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COUNCIL DIRECTIVE
of 15 July 1991
concerning the placing of plant protection products on the market

(91/414/EEC)

(OJ L 230, 19.8.1991, p. 1)

Amended by:

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►**M1**	Commission Directive 93/71/EEC of 27 July 1993	L 221	27	31.8.1993
►**M2**	Commission Directive 94/37/EC of 22 July 1994	L 194	65	29.7.1994
►**M3**	Council Directive 94/43/EC of 27 July 1994	L 227	31	1.9.1994

Corrected by:

►**C1** Corrigendum, OJ L 170, 25.6.1992, p. 40 (91/414/EEC)

►**C2** Corrigendum, OJ L 4, 6.1.1996, p. 16 (93/71/EEC)

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COUNCIL DIRECTIVE

of 15 July 1991

concerning the placing of plant protection products on the market

(91/414/EEC)

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;

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(1) OJ No C 89, 10. 4. 1989, p. 22.
(2) OJ No C 72, 18. 3. 1991, p. 33.
(3) OJ No C 56, 7. 3. 1990, p. 3.

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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;

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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 [1] 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 [2]; 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 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) [3], as last amended by Directive 84/291/EEC [4] 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 [5], as last amended by Directive 90/517/EEC [6].

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

(1) OJ No L 358, 18. 12. 1986, p. 1.
(2) OJ No L 117, 8. 5. 1990, p. 15.
(3) OJ No L 206, 29. 7. 1978, p. 13.
(4) OJ No L 144, 30. 5. 1984, p. 1.
(5) OJ No 196, 16. 8. 1967, p. 1.
(6) OJ No L 287, 19. 10. 1990, p. 37.

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including in this Directive [1] 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 [2].

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:

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'*

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[1] This Directive was notified to the Member States on 26 July 1991.
[2] OJ No L 155, 22. 6. 1988, p. 2.

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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

▼B

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:

(i) it is sufficiently effective;

(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;

(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 [1] and in Article 11 of Directive 86/362/EEC [2], as amended by Directive 88/298/EEC [3].

[1] OJ No L 350, 14. 12. 1990, p. 71.
[2] OJ No L 221, 7. 8. 1986, p. 36.
[3] OJ No L 126, 20. 5. 1988, p. 53.

▼B

In particular:

(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 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 [1], as last amended by Directive 90/533/EEC [2], or Article 6 (1) or Article 8 (1) or (2) of this Directive.

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(1) OJ No L 33, 8. 2. 1979, p. 36.
(2) OJ No L 296, 27. 10. 1990, p. 63.

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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

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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

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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.

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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,

▼B

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 the procedure 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,

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— 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

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(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, or to vary the conditions for, or to maintain the inclusion of an active substance 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.

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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 ►C1 where they consider an active substance as 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

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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 [1], 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;

►C1 (c) the name and amount of each active substance expressed as provided for in Article 6 of Directive 78/631/EEC and ◄ in particular paragraph (2) (d) of that Article.

[1] OJ No L 158, 23. 6. 1990, p. 56.

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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

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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 ([1]), hereinafter 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

([1]) OJ No L 340, 9. 12. 1976, p. 25.

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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.

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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.

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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.

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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.

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ANNEX I

ACTIVE SUBSTANCES AUTHORIZED FOR INCORPORATION IN PLANT PROTECTION PRODUCTS

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ANNEX II

REQUIREMENTS FOR THE DOSSIER TO BE SUBMITTED FOR THE INCLUSION OF AN ACTIVE SUBSTANCE IN ANNEX I

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INTRODUCTION

The information required shall:

1.1. include a technical dossier supplying the information necessary for evaluating the foreseeable risks, whether immediate or delayed, which the substance may entail for humans, animals and the environment and containing at least the information and results of the studies referred to below;

1.2. where relevant, be generated using test guidelines referred to or described in this Annex, in the case of studies initiated before the adoption of the modification of this Annex, the information shall be generated using suitable internationally or nationally validated test guidelines or, in the absence thereof, test guidelines accepted by the competent authority;

1.3. in the event of a test guideline being inappropriate or not described, or where another one than those referred to in this Annex has been used, inlcude a justification, which is acceptable to the competent authority for the guidelines used;

1.4. include, when required by the competent authority, a full description of test guidelines used, except if they are referred to or described in this Annex, and a full description of any deviations from them including a justification, which is acceptable to the competent authority, for these deviations;

1.5. include a full and unbiased report of the studies conducted as well as full description of them or a justification, which is acceptable to the competent authority where:

— particular data and information which would not be necessary owing to the nature of the product or its proposed uses, are not provided,

or

— it is not scientifically necessary, or technically possible to supply information and data;

1.6. where relevant, have been generated in accordance with the requirements of Directive 86/609/EEC.

2.1. Tests and analyses must be conducted in accordance with the principles laid down in Directive 87/18/EEC [1] where testing is done to obtain data on the properties and/or safety with respect to human or animal health or the environment.

2.2. By way of derogation from point 2.1, tests and analyses done to obtain data on the properties and/or safety with respect to honeybees and beneficial arthropods other than bees may have been conducted by official or officially recognized testing facilities or organizations which satisfy at least the requirements as set out under points 2.2 and 2.3 of the introduction to Annex III.

This derogation expires on 31 December 1999.

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PART A

Chemical substances [2]

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1. *Identity of the active substance*

The information provided must be sufficient to identify with precision each active substance, to define it in terms of its specification and to

[1] OJ No L 15, 17. 1. 1987, p. 29.
[2] Substance within the meaning of the definition of Article 2, point 3.

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characterize it as to its nature. The information and data referred to, unless otherwise specified, are required for all active substances.

1.1. Applicant (name, address, etc.)

The name and address of the applicant (permanent Community address) must be provided as must the name, position, telephone and telefax number of the appropriate person to contact.

Where, in addition, the applicant has an office, agent or representative in the Member State to which the application for inclusion in Annex I is submitted, and if different, in the Rapporteur Member State appointed by the Commission, the name and address of the local office, agent or representative must be provided, as must the name, position, telephone and telefax number of the appropriate person to contact.

1.2. Manufacturer (name, address, including location of plant)

The name and address of the manufacturer or manufacturers of the active substance must be provided as must the name and address of each manufacturing plant in which the active substance is manufactured. A contact point (preferably a central contact point, to include name, telephone and telefax number) must be provided, with a view to providing updating information and responding to queries arising, regarding manufacturing technology, processes and the quality of product (including where relevant, individual batches). Where following inclusion of the active substances in Annex I, there are changes in the location or number of manufacturers, the information required must again be notified to the Commission and the Member States.

1.3. Common name proposed or ISO-accepted, and synonyms

The ISO common name, or proposed ISO common name and where relevant, other proposed or accepted common names (synonyms), including the name (title) of the nomenclature authority concerned, must be provided.

1.4. Chemical name (IUPAC and CA nomenclature)

The Chemical name as given in Annex I to Directive 67/548/EEC, or, if not included in this Directive, in accordance with both IUPAC and CA nomenclature, must be provided.

1.5. Manufacturer's development code number(s)

Code numbers used to identify the active substance, and where available, formulations containing the active substance, during development work, must be reported. For each code number reported, the material to which it relates, the period for which it was used, and the Member States or other countries in which it was used and is being used, must be stated.

1.6. CAS, EEC and CIPAC numbers (if available)

Chemical Abstracts, EEC (EINECS or ELINCS), and CIPAC numbers, where they exist, must be reported.

1.7. Molecular and structural formula, molecular mass

The molecular formula, molecular mass and structural formula of the active substance, and where relevant, the structural formula of each stereo and optical isomer present in the active substance, must be provided.

1.8. Method of manufacture (synthesis pathway) of the active substance

The method of manufacture, in terms of the identity of the starting materials, the chemical pathways involved, and the identity of by-products and impurities present in the final product, must be provided, for each manufacturing plant. Generally process engineering information is not required.

Where the information provided relates to a pilot plant production system, the information required must again be provided once industrial scale production methods and procedures have stabilized.

1.9. Specification of purity of the active substance in g/kg

The minimum content in g/kg of pure active substance (excluding inactive isomers) in the manufactured material used for production of formulated products, must be reported.

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Where the information provided relates to a pilot plant production system, the information required must again be provided to the Commission and the Member States once industrial scale production methods and procedures have stabilized, if production changes result in a changed specification of purity.

1.10. Identity of isomers, impurities and additives (e.g. stabilizers), together with the structural formula and the content expressed as g/kg

The maximum content in g/kg of inactive isomers as well as the ratio of the content of isomers/diastereo-isomers, where relevant, must be provided. In addition, the maximum content in g/kg of each further component other than additives, including by-products, and impurities, must be provided. In the case of additives the content in g/kg must be provided.

For each component, present in quantities of 1 g/kg or more, the following information, where relevant, must be provided:

— chemical name according to IUPAC and CA nomenclature,
— ISO common name or proposed common name if available,
— CAS number, EEC (EINECS or ELINCS) number, and CIPAC number if available,
— molecular and structural formula,
— molecular mass, and
— maximum content in g/kg.

Where the manufacturing process is such that impurities and by-products which are particularly undesirable because of their toxicological, ecotoxicological or environmental properties could be present in the active substance, the content of each such compound must be determined and reported. In such cases, the analytical methods used and the limits of determination, which must be sufficiently low, for each compound of concern, must be reported. Additionally the following information, where relevant, must be provided:

— chemical name according to IUPAC and CA nomenclature,
— ISO common name or proposed common name if available,
— CAS number, EEC (EINECS or ELINCS) number, and CIPAC number if available,
— molecular and structural formula,
— molecular mass, and
— maximum content in g/kg.

Where the information provided relates to a pilot plant production system, the information required must again be provided once industrial scale production methods and procedures have stabilized, if production changes result in a changed specification of purity.

Where the information provided does not fully identify a component viz. condensates, detailed information on the composition must be provided for each such component.

The trade name of components added to the active substance, prior to manufacture of formulated product, to preserve stability and facilitate ease of handling, where they are used, must also be provided. Additionally the following information, where relevant, must be provided for such additives:

— chemical name according to IUPAC and CA nomenclature,
— ISO common name or proposed common name if available,
— CAS number, EEC (EINECS or ELINCS) number, and CIPAC number if available,
— molecular and structural formula,
— molecular mass, and
— maximum content in g/kg.

For added components, other than active substance and other than impurities resulting from the manufacturing process, the function of the component (additive) must be given:

— antifoaming agent,
— antifreeze,
— binder,
— other (specify),
— buffer,
— dispersing agent,

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— stabilizer.

1.11. Analytical profile of batches

Representative samples of the active substance must be analysed for content of pure active substance, inactive isomers, impurities and additives, as appropriate. The analytical results reported must include quantitative data, in terms of g/kg content, for all components present in quantities of more than 1 g/kg and typically should account for at least 98 % of the material analysed. The actual content of components which are particularly undesirable because of their toxicological, ecotoxicological or environmental properties, must be determined and reported. Data reported must include the results of the analysis of individual samples and a summary of that data, to show the minimum or maximum and typical content of each relevant component, as appropriate.

Where an active substance is produced in different plants this information must be provided for each of the plants separately.

In addition, where available and relevant, samples of the active substance produced in laboratory scale or pilot production systems, must be analyzed, if such material was used in generating toxicological or ecotoxicological data.

2. *Physical and chemical properties of the active substance*

(i) The information provided, must describe the physical and chemical properties of active substances and together with relevant information, must serve to characterize them. In particular, the information provided must permit:

— physical, chemical, and technical hazards associated with active substances, to be identified,

— classification of active substance as to harzard,

— appropriate restrictions and conditions to be associated with inclusions in Annex I to be selected, and

— appropriate risk and safety phrases to be specified.

The information and data referred to are required for all active substances, except where otherwise specified.

(ii) The information provided, taken together with that provided for relevant preparations, must permit the physical, chemical hazards associated with preparations, to be identified, permit preparations to be classified, and permit establishment that preparations can be used without unnecessary difficulty, and be such that exposure of man, animals, and the environment is minimized, taking account of manner of use.

(iii) The extent to wich active substances of which inclusion in Annex I is sought, comply with relevant FAO specifications, must be stated. Divergences from FAO specifications must be described in detail, and justified.

(iv) In certain specified instances, tests must be conducted using purified active substance of stated specification. In such cases the principles of the method(s) of purification must be reported. The purity of such test material, which must be as high as can be achieved using the best available technology, must be reported. A reasoned justification must be provided in cases where the degree of purity achieved is less than 980 g/kg.

Such justification must demonstrate that all technically feasible and reasonable possibilities for the production of the pure active substance have been exhausted.

2.1. Melting point and boiling point

2.1.1. The melting point or where appropriate the freezing or solidification point of purified active substance must be determined and reported according to EEC method A 1. Measurements should be taken up to 360 ºC.

2.1.2. Where appropriate the boiling point of purified active substances must be determined and reported according to EEC method A 2. Measurements should be taken up to 360 ºC.

2.1.3. Where melting point and/or boiling point cannot be determined because of decomposition or sublimation, the temperature at which decomposition or sublimation occurs, must be reported.

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2.2. Relative density

In the case of active substances which are liquids or solids, the relative density of the purified active substance must be determined and reported according to EEC method A 3.

2.3. Vapour pressure (in Pa), volatility (e.g. Henry's law constant)

2.3.1. The vapour pressure of purified active substance must be reported according to EEC method A 4. Where vapour pressure is less than 10^{-3} Pa, the vapour pressure at 20 or 25 °C may be estimated by a vapour pressure curve.

2.3.2. In the case of active substances which are solids or liquids, volatility (Henry's law constant) of purified active substance must be determined or calculated from its water solubility and vapour pressure and be reported (in $Pa \times m^3 \times mol^{-1}$).

2.4. Appearance (physical state, colour and odour; if known)

2.4.1. A description of both the colour, if any, and the physical state of both the active substance as manufactured and purified active substance, must be provided.

2.4.2. A description of any odour associated with the active substance as manufactured and purfied active substance, noted when handling the materials in laboratories or production plants, must be reported.

2.5. Spectra (UV/VIS, IR, NMR, MS), molecular extinction at relevant wavelengths

2.5.1. The following specta including a table of signal characteristica needed for interpretation must be determined and reported: Ultraviolet/Visible (UV/VIS), infrared (R), nuclear magnetic resonance (NMR), and mass spectra (MS) of purified active substance and molecular extinction at relevant wavelengths, must be determined and reported.

The wavelengths at which UV/visible molecular extinction occurs are to be determined and reported and must include where appropriate a wavelength at the highest absorption value above 290 nm.

In the case of active substances which are resolved optical isomers their optical purity must be measured and reported.

2.5.2. The UV/visible absorption spectra, IR, NMR and MS spectra, where necessary for the identification of the impurities considered to be of toxicological, ecotoxicological or environmental significance must be determined and reported.

2.6. Solubility in water including effect of pH (4 to 10) on solubility

The water solubility of purified active substances under atmospheric pressure must be determined and reported according to EEC method A 6. These water solubility determinations must be made in the neutral range (i.e. in distilled water in equilibrium with atmospheric carbon dioxide). Where the active substance is capable of forming ions, determinations must also be made in the acidic range (pH 4 to 6) and in the alkaline range (pH 8 to 10), and be reported. Where the stability of the active substance in aqueous media is such that water solubility cannot be determined, a justification based on test data must be provided.

2.7. Solubility in organic solvents

The solubility of the active substances as manufactured in the following organic solvents at 15 to 25 ºC must be determined and reported if less than 250 g/kg; the temperature applied must be specified:

— Aliphatic hydrocarbon: preferably n-heptane,

— Aromatic hydrocarbon: preferably xylene,

— Halogenated hydrocarbon: preferably 1,2-dichlorethane,

— Alcohol: preferably methanol or isopropyl alcohol,

— Ketone: preferably acetone,

— Ester: preferably ethyl acetate.

If for a particular active substance, one or more of these solvents is unsuitable (e.g. reacts with test material), alternative solvents can be used instead. In such cases, choices made must be justified in terms of their structure and polarity.

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2.8. Partition coefficient n-octanol/water including effect of pH (4 to 10)

The n-octanol/water partition coefficient of purified active substance must be determined and reported according to EEC method A 8. The effect of pH (4 to 10) must be investigated when the substance is acidic or basic as defined by its pKa value (< 12 for acids, > 2 for bases).

2.9. Stability in water, hydrolysis rate, photochemical degradation, quantum yield and identity of breakdown product(s), dissociation constant including effect of pH (4 to 9)

2.9.1. The hydrolysis rate of purified active substances (usually radiolabelled active substance, > 95 % purity), for each of the pH values 4, 7 and 9, under sterile conditions, in the absence of light, must be determined and report according to EEC method C 7. For substances with a low rate of hydrolysis, the rate can be determined at 50 ºC, or another appropriate temperature.

If degradation is observed at 50 ºC, degradation rate at another temperature must be determined, and an Arrhenius plot must be constructed to permit an estimate to be made of hydrolysis at 20 ºC. The identity of hydrolysis products formed and the rate constantly observed, must be reported. The estimated DT 50 value must also be reported.

2.9.2. For compounds with a molar (decadic) absorption coefficient (ε) > 10 ($1 \times mol^{-1} \times cm^{-1}$) at a wavelength $\lambda \geq 290$ nm, direct phototransformation in purified (e.g. distilled) water at 20 to 25 ºC, of purified active substance usually radio labelled using artificial light under sterile conditions, if necessary using a solubilizer, must be determined and reported. Sensitizers such as acetone must not be used as a cosolvent or solubilizer. The light source must simulate sunlight and be equipped with filters to exclude radiation at wavelengths $\lambda < 290$ nm. The identity of breakdown products formed which at any time during the study are present in quantities ≥ 10 % of the active substance added, a mass balance to account for at least 90 % of the applied radioactivity, as well as photochemical halflife must be reported.

2.9.3. Where necessary to investigate direct phototrans-formation, the *quantum yield of direct photodegradation in water* must be determined and reported, together with calculations to estimate theoretical lifetime of the active substance in the top layer of aqueous systems and the real lifetime of the substance.

The method is described in the FAO Revised Guidelines on Environmental Criteria for the Registration of Pesticides.

2.9.4. Where dissociation in water occurs, the dissociation constant(s) (pKa values) of the purified active substance must be determined and reported according to OECD Test Guideline 112. The identity of the dissociated species formed, based on theoretical considerations, must be reported. If the active, substance is a salt, the pKa value of the active principle must be given.

2.10. Stability in air, photochemical degradation, identity of breakdown product(s)

An estimation of the photochemical oxidative degradation (indirect hototransformation) of the active substance, must be submitted.

2.11. Flammability including auto-flammability

2.11.1. The flammability of active substances as manufactured, which are solids, gases, or are substances which evolve highly flammable gases, must be determined and reported according to EEC method A 10, A 11 or A 12 as as appropriate.

2.11.2. The auto-flamability of active substances as manufactured must be determined and reported according to EEC method A 15 or A 16 as appropriate, and/or, where necessary according to the UN-Bowes-Cameron-Cage-Test (UN-Recommendations on the Transport of Dangerous Goods, Chapter 14, No 14.3.4).

2.12. Flash point

The flash point of active substances as manufactured with a melting point below 40 ºC, must be determined and reported according to EEC method A 9; only closed cup methods should be used.

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2.13. Explosive properties

The explosive properties of active substances as manufactured, must be determined and reported according to EEC method A 14 where necessary.

2.14. Surface tension

The surface tension has to be determined and reported according to EEC method A 5.

2.15 Oxidizing properties

The oxidizing properties of active substances as manufactured, must be determined and reported according to EEC method A 17, except where examination of its sturctural formula, establishes beyond reasonable doubt that the active substance is incapable of reacting exothermically with a combustible material. In such cases, it is sufficient to provide that information as justification for not determining the oxidizing properties of the substance.

3. *Further information on the active substance*

(i) The information provided must describe the intended purposes for which preparations containing the active substance are used, or are to be used and the dose and manner of their use or proposed use.

(ii) The information provided must specify the normal methods and precautions to be followed, in the handling, storage and transport of the active substance.

(iii) The studies, data and information submitted, together with other relevant studies, data and information, must both specify and justify the methods and precautions to be followed in the event of fire. The possible products of combustion in the event of fire should be estimated, based on the chemical structure and the chemical and physical properties of the active substance.

(iv) The studies, data and information submitted, together with other relevant studies, data and information, must demonstrate the suitability of measures proposed for use in emergency situations.

(v) The informaton and data referred to are reqired for all active substances, except where otherwise specified.

3.1. Function, e.g. fungicide, herbicide, insecticide, repellant, growth regulator

The function must be specified from among the following:

— acaricide
— bactericide
— fungicide
— herbicide
— insecticide
— molluscicide
— nematicide
— plant growth regulator
— repellant
— rodenticide
— semio-chemicals
— talpicide
— viricide
— other (must be specified)

3.2. Effects on harmful organisms, e.g. contact poison, inhalation poison, stomach poison, fungitoxic, etc. systematic or not in plants

3.2.1. The nature of the effects on harmful organisms must be stated:

— contact action
— stomach action
— inhalation action
— fungitoxic action
— fungistatic action
— desiccant
— reproduction inhibitor
— other (must be specified)

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3.2.2. It must be stated whether or not the active substance is translocated in plants and where relevant whether such translocation is apoplastic, symplastic or both.

3.3. Field of use envisaged, e.g. field, protected crops, storage of plant products, home gardening

The field(s) of use, existing and proposed, for preparations containing the active substance must be specified from among the following:

— Field use, such as agriculture, horticulture, forestry and viticulture
— Protected crops
— Amenity
— Weed control on non-cultivated areas
— Home gardening
— House plants
— Plant products storage practice
— Other (specify)

3.4. Harmful organisms controlled and crops or products protected or treated

3.4.1. Details of existing and the intended use in terms of crops, groups of crops, plants, or plant products treated and where relevant protected, must be provided.

3.4.2. Where relevant, details of harmful organisms against which protection is afforded, must be provided.

3.4.3 Where relevant, effects achieved e.g. sprout suppression, retardation of ripening, reduction in stem length, enhanced fertilization etc., must be reported.

3.5. Mode of action

3.5.1. To the extent that is has elucidated, a statement must be provided as to the mode of action of the active substance in terms, where relevant, of the biochemical and physiological mechanism(s) and biochemical pathway(s) involved. Where availble, the results of relevant experimental studies must be reported.

3.5.2. Where it is known that to exert its intended effect, the active substance must be converted to a metabolite or degradation product following application or use of preparations containing it, the following information, cross referenced to and drawing on information provided in the context of paragraphs 5.6, 5.11, 6.1, 6.2, 6.7, 7.1, 7.2 and 9, where relevant, must be provided for active metabolite or degradation product:

— chemical name according to IUPAC and CA nomenclature,
— ISO common name or porposed common name,
— CAS EEC-number EEC (EINECS or ELINCS) number, and CIPAC number if available,
— empirical and structural formula, and
— molecular mass.

3.5.3. Available information relating to the formation of active metabolites and degradation products, must be provided, to include:

— the processes, mechanisms and reactions involved,
— kinetic and other data concerning the rate of conversion and if known the rate limiting step,
— environmental and other factors effecting the rate and extent of conversion.

3.6. Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies

Where available information on possible occurrence of the development of resistance or cross-resistance must be provided.

3.7. Recommended methods and precautions concerning handling, storage, transport or fire

A safety data sheet pursuant to Article 27 of Council Directive 65/548/EEC [1] must be provided for all active substances.

[1] OJ No L 196, 16. 8. 1967, p. 1.

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3.8. Procedures for destruction or decontamination

3.8.1. Controlled incineration

In many cases the preferred or sole means to safely dispose of active substances, contaminated materials, or contaminated packaging, is through controlled incineration in a licensed incinerator.

Where the content of halogens of the active substance is greater than 60 %, the pyrolytic behaviour of the active substance under controlled conditions (including where relevant supply of oxygen and defined residence time), at 800 ºC and the content of polyhalogenated dibenzo-p-dioxins and dibenzo-furans in the products of pyrolysis must be reported. The application must provide detailed instructions for safe disposal.

3.8.2. Others

Other methods to dispose of the active substance, contaminated packaging and contaminated materials, where proposed, must be fully described. Data must be provided for such methods, to establish their effectiveness and safety.

3.9. Emergency measures in case of an accident

Procedures for the decontamination of water in case of an accident must be provided.

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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

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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.

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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*

▼B

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

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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

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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*

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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.*

▼B

ANNEX III

REQUIREMENTS FOR THE DOSSIER TO BE SUBMITTED FOR THE AUTHORIZATION OF A PLANT PROTECTION PRODUCT

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INTRODUCTION

The information required shall:

1.1. 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, animals and the environment and containing at least the information and results of the studies referred to below;

1.2. where relevant, be generated using test guidelines referred to or described in this Annex; in the case of studies initiated before the adoption of the modification of this Annex, the information shall be generated using suitable internationally or nationally validated test guidelines or, in the absence thereof, test guidelines accepted by the competent authority;

1.3. in the event of a test guideline being inappropriate or not described, or where another one than those referred to in this Annex has been used, include a justification, which is acceptable to the competent authority for the guidelines used;

1.4. include when required by the competent authority, a full description of test guidelines used, except if they are referred to or described in this Annex, and a full description of any deviations from them including a justification, which is acceptable to the competent authority, for these deviations;

1.5. include a full and unbiased report of the studies conducted as well as a full description of them or a justification, which is acceptable to the competent authority where:

— particular data and information which would not be necessary owing to the nature of the product or its proposed uses, are not provided,

or

— it is not scientifically necessary, or technically possible to supply information and data.

1.6. where relevant, have been generated in accordance with the requirements of Directive 86/609/EEC.

2.1. Tests and analyses must be conducted in accordance with the principles laid down in Directive 87/18/EEC where testing is done to obtain data on the properties and/or safety with respect to human or animal health or the environment.

2.2. Tests and analyses, required under the provisions of Section 6 points 6.2 to 6.7 of this Annex, shall be conducted by official or officially recognized testing facilites or organizations which satisfy at least the following requirements:

— have at their disposal sufficient scientific and technical staff, having the necessary education, training, technical knowledge and experience for their assigned functions,

— have at their disposal suitable items of equipment required for correct performance of the tests and measurements which it claims to be competent to carry out. This equipment shall be properly maintained and calibrated where appropriate before being put into service and thereafter according to an established programme,

— have at their disposal appropriate experimental fields and, where necessary glasshouses, growth cabinets or storage rooms. The environment in which the tests are undertaken shall not invalide its results or adversely effect the required accuracy of measurement,

— make available to all relevant personnel operating procedures and protocols used for the trials,

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— make available, where requested by the competent authority, prior to the commencement of a test, detailed information on it, containing at least its location and the plant protection products included in it,

— ensure that the quality of the work performed is appropriate to its type, range, volume and intended purpose,

— ►C2 maintain records of all original observations, calculations and derived data, ◄ calibration records and the final test report as long as the product concerned authorized in the Community.

2.3. Member States shall require that officially recognized testing facilities and organizations, and, where requested, official facilities and organizations:

— report to the relevant national authority all detailed information necessary to demonstrate that they can satisfy the requirements provided for in point 2.2,

— accept at any time the inspections, which each Member State shall regularly organize on its territory in order to verify the compliance with the requirement as laid down in point 2.2.

2.4. By way of derogation from point 2.1 the provisions of points 2.2 and 2.3 also apply until 31 December 1999 for the tests and analyses done to obtain data on the properties and/or safety with respect to honeybees and beneficial arthropods other than bees.

3. The information required shall include the proposed classification and labelling of the plant protection product in accordance with relevant Community Directives.

4. In individial cases it may be necessary to require certain information as provided for in Annex II, Part A, for formulants. Before such information will be required and before possible new studies have to be performed, all information on the formulant, made available to the competent authority, will be considered, in particular when:

— the use of the formulant is permitted in food, animal feeding stuffs, medicines or cosmetics in accordance with Community legislation, or

— a safety data sheet has been submitted for the formulant in accordance with Council Directive 67/548/EEC.

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PART A

Chemical preparations

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1. *Identity of the plant protection product*

The information provided, taken together with that provided for the active substance(s), must be sufficient to precisely identify preparations and define them in terms of their specification and nature. The information and data referred to, unless otherwise specified, are required for all plant protection products.

1.1. Applicant (name and address, etc.)

The name and address of the applicant (permanent community address) must be provided as must the name, position, telephone and telefax number of the appropriate person to contact.

Where in addition, the applicant has an office, agent or representative in the Member State in which the authorization is being sought, the name and address of the local office agent or representative should be provided, as should the name, position, telephone and telefax number of the appropriate person to contact.

1.2. Manufacturer of the preparation and the active substance(s) (names and addresses etc. including location of plants)

The name and address of the manufacturer of the preparation and of each active substance in the preparation must be provided as must the name and address of each manufacturing plant in which the preparation and active substance are manufactured.

A contact point (preferable a central contact point, to include name, telephone and telefax numbers) must be provided for each.

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If the active substance originates from a manufacturer from which data according to Annex II had not been submitted previously, a statement of purity and detailed information on the impurities in Annex II have to be provided.

1.3. Trade name or proposed trade name, and manufacturer's development code number of the preparation if appropriate

All former and current trade names and proposed trade names and development code numbers of the preparation as well as the current names and numbers must be provided. Where trade names and code numbers referred to, relate to similar but different preparations (possibly absolete), full details of the differences, must be provided. (The proposed trade name may not give rise to confusion with the trade name of already registered plant protection products.)

1.4. Detailed quantitative and qualitative information on the composition of the preparation (active substance(s), and formulants)

1.4.1. For preparations the following information must be reported:

— the content of both technical active substance(s) and pure active substance(s);

— the content of formulants.

The concentrations should be expressed in terms as provided for in Article 6 (2) of Directive 78/631/EEC.

1.4.2. For active substances their ISO common names or proposed ISO common names and their CIPAC numbers, and, where available, the EEC (EINECS or ELINCS) numbers must be provided. Where relevant it must be stated which salt, ester, anion or cation is present.

1.4.3. Formulants must where possible, be identified both by their chemical name as given in Annex I to Directive 67/548/EEC, or, if not included in this Directive, in accordance with both IUPAC and CA nomenclature. Their structure or structural formula must be provided. For each component of the formulants the relevant EEC (EINECS or ELINCS) number and CAS number where they exist, must be provided. Where the information provided does not fully identify a formulant, an appropriate specification must be provided. The trade name of formulants, where they exist, must also be provided.

1.4.4. For formulants the function must be given:

— adhesive (sticker),

— antifoaming agent,

— antifreeze,

— binder,

— buffer,

— carrier,

— deodorant,

— dispersing agent,

— dye,

— emetic,

— emulsifier,

— fertilizer,

— preservative,

— odourant,

— perfume,

— propellant,

— repellent,

— safener,

— solvent,

— stabilizer,

— synergist,

— thickener,

— wetting agent,

— miscellaneous (specify).

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1.5. Physical state and nature of the preparation (emulsifiable concentrate, wettable powder, solution etc).

1.5.1. The type and code of preparation must be designated according to the 'Catalogue of pesticide formulation types and international coding system (GIFAP Technical Monograph No 2. 1989)'.

Where a particular preparation is not defined precisely in this publication a full description of the physical nature and state of the preparation must be provided, together with a proposal for a suitable description of the type of preparation and a proposal for its definition.

1.6. Function (herbicide, insecticide, etc.)

The function must be specified from among the following:

— acaricide,
— bactericide,
— fungicide,
— herbicide
— insecticide,
— molluscicide,
— nematicide,
— plant growth regulator,
— repellant,
— rodenticide,
— semio-chemicals,
— talpicide,
— viricide,
— other (must be specified).

2. *Physical, chemical and technical properties of the plant protection product*

The extent to which plant protection products for which authorization is sought, comply with relevant FAO specifications as agreed by the Group of Experts on Pesticide Specifications, of the FAO Panel of Experts on Pesticide Specifications, Registration Requirements and Application Standards, must be stated. Divergences from FAO specifications must be described in detail, and justified.

2.1. Appearance (colour and odour)

A description of both the colour and odour, if any, and the physical state of the preparation, must be provided.

2.2. Explosivity and oxidizing properties

2.2.1. The explosive properties of preparations must be reported according to EEC method A 14. Where available thermodynamic information establishes beyond reasonable doubt that the preparation is incapable of exothermic reaction, it is sufficient to provide that information as a justification for not determining the explosive properties of the preparation.

2.2.2. Oxidizing properties of preparations which are solids must be determined and exported according to EEC method A 17. For other preparations the method used must be justified. The oxidizing properties do not have to be determined if it can be shown without reasonable doubt on the basis of thermodynamic information, that the preparation is incapable of reacting exothermically with combustible materials.

2.3. Flash point and other indications of flammability or spontaneous ignition

The flash point of liquids which contain flammable solvents, must be determined and reported according to EEC Method A 9. The flammability of solid preparations and gases must be determined and reported according to EEC methods A 10, A 11 and A 12 as appropriate. The auto-flammability of preparations must be determined and reported in accordance with EEC methods A 15 or A 16 as appropriate, and or, where necessary, according to the UN-Bowes-Cameron-Cage-Test (UN-Recommendations on the Transport of Dangerous Goods, Chapter 14, No 14.3.4).

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2.4. Acidity/alkalinity and if necessary pH value

2.4.1. In the case of preparations which are acidic (pH < 4) or alkaline (pH > 10) the acidity or alkalinity and the pH value must be determined and reported according to CIPAC Method MT 31 and MT 75 respectively.

2.4.2. Where relevant (if to be applied as aqueous dilution) the pH of a 1 % aqueous dilution, emulsion or dispersion of the preparation, must be determined and reported according to CIPAC Method MT 75.

2.5. Viscosity and surface tension

2.5.1. In the case of liquid preparations for Ultra Low Volume use (ULV) the kinematic viscosity must be determined and reported according to OECD Test Guideline 114.

2.5.2. For non newtonian liquids the viscosity must be determined and reported together with the test conditions.

2.5.3. In the case of liquid preparations the surface tension has to be determined and reported according to EEC method A 5.

2.6. Relative density and bulk density

2.6.1. The relative density of liquid preparations must be determined and reported according to EEC Method A 3.

2.6.2. The bulk (tap) density of preparations which are powders or granules, must be determined and reported according to CIPAC Methods MT 33, MT 159 or MT 169 as appropriate.

2.7. Storage — stability and shelf-life: Effects of light, temperature and humidity on technical characteristics of the plant protection product

2.7.1. The stability of the preparation after storage for 14 days at 54 ºC must be determined and reported according to CIPAC Method MT 46.

Other times and/or temperatures may be needed (e.g. eight weeks at 40 ºC or 12 weeks at 35 ºC or 18 weeks at 30 ºC) if the preparation is heat sensitive.

If the active substance content after the heat stability test has decreased by more than 5 % of the initially found content, the minimum content shall be declared and information on the degradation products shall be supplied.

2.7.2. Additionally in the case of liquid preparations, the effect of low temperatures on stability, must be determined and reported according to CIPAC Methods MT 39, MT 48, MT 51 or MT 54 as appropriate.

2.7.3. The shelf life of the preparation at ambient temperature must be reported. Where shelf life is less than two years, the shelf life in months, with appropriate temperature specifications, must be reported. Useful information is given in GIFAP Monograph No. 17.

2.8. Technical characteristics of the plant protection product

The technical characteristics of the preparation must be determined to permit a decision to be made as to its acceptability.

2.8.1. Wettability

The wettability of solid preparations which are diluted for use (e.g. wettable powders, water soluble powders, water soluble granules and water dispersible granules), must be determined and reported according to CIPAC Method MT 53.3.

2.8.2. Persistent foaming

The persistence of foaming of preparations to be diluted with water, must be determined and reported according to CIPAC Method MT 47.

2.8.3. Suspensibility and suspension stability

— The suspensibility of water dispersible products (e.g. wettable powders, water dispersible granules, suspension concentrates) must be determined and reported according to CIPAC Method MT 15, MT 161 or MT 168 as appropriate.

— The spontaneity of dispersion of water dispersible products (e.g. suspension concentrates and water dispersible granules) must be determined and reported according to CIPAC Methods MT 160 or MT 174 as appropriate.

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2.8.4. Dilution stability

The dilution stability of water soluble products must be determined and reported according to CIPAC Method MT 41.

2.8.5. Dry sieve test and wet sieve test

In order to ensure that dustable powders have a suitable particle size distribution for ease of application, a dry sieve test must be conducted and reported according to CIPAC Method MT 59.1.

In the case of water dispersible products, a wet sieve test must be conducted and reported according to CIPAC Method MT 59.3 or MT 167 as appropriate.

2.8.6. Particle size distribution (dustable and wettable powders, granules), content of dust/fines (granules), attrition and friability (granules)

2.8.6.1. The size distribution of particles in the case of powders, must be determined and reported according to OECD Method 110.

The nominal size range of granules for direct application must be determined and reported in accordance with CIPAC MT 58.3, for water dispersible granules in accordance with CIPAC MT 170.

2.8.6.2. The dust content of granular preparations, must be determined and reported according CIPAC Method MT 171. If relevant for operator exposure the particle size of dust must be determined and reported according to OECD Method 110.

2.8.6.3. The friability and attrition characteristics of granules, must be determined and reported once internationally agreed methods are available. Where already data are available they must be reported together with the method used.

2.8.7. Emulsifiability, Re-emulsifiability, emulsion stability

2.8.7.1. The emulsifiability, emulsion stability and re-emul-sifiability of preparations which form emulsions, must be determined and reported according to CIPAC Methods MT 36 or MT 173 as appropriate.

2.8.7.2. The stability of dilute emulsions and of preparations which are emulsions, must be determined and reported according to CIPAC Method MT 20 or MT 173.

2.8.8. Flowability, pourability (rinsability) and dustability

2.8.8.1. The flowability of granular preparations must be determined and reported according to CIPAC Mehtod MT 172.

2.8.8.2. The pourability (including rinsed residue) of suspensions (e.g. suspension concentrates, suspo-emulsions), must be determined and reported according to CIPAC Method MT 148.

2.8.8.3. The dustability of dustable powders following accelerated storage according 2.7.1 must be determined and reported according to CIPAC Method MT 34 or another suitable method.

2.9. Physical and chemical compatibility with other products including plant protection products with which its use is to be authorized

2.9.1. The physical compatibility of tank mixes must be reported based on in-house test methods. A practical test would be an acceptable alternative.

2.9.2. The chemical compatibility of tank mixes must be determined and reported except where examination of the individual properties of the preparations would establish beyond reasonable doubt that there is no possibility of reaction taking place. In such cases it is sufficient to provide that information as justification for not practically determining the chemical compatibility.

2.10. Adherence and distribution to seeds

In the case of preparations for seed treatment, both distribution and adhesion must be investigated and reported; in the case of distribution according to CIPAC Method MT 175.

2.11. Summary and evaluation of data presented under points 2.1. to 2.10

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3. *Data on application*

3.1. Field of use envisaged, e.g. field, protected crops, storage of plant products, home gardening

The field(s) of use, existing and proposed, for preparations containing the active substance must be specified from among the following:

— field use, such as agriculture, horticulture, forestry and viticulture,
— protected crops,
— amenity,
— weed control on non-cultivated areas,
— home gardening,
— house plants,
— plant products storage practice,
— other (specify).

3.2. Effects on harmful organisms, e.g. contact, inhalation or stomach poison, fungitoxic or fungistatic, etc., systemic or not in plants

The nature of the effects on harmful organisms must be stated:

— contact action,
— stomach action,
— inhalation action,
— fungitoxic action,
— fungistatic action,
— desiccant,
— reproduction inhibitor,
— other (must be specified).

It must be stated whether or not the product is translocated in plants.

3.3. Details of intended use e.g. types of harmful organisms controlled and/or plants or plant products to be protected

Details of the intended use must be provided.

Where relevant, effects achieved e.g. sprout suppression, retardation of ripening, reduction in stem length, enhanced fertilization etc. must be reported.

3.4. Application rate

For each method of application and each use, the rate of application per unit (ha, m^2, m^3) treated, in terms of g or kg of both preparation and active substance, must be provided.

Application rates shall normally be expressed in g or kg/ha or in kg/m^3 and where appropriate in g or kg/tonne; for protected crops and home gardening use rates shall be expressed in g or kg/100 m^2 or g or kg/m^3.

3.5. Concentration of active substance in material used (e.g. in the diluted spray, baits or treated seed)

The content of active substance shall be reported, as appropriate, in g/l, g/kg, mg/kg or in g/tonne.

3.6. Method of application

The method of application proposed must be described fully, indicating the type of equipment to be used, if any, as well as the type and volume of diluent to be used per unit of area or volume.

3.7. Number and timing of applications and duration of protection

The maximum number of applications to be used and their timing, must be reported. Where relevant the growth stages of the crop or plants to be protected and the development stages of the harmful organisms, must be indicated. Where possible the interval between applications, in days, must be stated.

The duration of protection afforded both by each application and by the maximum number of applications to be used, must be indicated.

3.8. Necessary waiting periods or other precautions to avoid phytotoxic effects on succeeding crops

Where relevant, minimum waiting periods between last application and sowing or planting of succeeding crops, which are necessary to

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avoid phytotoxic effects on succeeding crops, must be stated, and follow from the data provided under paragraph 6.6.

Limitations on choice of succeeding crops, if any, must be stated.

3.9. Proposed instructions for use

The proposed instructions for use of the preparation, to be printed on labels and leaflets, must be provided.

4. *Further information on the plant protection product*

4.1. Packaging (type, materials, size etc.), compatibility of the preparation with proposed packaging materials

4.1.1. Packaging to be used must be fully described and specified in terms of the materials used, manner of construction (e.g. extruded, welded etc.), size and capacity, size of opening, type of closure and seals. It must be designed in accordance with the criteria and guidelines specified in the FAO 'Guidelines for the Packaging of Pesticides'.

4.1.2. The suitability of the packaging, including closures, in terms of its strength, leakproofness and resistance to normal transport and handling, must be determined and reported according to ADR Methods 3552, 3553, 3560, 3554, 3555, 3556 3558, or appropriate ADR Methods for intermediate bulk containers, and, where for the preparation child-resistant closures are required, according to ISO standards 8317.

4.1.3. The resistance of the packaging material to its contents must be reported according to GIFAP Monograph No 17.

4.2. Procedures for cleaning application equipment

Cleaning procedures for both application equipment and protective clothing must be described in detail. The effectiveness of the cleaning procedure, must be fully investigated and reported.

4.3. Re-entry periods, necessary waiting periods or other precautions to protect man, livestock and the environment

The information provided must follow from and be supported by the data provided for the active substance(s) and that provided under sections 7 and 8.

4.3.1. Where relevant pre-harvest intervals, re-entry periods or withholding periods necessary to minimize the presence of residues in or on crops, plants and plant products, or in treated areas or spaces, with a view to protecting man or livestock, must be specified e.g.:

— pre-harvest interval (in days) for each relevant crop,

— re-entry period (in days) for livestock, to areas to be grazed,

— re-entry period (in hours or days) for man to crops, buildings or spaces treated,

— withholding period (in days) for animal feedingstuffs,

— waiting period (in days), between application and handling treated products, or

— waiting period (in days), between last application and sowing or planting succeeding crops.

4.3.2. Where necessary, in the light of the test results, information on any specific agricultural, plant health or environmental conditions under which the preparation may or may not be used must be provided.

4.4. Recommended methods and precautions concerning: handling, storage, transport or fire

The recommended methods and precautions concerning handling procedures (detailed) for the storage, at both warehouse and user level of plant protection products, for their transport and in the event of fire must be provided. Where available information on combustion products must be provided. The risks likely to arise and the methods and procedures to minimize the hazards arising, must be specified. Procedures to preclude or minimize the generation of waste or leftovers must be provided.

Where relevant assessment has to be done according to ISO — TR 9122.

Where appropriate the nature and characteristics of protective clothing and equipment proposed must be provided. The data provided must be

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sufficient to evaluate the suitability and effectiveness under realistic conditions of use (e.g. field or glasshouse circumstances).

4.5. Emergency measures in the case of an accident

Whether arising during transport, storage or use, detailed procedures to be followed in the event of an emergency, must be provided; and include:

— containment of spillages,

— decontamination of areas, vehicles and buildings,

— disposal of damaged packaging, adsorbents and other materials,

— protection of emergency workers and bystanders,

— first aid measures.

4.6. Procedures for destruction or decontamination of the plant protection product and its packaging

Procedures for destruction and decontamination must be developed for both small quantities (user level) and large quantities (warehouse level). The procedures must be consistent with provisions in place relating to the disposal of waste and of toxic waste. The means of disposal proposed should be without unacceptable influence on the environment and be the most cost effective and practical means of disposal feasible.

4.6.1. Possibility of neutralization

Neutralization procedures (e.g by reaction with alkali to form less toxic compounds) for use in the event of accidental spillages, must where they are feasible, be described. The products produced after neutralization should be practically or theoretically evaluated and reported.

4.6.2. Controlled incineration

In many cases the preferred or sole means to safely dispose of active substances as well as plant protection products containing it, contaminated materials, or contaminated packaging, is through controlled incineration in a lincensed incinerator.

Where the content of halogens of the active substance(s) in the preparation is greater than 60 %, the pyrolytic behaviour of the active substance under controlled conditions (including where relevant supply of oxygen and defined residence time) at 800 ºC and the content of polyhalogenated dibenzo-p-dioxins and dibenzo-furans in the products of pyrolysis must be reported. The applicant must provide detailed instructions for safe disposal.

4.6.3. Others

Other methods to dispose of plant protection products, packaging and contaminated materials, where proposed, must be fully described. Data must be provided for such methods, to establish their effectiveness and safety.

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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

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6. *Efficacy data*

General

The data supplied must be sufficient to permit an evaluation of the plant protection product to be made. In particular it must be possible to evaluate the nature and extent of benefits that accrue following use of the preparation, where they exist in comparison to suitable reference products and damage thresholds, and to define its conditions of use.

The number of trials to be conducted and reported depends mainly on factors such as the extent to which the properties of the actieve substance(s) it contains are known and on the range of conditions that arise, including variability in plant health conditions, climatic differences, the range of agriculral practices, the uniformity of the crops, the mode of application the type of harmful organism and the type of plant protection product.

Sufficient data must be generated and submitted to confirm that patterns determined hold for the regions and the range of conditions, likely to be encountered in the regions concerned, for which its use is to be recommended. Where an applicant claims that tests in one or more of the proposed regions of use are unnecessary because conditions are comparable with those in other regions where tests have been carried out, the applicant must substantiate the claim for comparability with documentary evidence.

In order to assess seasonal differences, if any, sufficient data must be generated and submitted to confirm the performance of the plant protection product in each agronomically and climatically different region for each particular crop (or commodity)/harmful organism combination. Normally trials on effectiveness or phytotoxicity, where relevant, in at least two growing seasons must be reported.

If to the opinion of the applicant the trials from the first season adequately confirm the validity of claims made on the basis of extrapolation of results from other crops, commodities or situations or from tests with closely similar preparations, a justification, which is acceptable to the competent authority for not carrying out a second seaons's work must be provided. Conversely, where, because of climatic or plant health conditions or other reasons the data obtained in any particular season are of limited value for the assessment of performance, trials in one or more further seasons must be conducted and reported.

6.1. Preliminary tests

Reports in summary form of preliminary tests, including glasshouse and field studies, used to assess the biological activity and dose range finding of the plant protection product and of the active substance(s) it contains, must be submitted when requested by the competent authority. These reports will provide additional information for the competent authority when it evaluates the plant production product. Where this information is not submitted a justification which is acceptable to the competent authority must be provided.

6.2. Testing effectiveness

Aim of the tests

The tests shall provide sufficient data to permit an evaluation of the level, duration and consistency of control or protection or other intended effects of the plant protection product in comparison to suitable reference products, where they exist.

Test conditions

Normally a trial consists of three components: test product, reference product and untreated control.

The performance of the plant protection product must be investigated in relation to suitable reference products, where they exist. A suitable reference product is defined as an authorized plant protection product which has proved a sufficient performance in practice under the agricultural, plant health and environmental (including climatic) conditions in the area of proposed use. In general, formulation type, effects on the harmful organisms, working spectrum and method of application should be close to those of the tested plant protection product.

Plant protection products must be tested in circumstances where the target harmful organism has been shown to have been present at a

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level causing or known to cause adverse effects (yield, quality, operational benefit) on an unprotected crop or area or on plants or plant products which have not been treated or where the harmful organism is present at such a level that an evaluation of the plant protection product can be made.

Trials to provide data on plant protection products for control of harmful organisms must show the level of control of the species of harmful organisms concerned or of species representative of groups for which claims are made. Trials must include the different stages of growth of life cycle of the harmful species, where this is relevant and the different strains or races, where these are likely to show different degrees of susceptibility.

Similarly, trials to provide data on plant protection products which are plant growth regulators, must how the level of effects on the species to be treated, and include investigation of differences in the response of a representative sample of the range of cultivars on which its use is proposed.

In order to clarify the dose response, dose rates lower than the recommended one must be included in some trials in order to enable to assess whether the recommended rate is the minimum necessary to achieve the desired effect.

The duration of the effects of treatment must be investigated in relation to the control of the target organism or effect on the treated plants or plant products, as appropriate. When more than one application is recommended, trials must be reported which establish the duration of the effects of an application, the number of applications necessary and the desired intervals between them.

Evidence must be submitted to show that the dose, timing and medthod of application recommended give adequate control, protection or have the intended effect in the range of circumstances likely to be encountered in practical use.

Unless there are clear indications that the performance of the plant protection production is unlikely to be affected to a significant degree by environemental factors, such as temperature or rain, an investigation of the effects of such factors on performace must be carried out and reported, particularly where it is known that the performance of chemically related products os so affected.

Where proposed label claims include recommendations for the use of the plant protection product with other plant protection product(s) or adjuvant(s) information on the performance of the mixture must be provided.

Test guideline

Trials must be designed to investigate specified issues, to minimize the effects of random variation between different parts of each site and to enable statistical analysis to be applied to results amenable to such analysis. The design, analysis and reporting of trials must be in accordance with European and Mediterranean Plant Protection Organization (EPPO) guidelines 152 and 181. The report shall include a detailed and critical assessment of the data.

The trials must be carried out in accordance to specific EPPO guidelines, where available, or when a requires so and when the test is carried out on the territory of this, with guidelines satisfying at least the requirements of the corresponding EPPO guideline.

A statistical analysis of results amenable to such analysis must be carried out; where necessary the test guideline used must be adapted to enable such analysis.

6.3. Information on the occurrence or possible occurrence of the development of resistance

Laboratory data and where it exists, field information relating to the occurrence and development of resistance or cross-resistance in populations of harmful organisms to the active substance(s), or to related actived substances, must be provided. Where such information is not directly relevant to the uses for which authorization is ought or to be renewed (different species of harmful organism or different crops), it must, if available, nevertheless be provided, as it may provide and indication of the likelihood of resistance developing in the target population.

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Where there is evidence or information to suggest that, in commercial use, the development of resistance is likely, evidence must be generated and submitted as to the sensitivity of the population of the harmful organism concerned to the plant protection product. In such cases a management strategy designed to minimize the likelihood of resistance or cross-resistance developing in target species must be provided.

6.4. Effects on the yield of treated plants or plant products in terms of quantity and/or quality

6.4.1. Effects on the quality of plants or plant product

Aim of the tests

The tests shall provide sufficient data to permit an evaluation of the possible occurrence of taint or odour or other quality aspects of plants or plant products after treatment with the plant protection product.

Circumstances in which required

The possibility of the occurrence of taint or odour in food crops must be investigated and be reported where:

— the nature of the products or its use is such that a risk of occurrence of taint or odour might be expected,

or

— other products based on the same or a closely similar active ingredient have been shown to present a risk of occurrence of taint or odour.

The effects of plant protection products on other quality aspects of treated plants or plant products must be investigated and reported where:

— the nature of the plant protection product or it use could have an adverse influence on other quality aspects (for example in the case of use of plant growth regulators close or harvest), or

— other products based on the same or a closely similar active ingredient have been shown to have an adverse influence on the quality.

Testing should be conducted initially on the main crops on which the plant protection product is to be used, at twice the normal rates of application and using, where relevant, the main methods of processing. Where effects are observed it is necessary to perform testing at the normal rate of application.

The extent of investigation necessary on other crops will depend on their degree of similarity of the main crops already tested, the quantity and quality of data available on those main crops and how far the manner of use of the plant protection product and methods of processing the crops, are similar. It is generally sufficient to perform the test with the main formulation type to be authorized.

6.4.2. Effects on transformation processes

Aim of the tests

The tests shall provide sufficient data to permit an evaluation of the possible occurrence of adverse effects after treatment with the plant protection product on transformation processes or on the quality of their products.

Circumstances in which required

When the treated plants or plant products are normally intended for use in transformation process such as wine making, brewing or bread making and when at harvest significant residues are present, the possibility of the occurrence of adverse effects must be investigated and reported where:

— there are indications that the use of the plant protection product could have an influence on the processes involved (for example in the case of use of plant growth regulators or fungicides close to harvest),

or

— other products based on the same or a closely similar active ingredient have been shown to have an adverse influence on these processes or its products.

It is generally sufficient to perform the test with the main formulation type to be authorized.

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6.4.3. Effects on the yield of treated plants or plant products

Aim of the tests

The test shall provide sufficient data to permit an evaluation of the performance of the plant protection product and of possible occurrence of yield reduction or loss in storage of treated plants or plant products.

Circumstances in which required

The effects of plant protection products on the yield or yield components of treated plant products must be determined where relevant. When treated plants or plant products are likely to be stored the effect on the yield after storage, including data on starage life must be determined where relevant.

This information will normally be available from the tests required under the provisions of point 6.2.

6.5. Phytotoxicity to target plants (including different cultivars), or to target plant products

Aim of the tests

The test shall provide sufficient data to permit an evaluation of the performance of the plant protection product and of the possible occurrence of phytotoxicity after treatment with the plant protection product.

Circumstances in which required

For herbicides and for other plant protection products for which adverse effects, however transitory, are seen during the trials, performed in accordance to point 6.2, the margins of selectivity on target crops must be established, using twice the recommended rate of application. Where serious phytotoxic effects are seen, an intermediate application rate must also be investigated.

Where adverse effects occur, but are claimed to be unimportant in comparison with the benefits of use or transient, evidence to support this claim is required. If necessary yield measurement must be submitted.

The safety of a plant protection product to the main cultivars of the main crops for which it is recommended must be demonstrated, including effects of crop growh stage, vigour, and other factors which may influence suspectibility to damage or injury.

The extent of investigation necessary on other crops will depend on their degree of similarity to the main crops already tested, the quantity and quality of data available on those main crops and how far the manner of use of the plant protection product, if relevant, is similar. It is generally sufficient to perform the test with the main formulation type to be authorized.

Where proposed label claims include recommendations for the use of the plant protection product with other plant protection product(s), the provisions of the previous paragraphs apply for the mixture.

Test guideline

Observations concerning phytotoxicity must be performed in the tests provided for under point 6.2.

Where phytotoxic effects are seen, they must be accurately assessed and recorded in accordance with EPPO guideline 135 or when a Member State requires so and when the test is carried out on the territory of this Member State, with guidelines satisfying at least the requirements of this EPPO guideline.

A statistical analysis of results amenable to such analysis must be carried out, where necessary the test guideline used must be adapted to enable such analysis.

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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)

6.6.1. Impact on succeeding crops

Aim of the information required

Sufficient data must be reported to permit an evaluation of possible adverse effects of a treatment with the plant protection product on succeeding crops.

Circumstances in which required

Where data, generated in accordance with Section 9, point 9.1, shows that signification residues of the active substance, its metabolites or degradation products, which have or may have biological activity on succeeding crops, remain in soil or in plant materials, such as straw or organic material up to sowing or planting time of possible succeeding crops, observations must be submitted on effects on the normal range of succeedings crops.

6.6.2. Impact on other plants, including adjacent crops

Aim of the information required

Sufficient data must be reported to permit an evaluation of possible adverse effects of a treatment with the plant protection product on other plants, including adjacent crops.

Circumstances in which required

Observations must be submitted on adverse effects on other plants, including the normal range of adjacent crops, when there are indications that the plant protection product could affect these plants via vapour drift.

6.6.3. Impact on treated plants or plant products to be used for propagation

Aim of the information required

Sufficient data must be reported to permit an evaluation of possible adverse effects of a treatment with the plant protection product on plants or plant products ot be used for propagation.

Circumstances in which required

Observations must be submitted on the impact of plant protection products on plant parts used for propagation except where the proposed uses preclude use on crops intended for production of seeds, cuttings, runners or tubers for planting, as appropriate.

(i) for seeds — viability, germination and vigour;

(ii) cuttings — rooting and growth rates;

(iii) runners — establishment and growth rates;

(iv) tubers — sprouting and normal growth.

Test guideline

Seeds testing shall be done according to ISTA Methods [1].

6.6.4. Effects on beneficial and other non-target organisms

Any effects, positive or negative, on the incidence of other harmful organisms, observed in the tests performed in accordance with the requirements of this section, shall be reported. Any observed environmental effects must also be reported, especially effects on wildlife and/or beneficial organisms.

6.7. Summary and evaluation of data presented under 6.1 to 6.6

A summary of all data and informations provided under points 6.1 to 6.6 must be provided, together with a detailed and a critical assessment of the data, with particular reference to the benefits that the plant protection product offers, adverse effects that do or may arise and measures necessary to avoid or minimize adverse effects.

[1] International rules for seed testing, 1985. Proceedings of the International Seed Testing Association, *Seed Science and Technology*, Volume 13, No 2, 1985.

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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

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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.)

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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

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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

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6. *Efficacy data*

General

The data supplied must be sufficient to permit an evaluation of the plant protection product to be made. In particular it must be possible to evaluate the nature and extent of benefits that accrue following use of the preparation, where they exist in comparison to suitable reference products and damage thresholds, and to define its conditions of use.

The number of trials to be conducted and reported depends mainly on factors such as the extent to which the properties of the actieve substance(s) it contains are known and on the range of conditions that arise, including variability in plant health conditions, climatic differences, the range of agriculral practices, the uniformity of the crops, the mode of application the type of harmful organism and the type of plant protection product.

Sufficient data must be generated and submitted to confirm that patterns determined hold for the regions and the range of conditions, likely to be encountered in the regions concerned, for which its use is to be recommended. Where an applicant claims that tests in one or more of the proposed regions of use are unnecessary because conditions are comparable with those in other regions where tests have been carried out, the applicant must substantiate the claim for comparability with documentary evidence.

In order to assess seasonal differences, if any, sufficient data must be generated and submitted to confirm the performance of the plant protection product in each agronomically and climatically different region for each particular crop (or commodity)/harmful organism combination. Normally trials on effectiveness or phytotoxicity, where relevant, in at least two growing seasons must be reported.

If to the opinion of the applicant the trials from the first season adequately confirm the validity of claims made on the basis of extrapolation of results from other crops, commodities or situations or from tests with closely similar preparations, a justification, which is acceptable to the competent authority for not carrying out a second seaons's work must be provided. Conversely, where, because of climatic or plant health conditions or other reasons the data obtained in any particular season are of limited value for the assessment of performance, trials in one or more further seasons must be conducted and reported.

6.1. Preliminary tests

Reports in summary form of preliminary tests, including glasshouse and field studies, used to assess the biological activity and dose range finding of the plant protection product and of the active substance(s) it contains, must be submitted when requested by the competent authority. These reports will provide additional information for the competent authority when it evaluates the plant production product. Where this information is not submitted a justification which is acceptable to the competent authority must be provided.

6.2. Testing effectiveness

Aim of the tests

The tests shall provide sufficient data to permit an evaluation of the level, duration and consistency of control or protection or other

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intended effects of the plant protection product in comparison to suitable reference products, where they exist.

Test conditions

Normally a trial consists of three components: test product, reference product and untreated control.

The performance of the plant protection product must be investigated in relation to suitable reference products, where they exist. A suitable reference product is defined as an authorized plant protection product which has proved a sufficient performance in practice under the agricultural, plant health and environmental (including climatic) conditions in the area of proposed use. In general, formulation type, effects on the harmful organisms, working spectrum and method of application should be close to those of the tested plant protection product.

Plant protection products must be tested in circumstances where the target harmful organism has been shown to have been present at a level causing or known to cause adverse effects (yield, quality, operational benefit) on an unprotected crop or area or on plants or plant products which have not been treated or where the harmful organism is present at such a level that an evaluation of the plant protection product can be made.

Trials to provide data on plant protection products for control of harmful organisms must show the level of control of the species of harmful organisms concerned or of species representative of groups for which claims are made. Trials must include the different stages of growth of life cycle of the harmful species, where this is relevant and the different strains or races, where these are likely to show different degrees of susceptibility.

Similarly, trials to provide data on plant protection products which are plant growth regulators, must how the level of effects on the species to be treated, and include investigation of differences in the response of a representative sample of the range of cultivars on which its use is proposed.

In order to clarify the dose response, dose rates lower than the recommended one must be included in some trials in order to enable to assess whether the recommended rate is the minimum necessary to achieve the desired effect.

The duration of the effects of treatment must be investigated in relation to the control of the target organism or effect on the treated plants or plant products, as appropriate. When more than one application is recommended, trials must be reported which establish the duration of the effects of an application, the number of applications necessary and the desired intervals between them.

Evidence must be submitted to show that the dose, timing and medthod of application recommended give adequate control, protection or have the intended effect in the range of circumstances likely to be encountered in practical use.

Unless there are clear indications that the performance of the plant protection production is unlikely to be affected to a significant degree by environemental factors, such as temperature or rain, an investigation of the effects of such factors on performace must be carried out and reported, particularly where it is known that the performance of chemically related products os so affected.

Where proposed label claims include recommendations for the use of the plant protection product with other plant protection product(s) or adjuvant(s) information on the performance of the mixture must be provided.

Test guideline

Trials must be designed to investigate specified issues, to minimize the effects of random variation between different parts of each site and to enable statistical analysis to be applied to results amenable to such analysis. The design, analysis and reporting of trials must be in accordance with European and Mediterranean Plant Protection Organization (EPPO) guidelines 152 and 181. The report shall include a detailed and critical assessment of the data.

The trials must be carried out in accordance to specific EPPO guidelines, where available, or when a requires so and when the test is

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carried out on the territory of this, with guidelines satisfying at least the requirements of the corresponding EPPO guideline.

A statistical analysis of results amenable to such analysis must be carried out; where necessary the test guideline used must be adapted to enable such analysis.

6.3. Information on the occurrence or possible occurrence of the development of resistance

Laboratory data and where it exists, field information relating to the occurrence and development of resistance or cross-resistance in populations of harmful organisms to the active substance(s), or to related actived substances, must be provided. Where such information is not directly relevant to the uses for which authorization is ought or to be renewed (different species of harmful organism or different crops), it must, if available, nevertheless be provided, as it may provide and indication of the likelihood of resistance developing in the target population.

Where there is evidence or information to suggest that, in commercial use, the development of resistance is likely, evidence must be generated and submitted as to the sensitivity of the population of the harmful organism concerned to the plant protection product. In such cases a management strategy designed to minimize the likelihood of resistance or cross-resistance developing in target species must be provided.

6.4. Effects on the yield of treated plants or plant products in terms of quantity and/or quality

6.4.1. Effects on the quality of plants or plant product

Aim of the tests

The tests shall provide sufficient data to permit an evaluation of the possible occurrence of taint or odour or other quality aspects of plants or plant products after treatment with the plant protection product.

Circumstances in which required

The possibility of the occurrence of taint or odour in food crops must be investigated and be reported where:

— the nature of the products or its use is such that a risk of occurrence of taint or odour might be expected,

or

— other products based on the same or a closely similar active ingredient have been shown to present a risk of occurrence of taint or odour.

The effects of plant protection products on other quality aspects of treated plants or plant products must be investigated and reported where:

— the nature of the plant protection product or it use could have an adverse influence on other quality aspects (for example in the case of use of plant growth regulators close or harvest), or

— other products based on the same or a closely similar active ingredient have been shown to have an adverse influence on the quality.

Testing should be conducted initially on the main crops on which the plant protection product is to be used, at twice the normal rates of application and using, where relevant, the main methods of processing. Where effects are observed it is necessary to perform testing at the normal rate of application.

The extent of investigation necessary on other crops will depend on their degree of similarity of the main crops already tested, the quantity and quality of data available on those main crops and how far the manner of use of the plant protection product and methods of processing the crops, are similar. It is generally sufficient to perform the test with the main formulation type to be authorized.

6.4.2. Effects on transformation processes

Aim of the tests

The tests shall provide sufficient data to permit an evaluation of the possible occurrence of adverse effects after treatment with the plant protection product on transformation processes or on the quality of their products.

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Circumstances in which required

When the treated plants or plant products are normally intended for use in transformation process such as wine making, brewing or bread making and when at harvest significant residues are present, the possibility of the occurrence of adverse effects must be investigated and reported where:

— there are indications that the use of the plant protection product could have an influence on the processes involved (for example in the case of use of plant growth regulators or fungicides close to harvest),

or

— other products based on the same or a closely similar active ingredient have been shown to have an adverse influence on these processes or its products.

It is generally sufficient to perform the test with the main formulation type to be authorized.

6.4.3. Effects on the yield of treated plants or plant products

Aim of the tests

The test shall provide sufficient data to permit an evaluation of the performance of the plant protection product and of possible occurrence of yield reduction or loss in storage of treated plants or plant products.

Circumstances in which required

The effects of plant protection products on the yield or yield components of treated plant products must be determined where relevant. When treated plants or plant products are likely to be stored the effect on the yield after storage, including data on starage life must be determined where relevant.

This information will normally be available from the tests required under the provisions of point 6.2.

6.5. Phytotoxicity to target plants (including different cultivars), or to target plant products

Aim of the tests

The test shall provide sufficient data to permit an evaluation of the performance of the plant protection product and of the possible occurrence of phytotoxicity after treatment with the plant protection product.

Circumstances in which required

For herbicides and for other plant protection products for which adverse effects, however transitory, are seen during the trials, performed in accordance to point 6.2, the margins of selectivity on target crops must be established, using twice the recommended rate of application. Where serious phytotoxic effects are seen, an intermediate application rate must also be investigated.

Where adverse effects occur, but are claimed to be unimportant in comparison with the benefits of use or transient, evidence to support this claim is required. If necessary yield measurement must be submitted.

The safety of a plant protection product to the main cultivars of the main crops for which it is recommended must be demonstrated, including effects of crop growh stage, vigour, and other factors which may influence suspectibility to damage or injury.

The extent of investigation necessary on other crops will depend on their degree of similarity to the main crops already tested, the quantity and quality of data available on those main crops and how far the manner of use of the plant protection product, if relevant, is similar. It is generally sufficient to perform the test with the main formulation type to be authorized.

Where proposed label claims include recommendations for the use of the plant protection product with other plant protection product(s), the provisions of the previous paragraphs apply for the mixture.

Test guideline

Observations concerning phytotoxicity must be performed in the tests provided for under point 6.2.

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Where phytotoxic effects are seen, they must be accurately assessed and recorded in accordance with EPPO guideline 135 or when a Member State requires so and when the test is carried out on the territory of this Member State, with guidelines satisfying at least the requirements of this EPPO guideline.

A statistical analysis of results amenable to such analysis must be carried out, where necessary the test guideline used must be adapted to enable such analysis.

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)

6.6.1. Impact on succeeding crops

Aim of the information required

Sufficient data must be reported to permit an evaluation of possible adverse effects of a treatment with the plant protection product on succeeding crops.

Circumstances in which required

Where data, generated in accordance with Section 9, point 9.1, shows that signification residues of the active substance, its metabolites or degradation products, which have or may have biological activity on succeeding crops, remain in soil or in plant materials, such as straw or organic material up to sowing or planting time of possible succeeding crops, observations must be submitted on effects on the normal range of succeedings crops.

6.6.2. Impact on other plants, including adjacent crops

Aim of the information required

Sufficient data must be reported to permit an evaluation of possible adverse effects of a treatment with the plant protection product on other plants, including adjacent crops.

Circumstances in which required

Observations must be submitted on adverse effects on other plants, including the normal range of adjacent crops, when there are indications that the plant protection product could affect these plants via vapour drift.

6.6.3. Impact on treated plants or plant products to be used for propagation

Aim of the information required

Sufficient data must be reported to permit an evaluation of possible adverse effects of a treatment with the plant protection product on plants or plant products ot be used for propagation.

Circumstances in which required

Observations must be submitted on the impact of plant protection products on plant parts used for propagation except where the proposed uses preclude use on crops intended for production of seeds, cuttings, runners or tubers for planting, as appropriate.

(i) for seeds — viability, germination and vigour;

(ii) cuttings — rooting and growth rates;

(iii) runners — establishment and growth rates;

(iv) tubers — sprouting and normal growth.

Test guideline

Seeds testing shall be done according to ISTA Methods [1].

6.6.4. Effects on beneficial and other non-target organisms

Any effects, positive or negative, on the incidence of other harmful organisms, observed in the tests performed in accordance with the requirements of this section, shall be reported. Any observed environ-

[1] International rules for seed testing, 1985. Proceedings of the International Seed Testing Association, *Seed Science and Technology*, Volume 13, No 2, 1985.

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mental effects must also be reported, especially effects on wildlife and/or beneficial organisms.

6.7. Summary and evaluation of data presented under 6.1 to 6.6

A summary of all data and informations provided under points 6.1 to 6.6 must be provided, together with a detailed and a critical assessment of the data, with particular reference to the benefits that the plant protection product offers, adverse effects that do or may arise and measures necessary to avoid or minimize adverse effects.

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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

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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

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ANNEX IV

RISK PHRASES

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ANNEX V

SAFETY PHRASES

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ANNEX VI

UNIFORM PRINCIPLES FOR EVALUATION AND AUTHORIZATION OF PLANT PRODUCTION PRODUCTS

CONTENTS

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A. **INTRODUCTION**

1. The principles developed in this Annex aim to ensure that evaluations and decisions with regard to authorization of plant protection products, provided they are chemical preparations, result in the implementation of the requirements of Article 4 (1) (b), (c), (d) and (e) of this Directive by all the Member States at the high level of protection of human and animal health and the environment.

2. In evaluating applications and granting authorizations Member States shall:

   (a) — ensure that the dossier supplied is in accordance with the requirements of Annex III, at the latest at the time of finalization of the evaluation for the purpose of decision-making without prejudice, where relevant, to the provisions of Article 13 (1) (a), (4) and (6) of this Directive,

   — ensure that the data submitted are acceptable in terms of quantity, quality, consistency and reliability and sufficient to permit a proper evaluation of the dossier,

   — evaluate, where relevant, justifications submitted by the applicant for not supplying certain data;

   (b) take into account the Annex II data concerning the active substance in the plant protection product, submitted for the purpose of inclusion of the active substance concerned in Annex I, and the results of the evaluation of those data, without prejudice, where relevant, to the provisions of Article 13 (1) (b), (2), (3) and (6) of this Directive;

   (c) take into consideration other relevant technical or scientific information they can reasonably possess with regard to the performance of the plant protection product or to the potentially adverse effects of the plant protection product, its components or its residues.

3. Where in the specific principles on evaluation reference is made to Annex II data, this shall be understood as being the data referred to in point 2 (b).

4. Where the data and information provided are sufficient to permit completion of the evaluation for one of the proposed uses, applications must be evaluated and a decision made for the proposed use.

   Taking account of justifications provided and with the benefit of any subsequent clarifications, Member States shall reject applications for which the data gaps are such that it is not possible to finalize the evaluation and to make a reliable decision for at least one of the proposed uses.

5. During the process of evaluation and decision-making, Member States shall cooperate with the applicants in order to resolve any questions on the dossier quickly or to identify at an early stage any additional studies necessary for a proper evaluation of the dossier, or to amend any proposed conditions for the use of the plant protection product or to modify its nature or its composition in order to ensure full satisfaction of the requirements of this Annex or of this Directive.

   Member States shall normally come to a reasoned decision within 12 months of receiving a technically complete dossier. A technically complete dossier is one that satisfies all the requirements of Annex III.

6. The judgments made by the competent authorities of the Member States during the evaluation and decision-making process must be based on scientific principles, preferably recognized at international level (for example, by the EPPO), and be made with the benefit of expert advice.

B. **EVALUATION**

1. **General principles**

   1. Having regard to current scientific and technical knowledge, Member States shall evaluate the information referred to in Part A, point 2, and in particular:

      (a) assess the performance in terms of efficacy and phytotoxicity of the plant protection product for each use for which authorization is sought; and

      (b) identify the hazards arising, assess their significance and make a judgment as to the likely risks to humans, animals or the environment.

   2. In accordance with the terms of Article 4 of this Directive, which *inter alia* specifies that Member States shall have regard to all normal condi-

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tions under which the plant protection product may be used, and to the consequences of its use, Member States shall ensure that evaluations carried out have regard to the proposed practical conditions of use and in particular to the purpose of use, the dose, the manner, frequency and timing of applications, and the nature and composition of the preparation. Whenever possible Memeber States shall also take into account the principles of integrated control.

3. In the evaluation of applications submitted, Member States shall have regard to the agricultural, plant health or environmental (including climatic) conditions in the areas of use.

4. In interpreting the results of evaluations, Member States shall take into consideration possible elements of uncertainty in the information obtained during the evaluation, in order to ensure that the chances of failing to detect adverse effects or of under-estimating their importance are reduced to a minimum. The decision-making process shall be examined to identify critical decision points or items of data for which uncertainties could lead to a false classification of risk.

   The first evaluation made shall be based on the best available data or estimates reflecting the realistic conditions of use of the plant protection product.

   This should be followed by a repeat evaluation, taking account of potential uncertainties in the critical data and of a range of use conditions that are likely to occur and resulting in a realistic worst-case approach, to determine whether it is possible that the initial evaluation could have been significantly different.

5. Where specific principles of Section 2 provide for the use of calculation models in the evaluation of a plant protection product, those models shall:

   — make a best possible estimation of all relevant processes involved taking into account realistic parameters and assumptions,

   — be submitted to an analysis as referred to in B, point 1.4,

   — be reliably validated with measurements carried out under circumstances relevant for the use of the model,

   — be relevant to the conditions in the area of use.

6. Where metabolites, degradation or reaction products are referred to in the specific principles, only those that are relevant for the proposed criterion shall be taken into consideration.

2. **Specific principles**

Member States shall, for the evaluation of the data and information submitted in support of applications, and without prejudice to the general principles of Section 1, implement the following principles.

2.1. *Efficacy*

2.1.1. Where the proposed use concerns the control of or protection against an organism, Member States shall evaluate the possibility that this organism could be harmful under the agricultural, plant health and environmental (including climatic) conditions in the area of the proposed use.

2.1.2. Where the proposed use concerns an effect other than the control of or protection against an organism, Member States shall evaluate whether significant damage, loss or inconvenience could occur under the agricultural, plant health and environmental (including climatic) conditions in the area of proposed use if the plant protection product were not used.

2.1.3. Member States shall evaluate the efficacy data on the plant protection product as provided for in Annex III having regard to the degree of control or the extent of the effect desired and having regard to the relevant experimental conditions such as:

   — the choice of the crop or cultivar,

   — the agricultural and environmental (including climatic) conditions,

   — the presence and density of the harmful organism,

   — the development stage of crop and organism,

   — the amount of the plant protection product used,

   — if required on the label, the amount of adjuvant added,

   — the frequency and timing of the applications,

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— the type of application equipment.

2.1.4. Member States shall evaluate the performance of the plant protection product in a range of agricultural, plant health and environmental (including climatic) conditions likely to be encountered in practice in the area of proposed use and in particular:

(i) the level, consistency and duration of the effect sought in relation to the dose in comparison with a suitable reference product or products and an untreated control,

(ii) where relevant, effect on yield or reduction of loss in storage, in terms of quantity and/or quality, in comparison with a suitable reference product or products and an untreated control.

Where no suitable reference product exists, Member States shall evaluate the performance of the plant protection product to determine whether there is a consistent and defined benefit under the agricultural, plant health and environmental (including climatic) conditions in the area of proposed use.

2.1.5. Where the product label includes requirements for use of the plant protection product with other plant protection products and/or with adjuvants as a tank mix, Member States shall make the evaluations referred to in points 2.1.1 to 2.1.4 in relation to the information supplied for the tank mix.

Where the product label includes recommendations for use of the plant protection product with other plant protection products and/or with adjuvants as a tank mix, Member States shall evaluate the appropriateness of the mix and of its conditions of use.

2.2. *Absence of unacceptable effects on plants or plant products*

2.2.1. Member States shall evaluate the degree of adverse effects on the treated crop after use of the plant protection product according to the proposed conditions of use in comparison, where relevant, with suitable reference product or products, where they exist, and/or an untreated control.

(a) This evaluation will take into consideration the following information:

(i) the efficacy data provided for in Annex III;

(ii) other relevant information on the plant protection product such as nature of the preparation, dose, method of application, number and timing of applications;

(iii) all relevant information on the active substance as provided for in Annex II, including mode of action, vapour pressure, volatility and water solubility.

(b) This evaluation will include:

(i) the nature, frequency, level and duration of observed phytotoxic effects and the agricultural, plant health and environmental (including climatic) conditions that affect these;

(ii) the differences between main cultivars with regard to their sensitivity to phytotoxic effects;

(iii) the part of the treated crop or plant products where phytotoxic effects are observed;

(iv) the adverse impact on the yield of the treated crop or plant products in terms of quantity and/or quality;

(v) the adverse impact on treated plants or plant products to be used for propagation, in terms of viability, germination, sprouting, rooting and establishment;

(vi) where volatile products are concerned, the adverse impact on adjacent crops.

2.2.2. Where the available data indicate that the active substance or significant metabolites, degradation and reaction products persist in soils and/or in or on plant substances in significant quantities after use of the plant protection product according to the proposed conditions of use, Member States shall evaluate the degree of adverse effects on subsequent crops. This evaluation will be carried out as specified in point 2.2.1.

2.2.3. Where the product label includes requirements for use of the plant protection product with other plant protection products or with adjuvants as a tank mix, the evaluation as specified in point 2.2.1 will be carried out in relation to the information supplied for the tank mix.

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2.3. *Impact on vertebrates to be controlled*

Where the proposed use of the plant protection product aims to have an effect on vertebrates, Member States shall evaluate the mechanism by which this effect is obtained and the observed effects on the behaviour and health of the target animals; when the intended effect is to kill the target animal they shall evaluate the time necessary to obtain the death of the animal and the conditions under which death occurs.

This evaluation will take into consideration the following information:

(i) all relevant information as provided for in Annex II and the results of the evaluation thereof, including the toxicological and metabolism studies;

(ii) all relevant information on the plant protection product as provided for in Annex III, including toxicological studies and efficacy data.

2.4. *Impact on human or animal health*

2.4.1. Arising from the plant protection product

2.4.1.1. Member States shall evaluate operator exposure to active substance and/or to toxicologically relevant compounds in the plant protection product likely to occur under the proposed conditions of use (including in particular dose, application method and climatic conditions) using by preference realistic data on exposure and, if such data are not available, as suitable, validated calculation model.

(a) This evaluation will take into consideration the following information:

(i) the toxicological and metabolism studies as provided for in Annex II and the results of the evaluation thereof including the acceptable operator exposure level (AOEL). The acceptable operator exposure level is the maximum amount of active substance to which the operator may be exposed without any adverse health effects. The AOEL is expressed as milligrams of the chemical per kilogram body weight of the operator. The AOEL is based on the highest level at which no adverse effect is observed in tests in the most sensitive relevant animal species or, if appropriate data are available, in humans;

(ii) other relevant information on the active substances such as physical and chemical properties;

(iii) the toxicological studies provided for in Annex III, including where appropriate dermal absorption studies;

(iv) other relevant information as provided for in Annex III such as:

— composition of the preparation,

— nature of the preparation,

— size, design and type of packaging,

— field of use and nature of crop or target,

— method of application including handling, loading and mixing of product,

— exposure reduction measures recommended,

— protective clothing recommendations,

— maximum application rate,

— minimum spray application volume stated on the label,

— number and timing of applications.

(b) This evaluation shall be made for each type of application method and application equipment proposed for use of the plant protection product as well as for the different types and sizes of containers to be used, taking account of mixing, loading operations, application of the plant protection product and cleaning and routine maintenance of application equipment.

2.4.1.2. Member States shall examine information relating to the nature and characteristics of the packaging proposed with particular reference to the following aspects:

— the type of packaging,

— its dimensions and capacity,

— the size of the opening,

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— the type of closure,

— its strength, leakproofness and resistance to normal transport and handling,

— its resistance to and compatibility with the contents.

2.4.1.3. Member States shall examine the nature and characteristics of the protective clothing and equipment proposed with particular reference to the following aspects:

— obtainability and suitability,

— ease of wearing taking into account physical stress and climatic conditions.

2.4.1.4. Member States shall evaluate the possibility of exposure of other humans (bystanders or workers exposed after the application of the plant protection product) or animals to the active substance and/or to other toxicologically relevant compounds in the plant protection product under the proposed conditions of use.

This evaluation will take into consideration the following information:

(i) the toxicological and metabolism studies on the active substance as provided for in Annex II and the results of the evaluation thereof, including the acceptable operator exposure level,

(ii) the toxicological studies provided for in Annex III, including where appropriate dermal absorption studies,

(iii) other relevant information on the plant protection product as provided for in Annex III such as:

— re-entry periods, necessary waiting periods or other precautions to protect humans and animals,

— method of application, in particular spraying,

— maximum application rate,

— maximum spray application volume,

— composition of the preparation,

— excess remaining on plants and plant products after treatment,

— further activities whereby workers are exposed.

2.4.2. Arising from residues

2.4.2.1. Member States shall evaluate the specific information on toxicology as provided for in Annex II and in particular:

— the determination of an acceptable daily intake (ADI),

— the identification of metabolites, degradation and reaction products in treated plants or plant products,

— behaviour of residues of the active substance and its metabolites from the time of application until harvest, or in the case of post-harvest uses, until outloading of stored plant products.

2.4.2.2. Prior to evaluating the residue levels in the reported trials or in products of animal origin Member States shall examine the following information:

— data on the proposed good agricultural practice, including data on application as provided for in Annex III and proposed pre-harvest intervals for envisaged uses, or withholding periods or storage periods, in case of post-harvest uses,

— nature of preparation,

— analytical methods and the residue definition.

2.4.2.3. On the basis of suitable statistical models Member States shall evaluate the residue levels observed in the reported trials. This evaluation shall be made for each proposed use and shall take into consideration:

(i) the proposed conditions of use of the plant protection product;

(ii) the specific information on residues in or on treated plants, plant products, food and feed as provided for in Annex III and the distribution of residues between edible and non-edible parts;

(iii) the specific information on residues in or on treated plants, plant products, food and feed as provided for in Annex II and the results of the evaluation thereof;

(iv) the realistic possibilities of extrapolating data from one crop to another.

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2.4.2.4. Member States shall evaluate the residue levels observed in products of animal origin, taking into consideration the information provided for in Annex III, Part A, point 8.4 and residues resulting from other uses.

2.4.2.5. Member States shall estimate the potential exposure of consumers through diet and, where relevant, other ways of exposure, using as suitable calculation model. This evaluation will take account, where relevant, of other sources of information such as other authorized uses of plant protection products containing the same active substance or which give rise to the same residues.

2.4.2.6. Member States shall, where relevant, estimate the exposure of animals, taking into account residue levels observed in treated plants or plant products intended to be fed to animals.

2.5. *Influence on the environment*

2.5.1. Fate and distribution in the environment

In the evaluation of the fate and distribution of the plant protection product in the environment, Member States shall have regard to all aspects of the environment, including biota, and in particular to the following:

2.5.1.1. Member States shall evaluate the possibility of the plant protection product reaching the soil under the proposed conditions of use; if this possibility exists they shall estimate the rate and the route of degradation in the soil, the mobility in the soil and the change in the total concentration (extractable and non-extractable (*)) of the active substance and of relevant metabolites, degradation and reaction products that could be expected in the soil in the area of envisaged use after use of the plant protection product according to the proposed conditions of use.

This evaluation will take into consideration the following information:

(i) the specific information on fate and behaviour in soil as provided for in Annex II and the results of the evaluation thereof;

(ii) other relevant information on the active substance such as:

— molecular weight,
— solubility in water,
— octanol/water partition coefficient,
— vapour pressure,
— volatilization rate,
— dissociation constant,
— photodegradation rate and identity of breakdown products,
— hydrolysis rate in relation to pH and identity of breakdown products;

(iii) all information on the plant protection product as provided for in Annex III, including the information on distribution and dissipation in soil;

(iv) where relevant, other authorized uses of plant protection products in the area of proposed use containing the same active substance or which give rise to the same residues.

2.5.1.2. Member States shall evaluate the possibility of the plant protection product reaching the groundwater intended to produce drinking water under the proposed conditions of use; if this possibility exists, they shall estimate, using a suitable calculation model validated at Community level, the concentration of the active substance and of relevant metabolites, degradation and reaction products that could be expected in the groundwater in the area of envisaged use after use of the plant protection product according to the proposed conditions of use.

If there is no validated Community calculation model, Member States shall base their evaluation especially on the results of mobi-

(*) Non-extractable residues (sometimes referred to as ‘bound’ or ‘non-extracted’ residues) in plants and soils are defined as chemical species originating from pesticides used according to good agricultural practice that cannot be extracted by methods which do not significantly change the chemical nature of these residues. These non-extractable residues are not considered to include fragments through metabolic pathways leading to natural products.

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lity and persistence in soil studies as provided for in Annexes II and III.

This evaluation will also take into consideration the following information:

(i) the specific information on fate and behaviour in soil and water as provided for in Annex II and the results of the evaluation thereof;

(ii) other relevant information on the active substance such as:

— molecular weight,

— solubility in water,

— octanol/water partition coefficient,

— vapour pressure,

— volatilization rate,

— hydrolysis rate in relation to pH and identity of breakdown products,

— dissociation constant;

(iii) all information on the plant protection product as provided for in Annex III, including the information on distribution and dissipation in soil and water;

(iv) where relevant, other authorized uses of plant protection products in the area of envisaged use containing the same active substance or which give rise to the same residues;

(v) where relevant, data on dissipation including transformation and sorption in the saturated zone;

(vi) where relevant, data on the procedures for drinking water abstraction and treatment in the area of envisaged use;

(vii) where relevant, monitoring data on the presence or absence of the active substance in groundwater as a result of previous use of plant protection products containing the same active substance or which give rise to the same residues.

2.5.1.3. Member States shall evaluate the possibility of the plant protection product reaching surface water under the proposed conditions of use; if this possibility exists they shall estimate, using a suitable calculation model validated at Community level, the short-term and long-term predicted concentration of the active substance and of metabolites, degradation and reaction products that could be expected in the surface water in the area of envisaged use after use of the plant protection product according to the proposed conditions of use.

If there is no validated Community calculation model, Member States shall base their evaluation especially on the results of mobility and persistence in soil studies and the information on run-off and drift as provided for in Annexes II and III. This evaluation will also take into consideration the following information:

(i) the specific information on fate and behaviour in soil and water as provided for in Annex II and the results of the evaluation thereof;

(ii) other relevant information on the active substance such as:

— molecular weight,

— solubility in water,

— octanol/water partition coefficient,

— vapour pressure,

— volatilization rate,

— hydrolysis rate in relation to pH and identity of breakdown products,

— dissociation constant;

(iii) all relevant information on the plant protection product as provided for in Annex III, including the information on distribution and dissipation in soil and water;

(iv) possible routes of exposure:

— drift,

— run-off,

— overspray,

— discharge via drains,

— leaching,

— deposit in the atmosphere;

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(v) where relevant, other authorized uses of plant protection products in the area of envisaged use containing the same active substance or which give rise to the same residues;

(vi) where relevant, data on the procedures for drinking water abstraction and treatment in the area of envisaged use.

2.5.1.4. Member States shall evaluate the possibility of the plant protection product being dissipated in the air under the proposed conditions of use; if this possibility exists they shall make the best possible estimation, using where appropriate a suitable, validated calculation model, of the concentration of the active substance and of relevant metabolites, degradation and reaction products that could be expected in the air after use of the plant protection product according to the proposed conditions of use.

This evaluation will take into consideration the following information:

(i) the specific information on fate and behaviour in soil, water and air as provided for in Annex II and the results of the evaluation thereof;

(ii) other relevant information on the active substance such as:

— vapour pressure,

— solubility in water,

— hydrolysis rate in relation to pH and identity of breakdown products,

— photochemical degradation in water and air and identity of breakdown products,

— octanol/water partition coefficient;

(iii) all relevant information on the plant protection product as provided for in Annex III, including the information on distribution and dissipation in air.

2.5.1.5. Member States shall evaluate the procedures for destruction or decontamination of the plant protection product and its packaging.

2.5.2. Impact on non-target species

When calculating toxicity/exposure ratios Member States shall take into consideration toxicity to the most sensitive relevant organism used in the tests.

2.5.2.1. Member States shall evaluate the possibility of exposure of birds and other terrestrial vertebrates to the plant protection product under the proposed conditions of use; if this possibility exists they shall evaluate the extent of the short-term and long-term risk to be expected for these organisms, including their reproduction, after use of the plant protection product according to the proposed conditions of use.

(a) This evaluation will take into consideration the following information:

(i) the specific information relating to toxicological studies on mammals and to the effects on birds and other non-target terrestrial vertebrates, including effects on reproduction, and other relevant information concerning the active substance as provided for in Annex II and the results of the evaluation thereof;

(ii) all relevant information on the plant protection product as provided for in Annex III, including the information on effects on birds and other non-target terrestrial vertebrates;

(iii) where relevant, other authorized uses of plant protection products in the area of envisaged use containing the same active substance or which give rise in the same residues.

(b) This evaluation will include:

(i) the fate and distribution, including persistence and biocondition, of the active substance and of relevant metabolites, breakdown and reaction products in the various parts of the environment after application of the plant protection product;

(ii) the estimated exposure of the species likely to be exposed at the time of application or during the period that residues are present, taking into account all relevant routes of exposure such as ingestion of the formulated product or treated food, predation on invertebrates, feeding on vertebrate prey, contact by overspraying or with treated vegetation;

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(iii) a calculation of the acute, short-term and, where necessary, long-term toxicity/exposure ratio. The toxicity/exposure ratios are defined as respectively the quotient of LD_{50}, LC_{50} or NOEC expressed on an active substance basis and the estimated exposure expressed in mg/kg body weight.

2.5.2.2. Member States shall evaluate the possibility of exposure of aquatic organisms to the plant protection product under the proposed conditions of use; if this possibility exists that shall evaluate the degree of short-term and long-term risk to be expected for aquatic organisms after use of the plant protection product according to the proposed conditions of use.

(a) This evaluation will take into consideration the following information:

(i) the specific information relating to the effects on aquatic organisms as provided for in Annex II and the results of the evaluation thereof;

(ii) other relevant information on the active substance such as:

— solubility in water,

— octanol/water partition coefficient,

— vapour pressure,

— volatilization rate,

— KOC,

— biodegradation in aquatic systems and in particular the ready biodegradability,

— photodegradation rate and identity of breakdown products,

— hydrolysis rate in relation to pH and identity of breakdown products;

(iii) all relevant information on the plant protection product as provided for in Annex III and in particular the effects on aquatic organisms;

(iv) where relevant, other authorized uses of plant protection products in the area of envisaged use, containing the same active substance or which give rise to the same residues.

(b) This evaluation will include:

(i) the fate and distribution of residues of the active substance and of relevant metabolites, breakdown and reaction products in water, sediment or fish;

(ii) a calculation of the acute toxicity/exposure ratio for fish and Daphnia. This ratio is defined as the quotient of respectively acute LC_{50} or EC_{50} and the predicted short-term environmental concentration;

(iii) a calculation of the algal growth inhibition/exposure ratio for algae. This ratio is defined as the quotient of the EC_{50} and the predicted short-term environmental concentration;

(iv) a calculation of the long-term toxicity/exposure ratio for fish and Daphnia. The long-term toxicity/exposure ratio is defined as the quotient of the NOEC and the predicted long-term environmental concentration;

(v) where relevant, the bioconcentration in fish and possible exposure of predators of fish, including humans;

(vi) if the plant protection product is to be applied directly to surface water, the effect on the change of surface water quality, such as pH or dissolved oxygen content.

2.5.2.3. Member States shall evaluate the possibility of exposure of honeybees to the plant protection product under the proposed conditions of use; if this possibility exists they shall evaluate the short-term and long-term risk to be expected for honeybees after use of the plant protection product according to the proposed conditions of use.

(a) This evaluation will take into consideration the following information:

(i) the specific information on toxicity to honeybees as provided for in Annex II and the results of the evaluation thereof;

(ii) other relevant information on the active substance such as:

— solubility in water,

— octanol/water partition coefficient,

— vapour pressure,

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— photodegradation rate and identity of breakdown products,

— mode of action (e.g. insect growth regulating activity);

(iii) all relevant information on the plant protection product as provided for in Annex III, including the toxicity to honeybees;

(iv) where relevant, other authorized uses of plant protection products in the area of envisaged use, containing the same active substance or which give rise to the same residues.

(b) This evaluation will include:

(i) the ratio between the maximum application rate expressed in grammes of active substance per hectare and the contact and oral LD_{50} expressed in µg of active substance per bee (hazard quotients) and where necessary the persistence of residues on or, where relevant, in the treated plants;

(ii) where relevant, the effects of honeybee larvae, honeybee behaviour, colony survival and development after use of the plant protection product according to the proposed conditions of use.

2.5.2.4. Member States shall evaluate the possibility of exposure of beneficial arthropods other than honeybees to the plant protection product under the proposed conditions of use; if this possibility exists they will assess the lethal and sublethal effects on these organisms to be expected and the reduction in their activity after use of the plant protection product according to the proposed conditions of use.

This evaluation will take into consideration the following information:

(i) the specific information on toxicity to honeybees and other beneficial arthropods as provided for in Annex II and the results of the evaluation thereof:

(ii) other relevant information on the active substance such as:

— solubility in water,

— octanol/water partition coefficient,

— vapour pressure,

— photodegradation rate and identity of breakdown products,

— mode of action (e.g. insect growth regulating activity);

(iii) all relevant information on the plant protection product as provided for in Annex III such as:

— effects on beneficial arthropods other than bees,

— toxicity to honeybees,

— available data from biological primary screening,

— maximum application rate,

— maximum number and timetable of applications.

(iv) where relevant, other authorized uses of plant protection products in the area of envisaged use, containing the same active substance or which give rise to the same residues.

2.5.2.5. Member States shall evaluate the possibility of exposure of earthworms and other non-target soil macro-organisms to the plant protection product under the proposed conditions of use; if this possibility exists they shall evaluate the degree of short-term and long-term risk to be expected to these organisms after use of the plant protection product according to the proposed conditions of use.

(a) This evaluation will take into consideration the following information:

(i) the specific information relating to the toxicity of the active substance to earthworms and to other non-target soil macro-organisms as provided for in Annex II and the results of the evaluation thereof;

(ii) other relevant information on the active substance such as:

— solubility in water,

— octanol/water partition coefficient,

— Kd for adsorption,

— vapour pressure,

— hydrolysis rate in relation to pH and identity of breakdown products,

— photodegradation rate and identity of breakdown products,

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— DT_{50} and DT_{90} for degradation in the soil;

(iii) all relevant information on the plant protection product as provided for in Annex III, including the effects on earthworms and other non-target soil macro-organisms;

(iv) where relevant, other authorized uses of plant protection product in the area of envisaged use, containing the same active substance or which give rise to the same residues.

(b) This evaluation will include:

(i) the lethal and sublethal effects;

(ii) the predicted initial and long-term environmental concentration;

(iii) a calculation of the acute toxicity/exposure ratio (defined as the quotient of LC_{50} and predicted initial environmental concentration) and of the long-term toxicity/exposure ratio (defined as the quotient of the NOEC and predicted long-term environmental concentration);

(iv) where relevant, the bioconcentration and persistence of residues in earthworms.

2.5.2.6. Member States shall, where the evaluation carried out under Part B, point 2.5.1.1, does not exclude the possibility of the plant protection product reaching the soil under the proposed conditions of use, evaluate the impact on microbial activity such as the impact on nitrogen and carbon mineralization processes in the soil after use of the plant protection product according to the proposed conditions of use.

This evaluation will take into consideration the following information:

(i) all relevant information on the active substance, including the specific information relating to the effects on non-target soil micro-organisms as provided for in Annex II and the results of the evaluation thereof;

(ii) all relevant information on the plant protection product as provided for in Annex III, including the effects on non-target soil micro-organisms;

(iii) where relevant, other authorized uses of plant protection products in the area of proposed use, containing the same active substance or which give rise to the same residues;

(iv) all available information from biological primary screening.

2.6. *Analytical methods*

Member States shall evaluate the analytical methods proposed for post-registration control and monitoring purposes, to determine:

2.6.1. for formulation analysis:

the nature and quantity of the active substance(s) in the plant protection product and, where appropriate, any toxicologically, ecotoxicologically or environmentally significant impurities and co-formulants.

This evaluation will take into consideration the following information:

(i) the data on analytical methods as provided for in Annex II and the results of the evaluation thereof;

(ii) the data on analytical methods as provided for in Annex III and in particular:

— the specificity and linearity of the proposed methods,

— the importance of interferences,

— the precision of the proposed methods (intra-laboratory repeatability and inter-laboratory reproducibility);

(iii) the limit of detection and determination of the proposed methods for impurities;

2.6.2. for residue analysis:

the residues of the active substance, metabolites, breakdown or reaction products resulting from authorized uses of the plant protection product and which are of toxicological, ecotoxicological or environmental significance.

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This evaluation will take into consideration the following information:

(i) the data on analytical methods as provided for in Annex II and the results of the evaluation thereof;

(ii) the data on analytical methods as provided for in Annex III and in particular:

— the specificity of the proposed methods,

— the precision of the proposed methods (intra-laboratory repeatability and inter-laboratory reproducibility),

— the recovery rate of the proposed methods at appropriate concentrations;

(iii) the limit of detection of the proposed methods;

(iv) the limit of determination of the proposed methods.

2.7. *Physical and chemical properties*

2.7.1. Member States shall evaluate the actual active substance content of the plant protection product and its stability during storage.

2.7.2. Member States shall evaluate the physical and chemical properties of the plant protection product and in particular:

— where a suitable FAO specification exists, the physical and chemical properties addressed in that specification,

— where no suitable FAO specification exists, all the relevant physical and chemical properties for the formulation as referred to in the 'Manual on the development and use of FAO specifications for plant protection products'.

This evaluation will take into consideration the following information:

(i) the data on the physical and chemical properties of the active substance as provided for in Annex II and the results of the evaluation thereof;

(ii) the data on the physical and chemical properties of the plant protection product as provided for in Annex III.

2.7.3. Where proposed label claims include requirements or recommendations for use of the plant protection product with other plant protection products or adjuvants as a tank mix, the physical and chemical compatibility of the products in the mixture must be evaluated.

C. **DECISION-MAKING**

1. **General principles**

1. Where appropriate, Member States shall impose conditions or restrictions with the authorizations they grant. The nature and severity of these measures must be selected on the basis of, and be appropriate to, the nature and extent of the expected advantages and the risks likely to arise.

2. Member States shall ensure that, where necessary, decisions taken with respect to the granting of authorizations take account of the agricultural, plant health or environmental (including climatic) conditions in the areas of envisaged use. Such considerations may result in specific conditions and restrictions of use, and, where necessary, in authorization being granted for some but not other areas within the Member State in question.

3. Member States shall ensure that the authorized amounts, in terms of rates and number of applications, are the minimum necessary to achieve the desired effect even where higher amounts would not result in unacceptable risks to human or animal health or to the environment. The authorized amounts must be differentiated according to, and be appropriate to the agricultural, plant health or environmental (including climatic) conditions in the various areas for which an authorization is granted. However, the rates and the number of applications may not give rise to undesirable effects such as the development of resistance.

4. Member States shall ensure that decisions respect the principles of integrated control if the product is intended to be used in conditions where these principles are relied on.

5. Since the evaluation is to be based on data concerning a limited number of representative species, Member States shall ensure that use of plant protection products does not have any long-term repercussions for the abundance and diversity of non-target species.

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6. Before issuing an authorization, Member States shall ensure that the label of the product:

   — fulfils the requirements of Article 16 of this Directive,

   — also contains the information on protection of users required by Community legislation on worker protection,

   — specifies in particular the conditions or restrictions under which the plant protection product may or may not be used as referred to in points 1, 2, 3, 4 and 5.

   The authorization shall mention the particulars indicated in Article 6 (2) (g) and (h), (3) and (4) of 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) ([1]) and in Article 16 (g) and (h) of Directive 91/414/EEC.

7. Before issuing authorizations, Member States shall:

   (a) ensure that the proposed packaging is in accordance with the provisions of Directive 78/631/EEC;

   (b) ensure that:

      — the procedures for destruction of the plant protection product,

      — the procedures for neutralizaton of the adverse effects of the product if it is accidentally dispersed,

      — the procedures for the decontamination and destruction of the packagings,

      are in accordance with the relevant regulatory provisions.

8. No authorization shall be granted unless all the requirements referred to in Section 2 are satisfied. However:

   (a) when one or more of the specific decision-making requirements referred to in Part C, points 2.1, 2.2, 2.3 or 2.7, are not fully satisfied, authorizations shall be granted only when the advantages of the use of the plant protection product under the proposed conditions of use outweigh the possible adverse effects of its use. Any restrictions on use of the product relating to non-compliance with some of the aforementioned requirements must be mentioned on the label, and non-compliance with the requirements referred to in point 2.7 must not compromise proper use of the product. These advantages can be in terms of:

      — advantages for and compatibility with integrated control measures or organic farming,

      — facilitating strategies to minimize the risk of development of resistance,

      — the need for a greater diversity of types of active substances or biochemical modes of action, e.g. for use in strategies to avoid accelerated breakdown in the soil,

      — reduced risk for operators and consumers,

      — reduced contamination of the environment and reduced impact on non-target species;

   (b) where the criteria referred to in Part C, point 2.6, are not fully satisfied because of limitations in current analytical science and technology, authorization shall be granted for a limited period if the methods submitted prove adequate for the purposes intended. In this case the applicant shall be given a time limit in which to develop and submit analytical methods that are in accordance with the criteria referred to above. The authorization will be reviewed on expiry of the time limit accorded to the applicant;

   (c) where the reproducibility of the submitted analytical methods referred to in Part C, point 2.6, has only been verified in two laboratories, an authorization shall be granted for one year to permit the applicant to demonstrate the reproducibility of those methods in accordance with agreed criteria.

([1]) OJ No L 206, 29. 7. 1978, p. 13. Directive as last amended by Directive 92/32/EEC (OJ No L 154, 5. 6. 1992, p. 1).

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9. Where an authorization has been granted according to the requirements provided for in this Annex, Member States may, by virtue of Article 4 (6):

   (a) define, where possible, preferably in close cooperation with the applicant, measures to improve the performance of the plant protection product; and/or

   (b) define, where possible, in close cooperation with the applicant, measures to reduce further the exposure that could occur during and after use of the plant protection product.

   Member States shall inform the applicants of any measures identified under (a) or (b) and shall invite applicants to provide any supplementary data and information necessary to demonstrate performance or potential risks arising under the changed conditions.

2. **Specific principles**

The specific principles shall apply without prejudice to the general principles referred to in Section 1.

2.1. *Efficacy*

2.1.1. Where the proposed uses include recommendations for the control of or protection against organisms which are not considered to be harmful on the basis of experience acquired or scientific evidence under normal agricultural, plant health and environmental (including climatic) conditions in the areas of proposed use or where the other intended effects are not considered to be beneficial under those conditions, no authorization shall be granted for those uses.

2.1.2. The level, consistency and duration of control or protection or other intended effects must be similar to those resulting from the use of suitable reference products. If no suitable reference product exists, the plant protection product must be shown to give a defined benefit in terms of the level, consistency and duration of control or protection or other intended effects under the agricultural, plant health and environmental (including climatic) conditions in the area of proposed use.

2.1.3. Where relevant, yield response when the product is used and reduction of loss in storage must be quantitatively and/or qualitatively similar to those resulting from the use of suitable reference products. If no suitable reference product exists, the plant protection product must be shown to give a consistent and defined quantitative and/or qualitative benefit in terms of yield response and reduction of loss in storage under the agricultural, plant health and environmental (including climatic) conditions in the area of proposed use.

2.1.4. Conclusions as to the performance of the preparation must be valid for all areas of the Member State in which it is to be authorized, and must hold for all conditions under which its use is proposed, except where the proposed label specifies that the preparation is intended for use in certain specified circumstances (e.g. light infestations, particular soil types or particular growing conditions).

2.1.5. Where proposed label claims include requirements for use of the preparation with other specified plant protection products or adjuvants as a tank mix, the mixture must achieve the desired effect and comply with the principles referred to in points 2.1.1 and 2.1.4.

Where proposed label claims include recommendations for use of the preparation with other specified plant protection products or adjuvants as a tankmix, Member States shall not accept the recommendations unless they are justified.

2.2. *Absence of unacceptable effects on plants or plant products*

2.2.1. There must be no relevant phytotoxic effects on treated plants or plant products except where the proposed label indicates appropriate limitations of use.

2.2.2. There must be no reduction of yield at harvest due to phytotoxic effects below that which could be obtained without the use of the plant protection product, unless this reduction is compensated for by other advantages such as an enhancement of the quality of the treated plants or plant products.

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2.2.3. There must be no unacceptable adverse effects on the quality of treated plants or plant products, except in the case of adverse effects on processing where proposed label claims specify that the preparation should not be applied to crops to be used for processing purposes.

2.2.4. There must be no unacceptable adverse effects on treated plants or plant products used for propagation or reproduction, such as effects on viability, germination, sprouting, rooting and establishment, except where proposed label claims specify that the preparation should not be applied to plants or plant products to be used for propagation or reproduction.

2.2.5. There must be no unacceptable impact on succeeding crops, except where proposed label claims specify that particular crops, which would be affected, should not be grown following the treated crop.

2.2.6. There must be no unacceptable impact on adjacent crops, except where proposed label claims specify that the preparation should not be applied when particular sensitive adjacent crops are present.

2.2.7. Where proposed label claims include requirements for use of the preparation with other plant protection product or adjuvants, as a tank mix, the mixture must comply with the principles referred to in points 2.2.1 to 2.2.6.

2.2.8. The proposed instructions for cleaning the application equipment must be both practical and effective so that they can be applied with ease so as to ensure the removal of residual traces of the plant protection product which could subsequently cause damage.

2.3. *Impact on vertebrates to be controlled*

An authorization for a plant protection product intended to eliminate vertebrates shall be granted only when:

— death is synchronous with the extinction of consciousness, or

— death occurs immediately, or

— vital functions are reduced gradually without signs of obvious suffering.

For repellant products, the intended effect shall be obtained without unnecessary suffering and pain for the target animals.

2.4. *Impact on human or animal health*

2.4.1. Arising from the plant protection product

2.4.1.1. No authorization shall be granted if the extent of operator exposure in handling and using the plant protection product under the proposed conditions of use, including dose and application method, exceeds the acceptable operator exposure level (AOEL).

Moreover, the conditions of the authorization shall be in compliance with the limit value established for the active substance and/or toxicologically relevant compound(s) of the product in accordance with Council Directive 80/1107/EEC of 27 November 1980 on the protection of workers from the risks related to exposure to chemical, physical and biological agents at work [1] and in accordance with Council Directive 90/394/EEC of 28 June 1990 on the protection of workers from the risks related to exposure to carcinogens at work [2].

2.4.1.2. Where the proposed conditions of use require use of items of protective clothing and equipment, no authorization shall be granted unless those items are effective and in accordance with the relevant Community provisions and are readily obtainable by the user and unless it is feasible to use them under the circumstances of use of the plant protection product, taking into account climatic conditions in particular.

2.4.1.3. Plant protection products which because of particular properties or if mishandled or misused could lead to a high degree of risk must be subject to particular restrictions such as restrictions on the size of packaging, formulation type, distribution, use or manner of use.

(1) OJ No L 327, 3. 12. 1980, p. 8. Directive as last amended by Directive 88/642/EEC (OJ No L 356, 24. 12. 1988, p. 74).

(2) OJ No L 196, 26. 7. 1990, p. 1.

▼M3

Moreover, plant protection products which are classified as very toxic may not be authorized for use by non-professional users.

2.4.1.4. Waiting and re-entry safety periods or other precautions must be such that the exposure of bystanders or workers exposed after the application of the plant protection product does not exceed the AOEL levels established for the active substance or toxicologically relevant compound(s) in the plant protection product nor any limit values established for those compounds in accordance with the Community provisions referred to in point 2.4.1.1.

2.4.1.5. Waiting and re-entry safety periods or other precautions must be established in such a way that no adverse impact on animals occurs.

2.4.1.6. Waiting and re-entry periods or other precautions to ensure that the AOEL levels and limit values are respected must be realistic; if necessary special precautionary measures must be prescribed.

2.4.2. Arising from residues

2.4.2.1. Authorizations must ensure that residues occurring reflect the minimum quantities of the plant protection product necessary to achieve adequate control corresponding to good agricultural practice, applied in such a manner (including pre-harvest intervals or withholding periods or storage periods) that the residues at harvest, slaughter or after storage, as appropriate, are reduced to a minimum.

2.4.2.2. Where no Community MRL (*) or provisional MRL (at national or at Community level) exists, Member States shall establish a provisional MRL in accordance with Article 4 (1) (f) of this Directive; conclusions as to the levels fixed must be valid for all circumstances which could influence the residue levels in the crop such as timing of application, application rate and frequency or manner of use.

2.4.2.3. Where the new circumstances under which the plant protection product is to be used do not correspond to those under which a provisional MRL (at national or at Community level) was established previously, Member States shall not grant an authorization for the plant protection product unless the applicant can provide evidence that its recommended use will not exceed that MRL or unless a new provisional MRL has been established by the Member State or the Commission in accordance with Article 4 (1) (f) of this Directive.

2.4.2.4. Where a Community MRL exists Member States shall not grant an authorization for the plant protection product unless the applicant can provide evidence that its recommended use will not exceed that MRL, or unless a new Community MRL has been established in accordance with the procedures provided for in the relevant Community legislation.

2.4.2.5. In the cases referred to in points 2.4.2.2 and 2.4.2.3, each application for an authorization must be accompanied by a risk assessment taking into account worst-case potential exposure of consumers in the Member State concerned on the basis of good agricultural practice.

(*) A Community MRL will mean an MRL established pursuant to Council Directive 76/895/EEC of 23 November 1976 relating to the fixing of maximum levels for pesticide residues in and on fruit and vegetables ([1]), Council Directive 86/362/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on cereals ([2]), Council Directive 86/363/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on foodstuffs of animal origin ([3]), Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin ([4]), Council Directive 90/642/EEC of 27 November 1990 on the fixing of maximum levels for pesticide residues in and on certain products of plant origin, including fruit and vegetables ([5]) or Council Directive 91/132/EEC of 4 March 1991 amending Directive 74/63/EEC on undesirable substances and products in feedingstuffs ([6]).

([1]) OJ No L 340, 9. 12. 1976, p. 26. Directive as last amended by Directive 93/58/EEC (OJ No L 211, 23. 8. 1993, p. 6).
([2]) OJ No L 221, 7. 8. 1986, p. 37. Directive as last amended by Directive 93/57/EEC (OJ No L 211, 23. 8. 1993, p. 1).
([3]) OJ No L 221, 7. 8. 1986, p. 43. Directive as last amended by Directive 93/57/EEC (OJ No L 211, 23. 8. 1993, p. 1).
([4]) OJ No L 224, 18. 8. 1990, p. 1. Regulation as last amended by Commission Regulation (EEC) No 955/94 (OJ No L 108, 29. 4. 1994, p. 8).
([5]) OJ No L 350, 14. 12. 1990, p. 71. Directive as last amended by Directive 93/58/EEC (OJ No L 211, 23. 8. 1993, p. 6).
([6]) OJ No L 66, 13. 3. 1991, p. 16.

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Taking into account all registered uses, the proposed use cannot be authorized if the best possible estimate of dietary exposure exceeds the acceptable daily intake (ADI).

2.4.2.6. Where the nature of residues is affected during processing, a separate risk assessment may need to be carried out under the conditions provided for in point 2.4.2.5.

2.4.2.7. Where the treated plants or plant products are intended to be fed to animals, residues occurring shall not have an adverse effect on animal health.

2.5. *Influence on the environment*

2.5.1. Fate and distribution in the environment

2.5.1.1. No authorization shall be granted if the active substance and, where they are of significance from the toxicological, ecotoxicological or environmental point of view, metabolites and breakdown or reaction products, after use of the plant protection product under the proposed conditions of use:

— during tests in the field, persist in soil for more than one year (i.e. DT_{90} > 1 year and DT_{50} > 3 months), or

— during laboratory tests, form not extractable residues in amounts exceeding 70% of the initial dose after 100 days with a mineralization rate of less than 5 % in 100 days,

unless it is scientifically demonstrated that under field conditions there is no accumulation in soil at such levels that unacceptable residues in succeeding crops occur and/or that unacceptable phytotoxic effects on succeeding crops occur and/or that there is an unacceptable impact on the environment, according to the relevant requirements provided for in points 2.5.1.2, 2.5.1.3, 2.5.1.4 and 2.5.2.

2.5.1.2. (a) An authorization shall be granted only in the following cases:

(1) where adequate monitoring data relevant to the proposed conditions of use of the plant protection product are not available and on the basis of the evaluation it appears that, after use of the plant protection product under the conditions proposed, the foreseeable concentration of the active substance or of relevant metabolites or breakdown or reaction products in groundwater intended for the production of drinking water does not exceed the lower of the following concentrations:

(i) the maximum permissible concentration laid down by Council Directive 80/778/EEC of 15 July 1980 relating to the quality of water intended for human consumption [1];

or

(ii) the maximum conncentration laid down by the Commission when including the active substance in Annex I, on the basis of appropriate data, in particular toxicological data, or, where that concentration has not been laid down, the concentration corresponding to one tenth of the ADI laid down when the active substance was included in Annex I;

(2) where adequate monitoring data relevant to the proposed conditions of use of the plant protection product are available and support the conclusion that in practice, after use of the plant protection product under the conditions proposed, the concentration of the active substance or of relevant metabolites or breakdown or reaction products in groundwater intended for the production of drinking water has not exceeded or no longer exceeds and is not in danger of exceeding the appropriate maximum concentration as referred to in (1) above.

(b) Irrespective of the provisions in (a) above, where the concentration referred to in (a) (1) (ii) is greater than that referred to in (a) (1) (i), a conditional authorization, which is not an authorization within the meaning of Article 10 (1) of this Directive and

[1] OJ No L 229, 30. 8. 1980, p. 11. Directive as last amended by Directive 91/692/EEC (OJ No L 377, 31. 12. 1991, p. 48).

▼M3

which is for a limited period of not more than five years, may be issued only in those cases in which the conditions specified in (1) or (2) below are fulfilled:

(1) where adequate monitoring data relevant to the proposed conditions of use of the plant protection product are not available, every conditional authorization issued shall be subject to the following requirements:

(i) it appearing on the basis of the evaluation that, after use of the plant protection product under the conditions proposed, the foreseeable concentration of the active substance of relevant metabolites or breakdown or reaction products in groundwater intended for the production of drinking water does not exceed the maximum concentration referred to in (a) (1) (ii) above; and

(ii) it being ensured that an adequate monitoring programme covering areas liable to be contaminated is introduced or continued in the Member State, using suitable methods of sampling and analysis, so that it can be estimated whether the maximum concentration referred to in (a) (1) (i) above will be exceeded; it is for the Member States to decide who is to bear the cost of that monitoring programme;

(iii) where appropriate, attaching to the authorization of the conditions for or restrictions on the use of the product concerned, to appear on the label, having regard to agricultural plant health, and environmental (including climatic) conditions in the envisaged area of use;

(iv) if necessary, amendment or withdrawal of the conditional authorization, in accordance with Article 4 (5) and (6), where monitoring results show that, despite the imposing of the conditions or restrictions referred to in (iii) above, after use of the plant protection product under the conditions proposed, the concentration of the active substance or of relevant metabolites or breakdown or reaction products in groundwater intended for the production of drinking water will exceed the concentration referred to in (a) (1) (i) above;

(2) where adequate monitoring data relevant to the conditions of use of the plant protection product are available and support the conclusion that in practice, after use of the plant protection product under the conditions proposed, there is no risk that the concentration of the active substance or of relevant metabolites or breakdown or reaction products in groundwater intended for the production of drinking water will exceed the maximum concentration referred to in (a) (1) (ii) above, every conditional authorization issued shall be subject to the following requirements:

(i) prior investigation of the significance of the risk of the maximum concentration referred to in (a) (1) (i) being exceeded and of the factors involved;

(ii) it being ensured that an adequate programme, consisting of measures referred to in (b) (1) (ii), (iii) and (iv) above, is introduced or continued in the Member State so as to make sure that in practice the concentration does not exceed the maximum permissible concentration referred to in (a) (1) (i) above.

(c) If, upon expiry of the conditional authorization, monitoring results show that in practice the concentration of the active substance or of relevant metabolites or breakdown or reaction products, as a result of the use of the plant protection product under the proposed conditions of use, in groundwater intended for the production of drinking water has been reduced to a level approaching the maximum permissible concentration referred to in (a) (1) (i) above and if other amendments to the proposed conditions of use could be expected to ensure that the foreseeable concentration will be reduced below that maximum concentration, a further conditional authorization including those new amendments may be issued for a single period of not more than five years.

(d) A Member State may at any time introduce appropriate conditions for or restrictions on the product's use, having regard to local agricultural, plant health and environmental (including

▼M3

climatic) conditions, in order to comply with the concentration referred to in (a) (1) (i) above in water intended for human consumption, in accordance with Directive 80/778/EEC.

2.5.1.3. No authorization shall be granted if the concentration of the active substance or of relevant metabolites, breakdown or reaction products to be expected after use of the plant protection product under proposed conditions of use in surface water:

— exceeds, where the surface water in or from the area of envisaged use is intended for the abstraction of drinking water, the values fixed by Council Directive 75/440/EEC of 16 June 1975 concerning the quality required of surface water intended for the abstraction of drinking water in the Member States [1], or

— has an impact deemed unacceptable on non-target species, including animals, according to the relevant requirements provided for in point 2.5.2.

The proposed instructions for use of the plant protection product, including procedures for cleaning application equipment, must be such that the likelihood of accidental contamination of surface water is reduced to a minimum.

2.5.1.4. No authorization shall be granted if the airborne concentration of the active substance under the proposed conditions of use is such that either the AOEL or the limit values for operators, bystanders or workers as referred to in Part C, point 2.4.1, are exceeded.

2.5.2. Impact on non-target species

2.5.2.1. Where there is a possibility of birds and other non-target terrestrial vertebrates being exposed, no authorization shall be granted if:

— the acute and short-term toxicity/exposure ratio for birds and other non-target terrestrial vertebrates is less than 10 on the basis of LD_{50} or the long-term toxicity/exposure ratio is less than 5, unless it is clearly established through an appropriate risk assessment that under field conditions no unacceptable impact occurs after use of the plant protection product according to the proposed conditions of use,

— the bioconcentration factor (BCF, related to fat tissue) is greater than 1, unless it is clearly established through an appropriate risk assessment that under field conditions no unacceptable effects occur — directly or indirectly — after use of the plant protection product according to the proposed conditions of use.

2.5.2.2. Where there is a possibility of aquatic organisms being exposed, no authorization shall be granted if:

— the toxicity/exposure ratio for fish and Daphnia is less than 100 for acute exposure and less than 10 for long-term exposure, or

— the algal growth inhibition/exposure ratio is less than 10, or

— the maximum bioconcentration factor (BCF) is greater than 1 000 for plant protection products containing active substances which are readily biodegradable or greater than 100 for those which are not readily biodegradable, unless it is clearly established through an appropriate risk assessment that under field conditions no unacceptable impact on the viability of exposed species (predators) occurs — directly or indirectly — after use of the plant protection product according to the proposed conditions of use.

2.5.2.3. Where there is a possibility of honeybees being exposed, no authorization shall be granted if the hazard quotients for oral or contact exposure of honeybees are greater than 50, unless it is clearly established through an appropriate risk assessment that under field conditions there are no unacceptable effects on honeybee larvae, honeybee behaviour, or colony survival and development after use of the plant protection product according to the proposed conditions of use.

2.5.2.4. Where there is a possibility of beneficial arthropods other than honeybees being exposed, no authorization shall be granted if more than 30 % of the test-organisms are affected in lethal or sublethal laboratory tests conducted at the maximum proposed application rate, unless it is clearly established through an appropriate risk

[1] OJ No L 194, 25. 7. 1975, p. 34. Directive as last amended by Directive 91/692/EEC (OJ No L 377, 31. 12. 1991, p. 48).

▼M3

assessment that under field conditions there is no unacceptable impact on those organisms after use of the plant protection product according to the proposed conditions of use. Any claims for selectivity and proposals for use in integrated pest management systems shall be substantiated by appropriate data.

2.5.2.5. Where there is a possibility of earthworms being exposed, no authorization shall be granted if the acute toxicity/exposure ratio for earthworms is less than 10 or the long-term toxicity/exposure ratio is less than 5, unless it is clearly established through an appropriate risk assessment that under field conditions earthworm populations are not at risk after use of the plant protection product according to the proposed conditions of use.

2.5.2.6. Where there is a possibility of non-target soil micro-organisms being exposed, no authorization shall be granted if the nitrogen or carbon mineralization processes in laboratory studies are affected by more than 25 % after 100 days, unless it is clearly established through an appropriate risk assessment that under field conditions there is no unacceptable impact on microbial activity after use of the plant protection product according to the proposed conditions of use, taking account of the ability of micro-organisms to multiply.

2.6. *Analytical methods*

The methods proposed must reflect the state of the art. The following criteria must be met in order to permit validation of the analytical methods proposed for post-registration control and monitoring purposes:

2.6.1. for formulation analysis:

the method must be able to determine and to identify the active substance(s) and where appropriate any toxicologically, ecotoxicologically or environmentally significant impurities and co-formulants;

2.6.2. for residue analysis:

(i) the method must be able to determine and confirm residues of toxicological, ecotoxicological or environmental significance;

(ii) the mean recovery rates should be between 70 % and 110 % with a relative standard deviation of ≤ 20 %;

(iii) the repeatability must be less than the following values for residues in foodstuffs:

Residue levelmg/kg	*Differencemg/kg*	*Differencein %*
0,01	0,005	50
0,1	0,025	25
1	0,125	12,5
> 1		12,5

Intermediate values are determined by interpolation from a log-log graph;

(iv) the reproducibility must be less than the following values for residues in foodstuffs:

Residue levelmg/kg	*Differencemg/kg*	*Differencein %*
0,01	0,01	100
0,1	0,05	50
1	0,25	25
> 1		25

Intermediate values are determined by interpolation from a log-log graph;

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(v) in the case of residue analysis in treated plants, plant products, foodstuffs, feedingstuffs or products of animal origin, except where the MRL or the proposed MRL is at the limit of determination, the sensitivity of the methods proposed must satisfy the following criteria:

Limit of determination in relation to the proposed provisional or Community MRL:

MRL(mg/kg)	*Limit of determination(mg/kg)*
> 0,5	0,1
0,5—0,05	0,1—0,02
< 0,05	MRL × 0,5

2.7. *Physical and chemical properties*

2.7.1. Where an appropriate FAO specification exists, that specification must be met.

2.7.2. Where no appropriate FAO specification exists, the physical and chemical properties of the product must meet the following requirements:

(a) Chemical properties:

Throughout the shelf-life period, the difference between the stated and the actual content of the active substance in the plant protection product must not exceed the following values:

Declared content in g/kg or g/l at 20 ºC	Tolerance
up to 25	± 15 % homogeneous formulation
	± 25 % non-homogeneous formulation
more than 25 up to 100	± 10 %
more than 100 up to 250	± 6 %
more than 250 up to 500	± 5 %
more than 500	± 25 g/kg or ± 25 g/l

(b) Physical properties:

The plant protection product must fulfil the physical criteria (including storage stability) specified for the relevant formulation type in the ‘Manual on the development and use of FAO specifications for plant protection products’.

2.7.3. Where the proposed label claims include requirements or recommendations for use of the preparation with other plant protection products or adjuvants as a tank mix and/or where the proposed label includes indications on the compatibility of the preparation with other plant protection products as a tank mix, those products or adjuvants must be physically and chemically compatible in the tank mix.