjuvants, inert components, etc.)
1.5.
Physical state and nature of the preparation (emulsifiable concentrate, wettable powder, solution etc.)
1.6.
Use category (herbicide, insecticide, etc.)
2.
Physical, chemical and technical properties of the plant protection product
2.1.
Appearance (colour and odour)
2.2.
Explosivity and oxidizing properties
2.3.
Flash point and other indications of flammability or spontaneous ignition
2.4.
Acidity/alkalinity and if necessary pH value (1 % in water)
2.5.
Viscosity, surface tension
2.6.
Relative density
2.7.
Storage stability - stability and shelf-life. Effects of light, temperature and humidity on technical characteristics of the plant protection product
2.8.
Technical characteristics of the plant health product
2.8.1.
Wettability
2.8.2.
Persistent foaming
2.8.3.
Suspensibility and suspension stability
2.8.4.
Wet sieve test and dry sieve test
2.8.5.

Particle size distribution, content of dust/fines, attrition and friability
2.8.6.
In the case of granules: sieve test and indication of weight distribution of the granules, at least of the fraction with particle sizes bigger than 1 mm
2.8.7.
Content of active substance in or on bait particles, granules or treated seed
2.8.8.
Emulsifiability, re-emulsifiability, emulsion stability
2.8.9.
Flowability, pourability and dustability
2.9.
Physical and chemical compatibility with other products including plant protection products with which its use is to be authorized
2.10.
Wetting, adherence and distribution to target plants
3.
Data on application
3.1.
Field of use, e.g. field, glasshouse, food or feed storage, home garden
3.2.
Effects on harmful organisms, e.g. contact poison, inhalation poison or stomach poison, fungitoxic or fungistatic, etc., systemic or not in plants
3.3.
Details of intended use, e.g. types of harmful organisms controlled and/or plants or plant products to be protected
3.4.
Where necessary, in the light of the test results, any specific agricultural, plant health and/or environmental conditions under which the organism may or may not be used
3.5.
Application rate
3.6.
Concentration of active substance in material used (e.g. in the diluted spray, bait or treated seed)
3.7.
Method of application
3.8.
Number and timing of applications and duration of protection
3.9.
Necessary waiting periods or other precautions to avoid phytotoxic effects on succeeding crops
3.10.
Proposed instructions for use
4.
Further information on the plant protection product
4.1.
Packaging (type, materials, size, etc.) , compatibility of the preparation with proposed packaging materials
4.2.
Procedures for cleaning application equipment
4.3.
Re-entry periods, necessary waiting periods or other precautions to protect humans and animals
4.4.
Recommended methods and precautions concerning handling, storage, transport or fire

4.5.
Emergency measures in case of an accident
4.6.
Identity of combustion products relevant to cases of fire
4.7.
Procedures for destruction or decontamination of the plant protection product and its packaging
4.7.1.
Possibility of neutralization
4.7.2.
Controlled discharge
4.7.3.
Controlled incineration
4.7.4.
Water purification
4.7.5.
Others
5.
Analytical methods
5.1.
Analytical methods for determining the composition of the plant protection product
5.2.
In so far as not covered by Annex II, Part A, point 4.2, analytical methods including recovery rates and the limits of determination for residues in and where relevant on, the following;
5.2.1.
Treated plants, plant products, foodstuffs, feedingstuffs
5.2.2.
Soil
5.2.3.
Water (including drinking water)
5.2.4.
Air
5.2.5.
Animal and human body fluids and tissues
6.
Efficacy data
6.1.
Preliminary range-finding tests
6.2.
Field experimentation
6.3.
Information on the possible occurrence of the development of resistance
6.4.
Effects on the quality and where appropriate on the yield of treated plants or effects on the quality of treated plant products
6.5.
Phytotoxicity to target plants (including different cultivars) , or to target plant products
6.6.
Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms, on succeeding crops, other plants or parts of treated plants used for propagating purposes (e.g. seeds, cuttings, runners)
6.7.

Summary and evaluation of data presented under points 6.1 to 6.6
7.
Toxicological studies
7.1.
Acute toxicity
7.1.1.
Oral
7.1.2.
Percutaneous
7.1.3.
Inhalation
7.1.4.
Skin and, where relevant, eye irritation
7.1.5.
Skin sensitization
7.1.6.
Where appropriate, acute dermal toxicity, skin and eye irritation for combinations of plant protection products for which authorization is sought for use in such combinations
7.2.
Operator exposure
7.2.1.
Dermal absorption
7.2.2.
Likely operator exposure under field conditions, including where relevant quantitative analysis of operator exposure
7.2.3.
Available toxicological data relating to non-active substances
8.
Residues in or on treated products, food and feed
8.1.
Data from supervised trials in crops, food or feedingstuffs, for which authorized use is sought, giving all experimental conditions and details, including residue data concerning the active substance, relevant metabolites and relevant other constituents of the plant protection product, from time of application until harvest, or in the case of post-harvest treatment, breakdown of residues during storage and levels of residues at time of release from storage for marketing. Data should be available for the range of climatic and agronomic conditions likely to be encountered in the proposed area of use
8.2.
Effects of industrial processing and/or household preparation on the nature and magnitude of residues
8.3.
Effects on taint, odour, taste or other quality aspects due to residues in or on fresh or processed products
8.4.
Estimation of residues in products of animal origin resulting from ingestion of feedingstuffs or resulting from contact with bedding, on the basis of residue data referred to in point 8.1 and studies in livestock referred to in Annex II, Part A, point 6.5
8.5.
Residue data in succeeding or rotational crops where presence of residues might be expected
8.6.
Proposed pre-harvest intervals for envisaged uses, or witholding periods or storage periods, in

the case of post-harvest uses.
8.7.
Proposed maximum residue levels (MRLs) and justification of the acceptability of these residues
8.8.
Summary and evaluation of the residue behaviour on the basis of the data submitted under points 8.1 to 8.7
9.
Fate and behaviour in the environment
The information provided must, where relevant, include that referred to in Annex II, part A, point 7, and
9.1.
Testing for distribution and dissipation in soil
9.2.
Testing for distribution and dissipation in water
9.3.
Testing for distribution and dissipation in air
10.
Ecotoxicological studies
10.1.
Effects on birds
10.1.1.
Acute oral toxicity
10.1.2.
Supervised trials to assess risks to avian species under field conditions
10.1.3.
If appropriate, studies on acceptance of bait, granules, or treated seeds by birds
10.2.
Effects on aquatic organisms
10.2.1.
Acute toxicity to fish
10.2.2.
Acute toxicity to Daphnia magna
10.2.3.
Overspray study (if toxic to fish or other aquatic organisms and persistent in water) to assess risks to aquatic organisms under field conditions
10.2.4.
In case of application in/at surface waters
10.2.4.1.
Particular studies with fish and other aquatic organisms
10.2.4.2.
Residue data in fish concerning the active substance and including toxicologically relevant metabolites
10.2.5.
The studies referred to in Annex II, Part A points 8.2.2, 8.2.3, 8.2.4, 8.2.6, and 8.2.7 may be required for particular plant protection products
10.3.
Effects on other non-target organisms
10.3.1.
Effects on terrestrial vertebrates other than birds
10.3.2.
Toxicity to honey-bees

10.3.3.
Toxicity to foraging bees under field conditions
10.3.4.
Effects on beneficial arthropods other than bees
10.3.5.
Effects on earthworms and other soil non-target macro-organisms, believed to be at risk
10.3.6.
Effects on soil non-target micro-organisms
10.3.7.
Available data from biological primary screening in summary form
11.
Summary and evaluation of points 9 and 10
12.
Further information
12.1.
Information on authorizations in other countries
12.2.
Information on established maximum residue limits (MRL) in other countries
12.3.
Proposals including justification for the classification and labelling proposed in accordance with Directive 67/548/EEC and Directive 78/631/EEC
- Hazard symbol(s)
- Indications of danger
- Risk phrases
- Safety phrases
12.4.
Proposals for risk and safety phrases in accordance with Article 15 (1) , (g) and (h) and proposed label
12.5.
Specimens of proposed packaging

PART B Preparations of micro-organisms or viruses (this part does not apply to GMOs where points come under Directive 90/220/EEC)
1.
Identity of the plant protection product
1.1.
Applicant (name, address, etc.)
1.2.
Manufacturer of the preparation and the active agent(s) (names, addresses, etc., including location of plants)
1.3.
Trade name or proposed trade name and manufacturer' s development code number/or the plant protection product, if appropriate
1.4.
Detailed quantitative and qualitative information on the composition of the plant protection product (active organism(s) , inert components, extraneous organisms, etc.)
1.5.
Physical state and nature of the plant protection product (emulsifiable concentrate, wettable powder, etc.)
1.6.
Use category (insecticide, fungicide, etc.) .

2.
Technical properties of the plant protection product
2.1.
Appearance (colour and odour)
2.2.
Storage stabilitiy - stability and shelf-life. Effects of temperature, method of packaging and storage, etc. on retention of biological activity
2.3.
Methods for establishing storage and shelf-life stability
2.4.
Technical characteristics of the preparation
2.4.1.
Wettability
2.4.2.
Persistent foaming
2.4.3
Suspensibility and suspension stability
2.4.4.
Wet sieve test and dry sieve test
2.4.5.
Particle size distribution, content of dust/fines, attrition and friability
2.4.6.
In the case of granules, sieve test and indications of weight distribution of the granules, at least of the fraction with particle sizes bigger than 1 mm
2.4.7.
Content of active substance in or on bait particles, granules or treated seed
2.4.8.
Emulsifiability, re-emulsifiability, emulsion stability
2.4.9.
Flowability, pourability and dustability
2.5.
Physical and chemical compatibility with other products including plant protection products with which its use is to be authorized
2.6.
Wetting, adherence and distribution to target plants
3.
Data on application
3.1.
Field of use, e.g. field, glasshouse, food or feed storage, home garden
3.2.
Details of intended use, e.g. types of harmful organism controlled and/or plants or plant products to be protected
3.3.
Application rate
3.4.
Where necessary, in the light of the test results, any specific agricultural, plant health and/or environmental conditions under which the product may or may not be used.
3.5.
Concentration of active substance in material used (e.g. % concentration in the diluted spray)
3.6.
Method of application

3.7.
Number and timing of applications
3.8.
Phytopathogenicity
3.9.
Proposed instructions for use
4.
Further information on the preparation
4.1.
Packaging (type, materials, size, etc.) , compatibility of the preparation with proposed packaging materials
4.2.
Procedures for cleaning application equipment
4.3.
Re-entry periods, necessary waiting periods or other precautions to protect humans and animals
4.4.
Recommended methods and precautions concerning handling, storage, transport
4.5.
Emergency measures in case of an accident
4.6.
Procedures for destruction or decontamination of the plant protection product and its packaging
5.
Analytical methods
5.1.
Analytical methods for determining the composition of the plant protection product
5.2.
Methods for determining residues in or on treated plants or in or on plant products (e.g. biotest)
5.3.
Methods used to show microbiological purity of the plant protection product
5.4.
Methods used to show the plant protection product to be free from any human and other mammalian pathogens or, if need be, from honey-bee pathogens
5.5.
Techniques used to ensure a uniform product and assay methods for its standardization
6.
Efficacy data
6.1.
Preliminary range-finding tests
6.2.
Field experimentation
6.3.
Information on the possible occurrence of the development of resistance
6.4.
Effects on the quality and where appropriate on the yield of treated plants or effects on the quality of treated plant products
6.5.
Phytotoxicity to target plants (including different cultivars) , or to target plant products
6.6.
Observations concerning undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms, on succeeding crops, other plants or parts of treated plants used for propagation purposes (e.g. seeds, cuttings, runners)

6.7.
Summary and evaluation of data presented under points 6.1 to 6.6
7.
Toxicity and/or pathogenicity and infectivity studies
7.1.
Oral single dose
7.2.
Percutaneous single dose
7.3.
Inhalation
7.4.
Skin and where relevant eye irritation
7.5.
Skin sensitization
7.6.
Available toxicological data relating to non-active substances
7.7.
Operator exposure
7.7.1.
Percutaneous absorption
7.7.2.
Likely operator exposure under field conditions, including where relevant quantitative analysis of operator exposure.
8.
Residues in or on treated products, food and feed
8.1.
Residue data concerning the active substance including data from supervised trials in crops, food or feedingstuffs for which authorization for use is sought, giving all experimental conditions and details. Data should be available for the range of different climatic and agronomic conditions encountered in the proposed area of use. It is also necessary to identify viable and non-viable residues in treated crops
8.2.
Effects of industrial processing and/or household preparation on the nature and magnitude of residues, if appropriate
8.3.
Effects on taint, odour, taste or other quality aspects due to residues on or in fresh or processed products, if appropriate
8.4.
Residue data in products of animal origin resulting from ingestion of feedingstuffs or contact with bedding, if appropriate
8.5.
Residue data in succeeding or rotational crops where presence of residues might be expected
8.6.
Proposed pre-harvest intervals for envisaged uses or witholding periods, or storage periods, in the case of post-harvest uses
8.7.
Proposed maximum residue levels (MRLs) and the justification of the acceptability of these levels (for toxins) , if appropriate
8.8.
Summary and evaluation of the residue behaviour on the basis of the data submitted under points 8.1 to 8.7

9.
Fate and behaviour in the environment
9.1.
In cases where toxins are produced, data as outlined under Part A, point 9 are required, if appropriate
10.
Ecotoxicological studies
10.1.
Effects on aquatic organisms
10.1.1.
Fish
10.1.2.
Studies in Daphnia magna and in species closely related to the target organisms
10.1.3.
Studies in aquatic micro-organisms
10.2.
Effects on beneficial and other non-target organisms
10.2.1.
Effects on honey-bees, if appropriate
10.2.2.
Effects on other beneficial organisms
10.2.3.
Effects on earthworms
10.2.4.
Effects on other soil fauna
10.2.5.
Effects on other non-target organisms believed to be at risk
10.2.6.
Effects on soil microflora
11.
Summary and evaluation of points 9 and 10
12.
Further information
12.1.
Information on authorizations in other countries
12.2.
Information on established maximum residue limits (MRLs) in other countries
12.3.
Proposals including justification for the classification and labelling proposed in accordance with Directives 67/548/EEC and 78/631/EEC
- Hazard symbol(s)
- Indications of danger
- Risk phrases
- Safety phrases
12.4.
Proposals for risk and safety phrases in accordance with Article 15(1) (g) and (h) and proposed label
12.5.
Specimens of proposed packaging

ANNEX IV

RISK PHRASES
ANNEX V
SAFETY PHRASES
ANNEX VI
UNIFORM PRINCIPLES FOR THE EVALUATION OF PLANT PROTECTION PRODUCTS