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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:

		Official Journal		
		No	page	date
►**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
►**M4**	Commission Directive 94/79/EC of 21 December 1994	L 354	16	31.12.1994
►**M5**	Commission Directive 95/35/EC of 14 July 1995	L 172	6	22.7.1995
►**M6**	Commission Directive 95/36/EC of 14 July 1995	L 172	8	22.7.1995
►**M7**	Commission Directive 96/12/EC of 8 March 1996	L 65	20	15.3.1996
►**M8**	Commission Directive 96/46/EC of 16 July 1996	L 214	18	23.8.1996
►**M9**	Commission Directive 96/68/EC of 21 October 1996	L 277	25	30.10.1996
►**M10**	Council Directive 97/57/EC of 22 September 1997	L 265	87	27.9.1997
►**M11**	Commission Directive 97/73/EC of 15 December 1997	L 353	26	24.12.1997
►**M12**	Commission Directive 98/47/EC of 25 June 1998	L 191	50	7.7.1998
►**M13**	Commission Directive 1999/1/EC of 21 January 1999	L 21	21	28.1.1999
►**M14**	Commission Directive 1999/73/EC of 19 July 1999	L 206	16	5.8.1999
►**M15**	Commission Directive 1999/80/EC of 28 July 1999	L 210	13	10.8.1999
►**M16**	Commission Directive 2000/10/EC of 1 March 2000	L 57	28	2.3.2000
►**M17**	Commission Directive 2000/49/EC of 26 July 2000	L 197	32	3.8.2000
►**M18**	Commission Directive 2000/50/EC of 26 July 2000	L 198	39	4.8.2000
►**M19**	Commission Directive 2000/66/EC of 23 October 2000	L 276	35	28.10.2000
►**M20**	Commission Directive 2000/67/EC of 23 October 2000	L 276	38	28.10.2000
►**M21**	Commission Directive 2000/68/EC of 23 October 2000	L 276	41	28.10.2000
►**M22**	Commission Directive 2000/80/EC of 4 December 2000	L 309	14	9.12.2000
►**M23**	Commission Directive 2001/21/EC of 5 March 2001	L 69	17	10.3.2001
►**M24**	Commission Directive 2001/28/EC of 20 April 2001	L 113	5	24.4.2001
►**M25**	Commission Directive 2001/36/EC of 16 May 2001	L 164	1	20.6.2001
►**M26**	Commission Directive 2001/47/EC of 25 June 2001	L 175	21	28.6.2001
►**M27**	Commission Directive 2001/49/EC of 28 June 2001	L 176	61	29.6.2001
►**M28**	Commission Directive 2001/87/EC of 12 October 2001	L 276	17	19.10.2001
►**M29**	Commission Directive 2001/99/EC of 20 November 2001	L 304	14	21.11.2001

►**M30** Commission Directive 2001/103/EC of 28 November 2001	L 313	37	30.11.2001
►**M31** Commission Directive 2002/18/EC of 22 February 2002	L 55	29	26.2.2002
►**M32** Commission Directive 2002/37/EC of 3 May 2002	L 117	10	4.5.2002
►**M33** Commission Directive 2002/48/EC of 30 May 2002	L 148	19	6.6.2002
►**M34** Commission Directive 2002/64/EC of 15 July 2002	L 189	27	18.7.2002
►**M35** Commission Directive 2002/81/EC of 10 October 2002	L 276	28	12.10.2002
►**M36** Commission Directive 2003/5/EC of 10 January 2003	L 8	7	14.1.2003
►**M37** Commission Directive 2003/23/EC of 25 March 2003	L 81	39	28.3.2003
►**M38** Commission Directive 2003/31/EC of 11 April 2003	L 101	3	23.4.2003
►**M39** Council Regulation (EC) No 806/2003 of 14 April 2003	L 122	1	16.5.2003
►**M40** Commission Directive 2003/39/EC of 15 May 2003	L 124	30	20.5.2003
►**M41** Commission Directive 2003/68/EC of 11 July 2003	L 177	12	16.7.2003
►**M42** Commission Directive 2003/70/EC of 17 July 2003	L 184	9	23.7.2003
►**M43** Commission Directive 2003/79/EC of 13 August 2003	L 205	16	14.8.2003
►**M44** Commission Directive 2003/81/EC of 5 September 2003	L 224	29	6.9.2003
►**M45** Commission Directive 2003/82/EC of 11 September 2003	L 228	11	12.9.2003
►**M46** Commission Directive 2003/84/EC of 25 September 2003	L 247	20	30.9.2003
►**M47** Commission Directive 2003/112/EC of 1 December 2003	L 321	32	6.12.2003
►**M48** Commission Directive 2003/119/EC of 5 December 2003	L 325	41	12.12.2003
►**M49** Commission Directive 2004/20/EC of 2 March 2004	L 70	32	9.3.2004
►**M50** Commission Directive 2004/30/EC of 10 March 2004	L 77	50	13.3.2004
►**M51** Commission Directive 2004/58/EC of 23 April 2004	L 120	26	24.4.2004
►**M52** Commission Directive 2004/60/EC of 23 April 2004	L 120	39	24.4.2004
►**M53** Commission Directive 2004/62/EC of 26 April 2004	L 125	38	28.4.2004
►**M54** Commission Directive 2004/71/EC of 28 April 2004	L 127	104	29.4.2004
►**M55** Council Directive 2004/66/EC of 26 April 2004	L 168	35	1.5.2004
►**M56** Commission Directive 2004/99/EC of 1 October 2004	L 309	6	6.10.2004
►**M57** Commission Directive 2005/2/EC of 19 January 2005	L 20	15	22.1.2005
►**M58** Commission Directive 2005/3/EC of 19 January 2005	L 20	19	22.1.2005
►**M59** Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005	L 70	1	16.3.2005
►**M60** Council Directive 2005/25/EC of 14 March 2005	L 90	1	8.4.2005
►**M61** Commission Directive 2005/34/EC of 17 May 2005	L 125	5	18.5.2005

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)

►**C3** Corrigendum, OJ L 280, 23.11.1995, p. 58 (94/79/EC)

►**C4** Corrigendum, OJ L 221, 21.8.1999, p. 19 (1999/73/EC)

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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;

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;

([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 it is therefore necessary to establish a Community list of authorized active substances;

Whereas a Community procedure must be laid down for assessing whether an active substance can be entered on the Community list; whereas the information that interested parties must submit with a view to admission of a substance to the list should be specified;

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

Whereas, in the interests of safety, substances on the Community list should be reviewed periodically, to take account of developments in science and technology and of impact studies based on the actual use of plant protection products containing the said substances;

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

Whereas it is therefore desirable that a system for the mutual supply of information should be established and that Member States should make available to each other on request the particulars and scientific documentation submitted in connection with applications for authorization of plant protection products;

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

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

Whereas it is necessary to maintain consistency between this Directive and Community rules on the residues of plant protection products in agricultural products and the free movement of the latter in the Community; whereas this Directive complements Community provisions relating to maximum permissible levels for pesticide residues and will facilitate the adoption of such levels in the Commission; whereas together with the latter provisions it considerably improves the protection of consumers of plants and plant products;

Whereas resources devoted to the conduct of tests on vertebrate animals should not be dissipated as a result of the differences in the laws of the Member States and whereas considerations of public interest and Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes [1] militate against needless repetition of tests on animals;

[1] OJ No L 358, 18. 12. 1986, p. 1.

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

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

The Commission shall submit to the Council, in sufficient time for the latter to be able to act not later than two years after the date of notification of this Directive, a proposal for an amendment with a view to including in this Directive ([6]) 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

([1]) OJ No L 117, 8. 5. 1990, p. 15.
([2]) OJ No L 206, 29. 7. 1978, p. 13.
([3]) OJ No L 144, 30. 5. 1984, p. 1.
([4]) OJ No 196, 16. 8. 1967, p. 1.
([5]) OJ No L 287, 19. 10. 1990, p. 37.
([6]) This Directive was notified to the Member States on 26 July 1991.

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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 ([1]).

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'*

   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;

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

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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

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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;

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(f) where appropriate, the MRLs for the agricultural products affected by the use referred to in the authorisation have been set or modified in accordance with Regulation (EC) No 396/2005 ([1]).

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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

([1]) OJ L 70, 16.3.2005, p. 1.

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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.

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;

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

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(b) their use, consequent on application consistent with good plant protection practice, does not have any harmful effects on human or animal health or any anacceptable influence on the environment as provided for in Article 4 (1) (b) (iv) and (v).

2. For inclusion of an active substance in Annex I, the following shall be taken into particular account:

(a) where relevant, an acceptable daily intake (ADI) for man;

(b) an acceptable operator exposure level if necessary;

(c) where relevant, an estimate of its fate and distribution in the environment as well as its impact on non-target species.

3. For the first inclusion of an active substance which was not yet on the market two years after notification of this Directive, the requirements shall be deemed to be satisfied where this has been established for at least one preparation containging the said active substance.

4. Inclusion of an active substance in Annex I may be subject to requirements such as:

— the minimum degree of purity of the active substance,

— the nature and maximum content of certain impurities,

— restrictions arising from evaluation of the information referred to in Article 6, taking account of the agricultural, plant health and environmental (including climatic) conditions in question,

— type of preparation,

— manner of use.

5. On request, the inclusion of a substance in Annex I may be renewed once or more for periods not exceeding 10 years; such inclusion may be reviewed at any time if there are indications that the criteria referred to in paragraphs 1 and 2 are no longer satisfied. Renewal shall be granted for the period necessary to complete a review, where an application has been made for such renewal in sufficient time, and in any case not less than two years before the entry is due to lapse, and shall be granted for the period necessary to provide information requested in accordance with Article 6 (4).

Article 6

1. Inclusion of an active substance in Annex I shall be decided in accordance with the procedure laid down in Article 19.

The following shall also be decided in accordance with that procedure:

— any conditions for inclusion,

— amendements to Annex I, where necessary,

— removal of an active substance form Annex I if it no longer satisfies the requirements of Article 5 (1) and (2).

2. A Member State receiving an application for the inclusion of an active substance in Annex I shall without undue delay ensure that a dossier which is believed to satisfy the requirements of Annex II is forwarded by the applicant to the other Member States and to the Commission together with a dossier complying with Annex III on at least one preparation containing that active substance. The Commission shall refer the dossier to the Standing Committee on Plant Health referred to in Article 19 for examination.

3. Without prejudice to the provisions of paragraph 4, at the request of a Member State, and within three to six months after the date of referral to the committee mentioned in Article 19, it shall be established by the procedure laid down in Article 20 whether the dossier has been submitted in accordance with the requirements of Annexes II and III.

4. If the assessment of the dossier referred to in paragraph 2 shows that further information is necessary, the Commission may ask the

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applicant to submit such information. The applicant or his authorized representative may be asked by the Commission to submit his remarks to it, in particular whenever an unfavourable decision is envisaged.

These provisions shall also apply if, after inclusion of an active substance in Annex I, facts emerge that cast doubt on its conformity with the requirements indicated in Article 5 (1) and (2), or if renewal in accordance with Article 5 (5) is being considered.

5. The procedure concerning the submission and appraisal of applications for inclusion in Annex I and setting or varying any conditions for inclusion shall be adopted in accordance with the procedure laid down in Article 21.

Information on potentially harmful effects

Article 7

Member States shall prescribe that the holder of an authorization or those to whom an extension of the field of application has been granted in accordance with Article 9 (1) must immediately notify the competent authority of all new information on the potentially dangerous effects of any plant protection product, or of residues of an active substance on human or animal health or on groundwater, or their potentially dangerous effects on the environment. Member States shall ensure that the parties concerned immediately notify this information to the other Member States and to the Commission, which shall refer the information to the committee referred to in Article 19.

Transitional measures and derogations

Article 8

1. By way of derogation from Article 4, a Member State may, to enable a gradual assessment to be made of the properties of new active substances and to make it easier for new preparations to be made available for use in agriculture, authorize, for a provisional period not exceeding three years, the placing on the market of plant protection products containing an active substance not listed in Annex I and not yet available on the market two years after notification of this Directive, provided that:

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

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

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

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

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

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

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

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

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

During the 12-year period referred to in the first subparagraph it may, following examination by the Committee referred to in Article 19 of such active substance, be decided by the procedure laid down in that Article that the substance can be included in Annex I and under which conditions, or, in cases where the requirements of Article 5 are not satisfied or the requisite information and data have not been submitted within the prescribed period, that such active substance will not be included in Annex I. The Member States shall ensure that the relevant authorizations are granted, withdrawn or varied, as appropriate, within a prescribed period.

3. Where they review plant protection products containing an active substance in accordance with paragraph 2, and before such review has taken place, Member States shall apply the requirements laid down in Article 4 (1) (b) (i) to (v), and (c) to (f) in accordance with national provisions concerning the data to be provided.

4. By way of further derogation from Article 4, in special circumstances a Member State may authorize for a period not exceeding 120 days the placing on the market of plant protection products not complying with Article 4 for a limited and controlled use if such a measure appears necessary because of an unforeseeable danger which cannot be contained by other means. In this case, the Member State concerned shall immediately inform the other Member States and the Commission of its action. It shall be decided without delay, in accordance with the procedure laid down in Article 19, whether and under which conditions the action taken by the Member State may be extended for a given period, repeated, or revoked.

Application for authorization

Article 9

1. Application for authorization of a plant protection product shall be made by or on behalf of the person responsible for first placing it on the market in a Member State to the competent authorities of each Member State where the plant protection product is intended to be placed on the market.

Official or scientific bodies involved in agricultural activities or professional agricultural organizations and professional users may request that the field of application of a plant protection product already authorized in the Member State in question be extended to purposes other than those covered by this authorization.

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Member States shall grant an extension of the field of application of an authorized plant protection product and shall be obliged to grant such an extension when it is in the public interest to the extent that:

— the documentation and information to support an extension of the field of application has been submitted by the applicant,

— they have established that the conditions referred to in Article 4 (1) (b) (iii), (iv) and (v) are satisfied,

— the intended use is minor in nature,

— users are fully and specifically informed as to instructions for use, by means of an addition to the labelling or, failing that, by means of an official publication.

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

3. Member States may require that applications for authorization be submitted in their national or official languages or one of those languages. They may also require that samples of the preparation and of its ingredients be provided.

4. Each Member State shall agree to consider any application for authorization made to it and shall decide thereon within a reasonable period, provided that it has the necessary scientific and technical structures at its disposal.

5. Member States shall ensure that a file is compiled on each application. Each file shall contain at least a copy of the application, a record of the administrative decisions taken by the Member State concerning the application and concerning the particulars and documentation laid down in Article 13 (1) together with a summary of the latter. Member States shall on request make available to the other Member States and to the Commission the files provided for in this paragraph; they shall supply to them on request all information necessary for full comprehension of applications, and shall where requested ensure that applicants provide a copy of the technical documentation laid down in Article 13 (1) (a).

Mutual recognition of authorizations

Article 10

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

— refrain from requiring the repetition of tests and analyses already carried out in connection with the authorization of the product in that Member State, and to the extent that agricultural, plant health and environmental (including climatic) conditions relevant to the use of the product are comparable in the regions concerned, and

— to the extent that the uniform principles have been adopted in accordance with Article 23, where the product contains only active substances listed in Annex I, also authorize the placing of that product on the market in its territory, to the extent that agricultural, plant health and environmental (including climatic) conditions relevant to the use of the product are comparable in the regions concerned.

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

Subject to compliance with the Treaty, authorization may also be accompanied by restrictions on use arising from differences in dietary patterns and necessary in order to avoid exposure of consumers of

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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,

— 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.

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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

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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 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

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

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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.

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;

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(f) the particulars required under Article 6 of Directive 78/631/EEC, in particular those mentioned in paragraph 2 (d), (g), (h) and (i), and paragraphs 3 and 4 of that Article and information on first aid;

(g) the nature of any special risks for humans, animals or the environment, by means of standard phrases selected as appropriate from those given in Annex IV;

(h) safety precautions for the protection of humans, animals or the environment, in the form of standard phrases selected as appropriate from those given in Annex V;

(i) the type of action of the plant protection product (e.g. insecticide, growth regulator, weedkiller, etc.);

(j) the type of preparation (e.g. wettable powder, emulsifiable concentrate, etc.);

(k) the uses for which the plant protection product has been authorized and any specific agricultural, plant health and environmental conditions under which the product may be used or should not be used;

(l) directions for use and the dose rate, expressed in metric units, for each use provided for under the terms of the authorization;

(m) where necessary, the safety interval for each use between application and:

— sowing or planting of the crop to be protected,

— sowing or planting of succeeding crops,

— access by humans or animals,

— harvesting,

— use or consumption;

(n) particulars of possible phytotoxicity, varietal susceptibility, and any other direct or indirect adverse side effects on plants or products of plant origin together with the intervals to be observed between application and sowing or planting of:

— the crop in question, or

— subsequent crops;

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

(p) directions for safe disposal of the plant protection product and of the packaging; and

(q) the expiry date relevant to normal conditions of storage where the shelf life of the product is limited to less than two years.

2. Member States may permit the requirements in paragraph 1 (l), (m) and (n) to be indicated on a separate leaflet accompanying the package if the space available on the package is too small. Such a leaflet shall be regarded as part of the label for the purposes of this Directive.

3. Taking account of the rules in force within their territories regarding the supply of certain plant protection products to certain categories of users, pending Community harmonization, the Member States shall require that it be indicated on the label whether a product is restricted to certain categories of users.

4. In no circumstances may the label of the packaging of a plant protection product bear the indications ‘non-toxic’, ‘harmless’, or similar indications. However, information to the effect that the plant protection product may be used when bees or other non-target species are active, or when crops or weeds are in flower or other such phrases to protect bees or other non-target species may be given on the label, if the authorization relates explicitly to use

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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.

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Article 19

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health set up pursuant to Article 58 of Regulation (EC) No 178/2002 ([1]).

2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC ([2]) shall apply.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its Rules of Procedure.

([1]) OJ L 31, 1.2.2002, p. 1.
([2]) OJ L 184, 17.7.1999, p. 23.

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Article 20

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health.

2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC shall apply.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at 15 days.

Article 21

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health.

2. Where reference is made to this Article, Articles 3 and 7 of Decision 1999/468/EC shall apply.

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Research and development

Article 22

1. The Member States shall prescribe that any experiment or test for research or development purposes involving the release into the environment of an unauthorized plant protection product may only be carried out after authorization for trial purposes has been granted and under controlled conditions and for limited quantities and areas.

2. The persons concerned shall submit an application to the competent authority of the Member State in whose territory the experiment or test is to be conducted, within time periods prescribed by the Member State before the commencement of the experiment or test, together with a dossier containing all the available data to permit an assessment to be made of possible effects on human or animal health or the possible impact on the environment.

If the proposed experiments or tests referred to in paragraph 1 are liable to have harmful effects on human or animal health or to have an unacceptable adverse influence on the environment, the Member State concerned may either prohibit them or permit them subject to such conditions as it considers necessary to prevent those consequences.

3. Paragraph 2 shall not apply if the Member State has granted the person concerned the right to undertake certain experiments and tests and has determined the conditions under which the experiments and tests have to be undertaken.

4. Common conditions for the application of this Article, in particular the maximum quantities of pesticides that may be released during experiments covered by paragraph 1, and the minimum data to be submitted in accordance with paragraph 2, shall be adopted in accordance with the procedure laid down in Article 19.

5. This Article shall not apply to experiments or tests covered by Part B of Directive 90/220/EEC.

Implementation of the Directive

Article 23

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive within two years following notification thereof. They shall immediately inform the Commission thereof. The uniform principles shall be adopted one year after the date of notification.

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

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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 AUTHORISED FOR USE IN PLANT PROTECTION PRODUCTS

General provisions applying to all substances listed in this Annex:

For the implementation of the uniform principles of Annex VI in relation to each substance, the conclusions of the review report on it, and in particular the Appendices I and II thereof, as finalised in the Standing Committee on Plant Health on the date indicated under 'specific provisions' for that substance shall be taken into account.

Member States shall keep available all review reports (except for confidential information within the meaning of Article 14 of the Directive) for consultation by any interested parties or shall make it available to them on specific request.

Number	Common name, identification numbers	IUPAC name	Purity [1]	Entry into force	Expiration of inclusion	Specific provisions
1	Imazalil CAS No 73790-28-0, 35554-44-0 CIPAC No 335	(±)-1-(β-allyloxy-2,4-dichlorophenylethyl) imidazole or (±)-allyl 1-(2,4-dichlorophenyl)-2-imidazol-1-ylethyl ether	975 g/kg	1.1.1999	31.12.2008	Only uses as fungicide may be authorised For the following uses the following particular conditions apply: — post harvest fruit, vegetable and potato treatments may only be authorised when an appropriate decontamination system is available or a risk assessment has demonstrated to the authorising Member State that the discharge of the treatment solution does not have an unacceptable risk to the environment and in particular to aquatic organisms, — post harvest treatment of potatoes may only be authorised when a risk assessment has demonstrated to the authorising Member State that the discharge of the processing waste from treated potatoes does not have an unacceptable risk to aquatic organisms, — outdoor foliar uses may only be authorised when a risk assessment has demonstrated to the authorising Member State that the use has no unacceptable effects on human and animal health and the environment Date of Standing Committee on Plant Health at which the review report was finalised: 11.7.1997.
2	Azoxystrobin CAS No 131860-33-8 CIPAC No 571	Methyl (E)-2-{2[6-(2-cyanophenoxy)pyrimidin-4-yloxy] phenyl}-3-methoxyacrylate	930 g/kg (Z isomer max. 25 g/kg)	1.7.1998	1.7.2008	Only uses as fungicide may be authorised In the decision-making according to the uniform principles, particular attention should be given to the impact on aquatic organisms. Authorisation conditions should include appropriate risk mitigation measures Date of Standing Committee on Plant Health at which the review report was finalised: 22.4.1998

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Number	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
3	Kresoxim-methyl CAS No 143390-89-0 CIPAC No 568	Methyl (E)-2-methoxyimino-2-[2-(o-tolyloxymethyl) phenyl] acetate	910 g/kg	1.2.1999	31.1.2009	Only used as fungicide may be authorised In their decision-making according to the uniform principles, Member States shall pay particular attention to the protection of groundwater under vulnerable conditions Date of Standing Committee on Plant Health at which the review report was finalised: 16.10.1998
4	Spiroxamine CAS No 1181134-30-8 CIPAC No 572	(8-tert-Butyl-1,4-dioxaspiro [4.5] decan-2-ylmethyl)-ethyl-propylamine	940 g/kg (diastereomers A and B combined)	1.9.1999	1.9.2009	Only uses as a fungicide may be authorised In their decision-making according to the uniform principles, Member States: — must pay particular attention to operator safety and must ensure that the conditions of authorisation include appropriate protective measures, and — must pay particular attention to the impact on aquatic organisms and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures Date of Standing Committee on Plant Health at which the review report was finalised: 12.5.1999
5	Azimsulfuron CAS No 120162-55-2 CIPAC No 584	1-(4,6-dimethoxypyrimidin-2-yl)-3-[1-methyl-4-(2-methyl-2H-tetrazol-5-yl)-pyrazol-5-ylsulfonyl]-urea.	980 g/kg	1.10.1999	1.10.2009	Only uses as herbicide may be authorised Aerial application may not be authorised In their decision making according to the uniform principles, Member States must pay particular attention to the impact on aquatic organisms and terrestrial non-target plants and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures (e. g. in rice cultivation minimum holding periods for water prior to discharge) Date of Standing Committee on Plant Health at which the review report was finalised: 2.7.1999
6	Fluroxypyr CAS No 69377-81-7 CIPAC No 431	4-amino-3,5-dichloro-6-fluoro-2-pyridyloxyacetic acid	950 g/kg	1.12.2000	30.11.2010	Only uses as herbicide may be authorised In their decision-making according to the uniform principles, Member States: — shall take into account the additional information requested in point 7 of the review report, — must pay particular attention to the protection of groundwater, — must pay particular attention to the impact on aquatic organisms and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures Member States shall inform the Commission if the requested additional trials and information as outlined in point 7 of the review report were not submitted by 1.12.2000 Date of Standing Committee on Plant Health at which the review report was finalised: 30.11.1999

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Number	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
7	Metsulfuron-methyl CAS No 74223-64-6 EEC No 441	Methyl-2-(4-methoxy-6-methyl-1,3,5,-triazin-2-ylcarbamoylsulfamoyl) benzoate	960 g/kg	1.7.2001	30.6.2011	Only uses as herbicide may be authorised In their decision making according to the uniform principles, Member States: — must pay particular attention to the protection of groundwater, — must pay particular attention to the impact on aquatic organisms and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures Date of Standing Committee on Plant Health at which the review report was finalised: 16.6.2000
8	Prohexadione-calcium CAS No 127277-53-6 CIPAC No 567	Calcium 3,5-dioxo-4-propionylcyclohexanecarboxylate	890 g/kg	1.10.2000	1.10.2010	Only uses as plant growth regulator may be authorised Date of Standing Committee on Plant Health at which the review report was finalised: 16.6.2000
9	Triasulfuron CAS No 82097-50-5 CIPAC No 480	1-[2-(2-chloroethoxy) phenylsulfonyl]-3-(4-methoxy-6-methyl-1,3,5-triazin-2-yl)urea	940 g/kg	1.8.2001	31.7.2011	Only uses as herbicide may be authorised In their decision making according to the uniform principles, Member States: — must pay particular attention to the protection of groundwater, — must pay particular attention to the impact on aquatic organisms and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures Date of Standing Committee on Plant Health at which the review report was finalised: 13.7.2000
10	Esfenvalerate CAS No 66230-04-4 CIPAC No 481	(S)-α-Cyano-3-phenoxy-benzyl-(S)-2-(4-chloro-phenyl)-3-methylbutyrate	830 g/kg	1.8.2001	31.7.2011	Only uses as insecticide may be authorised In their decision making according to the uniform principles, Member States: — must pay particular attention to the potential impact on aquatic organisms and non-target arthropods and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures Date of Standing Committee on Plant Health at which the review report was finalised: 13.7.2000
11	Bentazone CAS No 25057-89-0 CIPAC No 366	3-isopropyl-(1H)-2,1,3-benzothiadiazin-4-(3H)-one-2,2-dioxide	960 g/kg	1.8.2001	31.7.2011	Only uses as herbicide may be authorised In their decision-making according to the uniform principles, Member States must pay particular attention to the protection of groundwater Date of Standing Committee on Plant Health at which the review report was finalised: 13.7.2000

▼M22

Number	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
12	Lambda-cyhalothrin CAS No 91465-08-6 CIPAC No 463	A 1:1 mixture of: (S)-α-cyano-3-phenoxybenzyl (Z)-(1R,3R)-3-(2-chloro-3,3,3-trifluoropropenyl)-2,2-dimethylcyclopropanecarboxylate, and (R)-α-cyano-3-phenoxybenzyl (Z)-(1S,3S)-3-(2-chloro-3,3,3-trifluoropropenyl)-2,2-dimethylcyclopropanecarboxylate	810 g/kg	1.1.2002	31.12.2011	Only uses as insecticide may be authorised In their decision-making according to the uniform principles, Member States: — must pay particular attention to operator safety, — must pay particular attention to the potential impact on aquatic organisms and non-target arthropods including bees and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures, — must pay particular attention to the residues in food and especially the acute effects thereof Date of Standing Committee on Plant Health at which the review report was finalised: 19.10.2000

▼M24

13	Fenhexamid CAS No 126833-17-8 CIPAC No 603	N-(2,3-dichloro-4-hydroxyphenyl)-1-methylcyclohexanecarboxamide	≥ 950 g/kg (2)	1 June 2001	31 May 2011	Only uses as a fungicide may be authorised. In decision making according to the Uniform Principles Member States must pay particular attention to the potential impact on aquatic organisms and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures. Date of Standing Committee on Plant Health at which the review report was finalised: 19 October 2000

▼M23

14	Amitrole CAS No 61-82-5 CIPAC No 90	H-[1,2,4]-triazole-3-ylamine	900 g/kg	1.1.2002	31.12.2011	Only uses as herbicide may be authorised For the implementation of the uniform principles of Annex VI, the conclusions of the review report on amitrole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plant Health on 12 December 2000 shall be taken into account. In this overall assessment Member States: — must pay particular attention to the protection of operators — must pay particular attention to the protection of the groundwater in vulnerable areas, in particular with respect to non-crop uses — must pay particular attention to the protection of beneficial arthropods — must pay particular attention to the protection of birds and wild mammals. Use of amitrole during the breeding season may only be authorised when an appropriate risk assessment has demonstrated that there is no unacceptable impact and when the conditions of authorisation include, where appropriate, risk mitigation measures

▼M23

Number	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
15	Diquat CAS No 2764-72-9 (ion), 85-00-7 (dibromide) CIPAC No 55	9,10-Dihydro-8a,10a-diazoniaphenanthrene ion (dibromide)	950 g/kg	1.1.2002	31.12.2011	On the basis of currently available information, only uses as terrestrial herbicide and desiccant may be authorised. Uses in aquatic weed control shall not be authorised For the implementation of the uniform principles of Annex VI, the conclusions of the review report on diquat, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plant Health on 12 December 2000 shall be taken into account. In this overall assessment Member States: — must pay particular attention to the potential impact on aquatic organisms and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures — must pay particular attention to operator safety as related to non-professional use and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures
16	Pyridate CAS No 55512-33.9 CIPAC No 447	6-Chloro-3-phenylpyridazin-4-yl S-octyl thiocarbonate	900 g/kg	1.1.2002	31.12.2011	Only uses as herbicide may be authorised For the implementation of the uniform priciples of Annex VI, the conclusions of the review report on pyridate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plant Health on 12 December 2000 shall be taken into account. In this overall assessment Member States: — must pay particular attention to the protection of groundwater — must pay particular attention to the potential impact on aquatic organisms and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures
17	Thiabendazole CAS No 148-79-8 CIPAC No 323	2-Thiazol-4-yl-1H-benzimidazole	985 g/kg	1.1.2002	31.12.2011	Only uses as fungicide may be authorised. Foliar spray applications shall not be authorised For the implementation of the uniform priciples of Annex VI, the conclusions of the review report on thiabendazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plant Health on 12 December 2000 shall be taken into account. In this overall assessment Member States: — must pay particular attention to the protection of aquatic and sediment-dwelling organisms and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures Suitable risk mitigation measures (e.g. depuration with diatom earth or activated carbon) have to be implemented to protect surface waters from unacceptable levels of contamination via wastewater

▼M23

Number	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
▼M26 18	Paecilomyces fumosoroseus Apopka strain 97, PFR 97 or CG 170, ATCC20874	Not applicable	The absence of secondary metabolites should be checked in each fermentation broth by HPLC	1 July 2001	30 June 2011	Only uses as an insecticide may be authorised Each fermentation broth should be checked by HPLC to ensure that no secondary metabolites are present Date of Standing Committee on Plant Health at which the review report was finalised: 27 April 2001
▼M27 19	DPX KE 459 (flupyrsulfuron-methyl) CAS No 144740-54-5 CIPAC No 577	2-(4,6-dimethoxypyrimidin-2-ylcarbamoylsulfamoyl)-6-trifluromethylnicotinate monosodium salt	903 g/kg (3)	1 July 2001	30 June 2011	Only uses as a herbicide may be authorised. In decision-making according to the Uniform Principles Member States must pay particular attention to the protection of groundwater. Date of Standing Committee on Plant Health at which the review report was finalised: 27 April 2001.
▼M28 20	Acibenzolar-s-methyl CAS No 135158-54-2 CIPAC No 597	Benzo[1,2,3]thiadiazole-7-carbothioic acid S-methyl ester	970 g/kg	1 November 2001	31 October 2011	Only uses as a plant activator may be authorised. Date of Standing Committee on Plant Health at which the review report was finalised: 29 June 2001.
21	Cyclanilide CAS No 113136-77-9 CIPAC No 586	Not available	960 g/kg	1 November 2001	31 October 2011	Only uses as a plant growth regulator may be authorised. The maximum content of the impurity 2,4-dichloroaniline (2,4-DCA) in the active substance as manufactured should be 1 g/kg. Date of Standing Committee on Plant Health at which the review report was finalised: 29 June 2001.
22	Ferric phosphate CAS No 10045-86-0 CIPAC No 629	Ferric phosphate	990 g/kg	1 November 2001	31 October 2011	Only uses as a molluscicide may be authorised. Date of Standing Committee on Plant Health at which the review report was finalised: 29 June 2001
23	Pymetrozine CAS No 123312-89-0 CIPAC No 593	(*E*)-6-methyl-4-[(pyridin-3-ylmetylene)amino]-4,5-dihydro-2H-[1,2,4]-triazin-3 one	950 g/kg	1 November 2001	31 October 2011	Only uses as an insecticide may be authorised. In decision-making according to the uniform principles Member States must pay particular attention to the protection of aquatic organisms. Date of Standing Committee on Plant Health at which the review report was finalised: 29 June 2001.

▼M28

Number	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
24	Pyraflufen-ethyl CAS No 129630-19-9 CIPAC No 605	Ethyl-2-chloro-5-(4-chloro-5-difluoro-methoxy-1-mhypyrazol-3-yl)-4-fluorophenoxya-cetate	956 g/kg	1 November 2001	31 October 2011	Only uses as a herbicide may be authorised. In decision-making according to the uniform principles Member States must pay particular attention to the protection of algae and aquatic plants and should apply, where appropriate, risk mitigation measures. Date of Standing Committee on Plant Health at which the review report was finalised: 29 June 2001.

▼M29

25	Glyphosate CAS No 1071-83-6 CIPAC No 284	N-(phosphonomethyl)-glycin	950 g/kg	1 July 2002	30 June 2012	Only uses as herbicide may be authorised For the implementation of the uniform principles of Annex VI, the conclusions of the review report on glyphosate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plant Health on 29 June 2001 shall be taken into account. In this overall assessment Member States: — must pay particular attention to the protection of the groundwater in vulnerable areas, in particular with respect to non-crops uses
26	Thifensulfuron-methyl CAS No 79277-27-3 CIPAC No 452	Methyl 3-(4-methoxy-6-methyl-1,3,5-triazin-2-ylcarbamoyl-sulfamoyl) thiophene-2-carboxylate	960 g/kg	1 July 2002	30 June 2012	Only uses as herbicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on thifensulfuron-methyl, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plant Health on 29 June 2001 shall be taken into account. In this overall assessment Member States: — must pay particular attention to the protection of groundwater, — must pay particular attention to the impact on aquatic plants and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures

▼M30

27	2,4-D CAS No 94-75-7 CIPAC No 1	(2,4-dichlorophenoxy) acetic acid	960 g/kg	1.10.2002	30.9.2012	Only uses as herbicide may be authorised For the implementation of the uniform principles of Annex VI, the conclusions of the review report on 2,4-D, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plant Health on 2 October 2001 shall be taken into account. In this overall assessment Member States: — must pay particular attention to the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions — must pay particular attention to the dermal absorption — must pay particular attention to the protection of non-target arthropods and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures

▼M30

Number	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
▼M31 28	Isoproturon CAS No 34123-59-6 CIPAC No 336	3-(4-isopropylphenyl)-1,1-dimethylurea	970 g/kg	1 January 2003	31 December 2012	Only uses as herbicide may be authorised For the implementation of the uniform principles of Annex VI, the conclusions of the review report on isoproturon, and in particular Appendices I and II thereto, as finalised in the Standing Committee on Plant Health on 7 December 2001 shall be taken into account. In this overall assessment Member States: — must pay particular attention to the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions or at use rates higher than those described in the review report and must apply risk mitigation measures, where appropriate, — must pay particular attention to the protection of aquatic organisms and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures
▼M32 29	Ethofumesate CAS No 26225-79-6 CICAP No 223	(±)-2-ethoxy-2,3-dihydro-3,3-dimethylbenzofuran-5-ylmethanesulfonate	960 g/kg	1 March 2003	28 February 2013	Only uses as herbicide may be authorised For the implementation of the uniform principles of Annex VI, the conclusions of the review report on ethofumesate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 26 February 2002 shall be taken into account. In this overall assessment Member States may pay particular attention to the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions and must apply risk mitigation measures, where appropriate.
▼M33 30	Iprovalicarb CAS No 140923-17-7 CICAP No 620	{2-Methyl-1-[1-(4-methylphenyl)ethylcarbonyl] propyl}-carbamic acid isopropylester	950 g/kg (provisional specification)	1 July 2002	30 June 2011	Only uses as fungicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on iprovalicarb, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 26 February 2002 shall be taken into account. In this overall assessment: — the specification of the technical material as commercially manufactured must be confirmed and supported by apporpriate analytical data. The test material used in the toxicity dossier should be compared and verified against this specification of the technical material, — Member States must pay particular attention to the protection of operators.

▼M33

Number	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
31	Prosulfuron CAS No 94125-34-5 CICAP No 579	1-(4-methoxy-6-methyl-1,3,5-triazin-2-yl)-3-[2-(3,3,3-trifluoropropyl)-phenylsulfonyl]-urea	950 g/kg	1 Juli 2002	30 June 2011	Only uses as herbicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on prosulfuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 26 February 2002 shall be taken into account. In this overall assessment Member States: — must carefully consider the risk to aquatic plants if the active substance is applied adjacent to surface waters. Risk mitigation measures should be applied where appropriate, — must pay particular attention to the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climate conditions. Risk mitigation measures should be applied where appropriate.
32	Sulfosulfuron CAS No 141776-32-1 CICAP No 601	1-(4,6-dimethoxypyrimidin-2-yl)-3-[2-ethanesulfonyl-imidazo[1,2-*a*]pyridine) sulfonyl]urea	980 g/kg	1 July 2002	30 June 2011	Only uses as a herbicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on sulforsulfuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 26 February 2002 shall be taken into account. In this overall assessment: — Member States must pay particular attention to the protection of aquatic plants and algae. Where apporpriate, risk mitigation measures should be applied, — Member States must pay particular attention to the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditons.

▼M34

Number	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
33	Cinidon-ethyl CAS No 142891-20-1 CIPAC No 598	(Z)-ethyl 2-chloro-3-[2-chloro-5-(cyclohex-1-ene-1,2-dicarboximido) phenyl]acrylate	940 g/kg	1 October 2002	30 September 2012	Only uses as herbicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on cinidon-ethyl, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 19 April 2002 shall be taken into account. In this overall assessment Member States: — should pay particular attention to the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil (e.g. soils with neutral or high pH values) and/or climatic conditions, — should pay particular attention to the protection of aquatic organisms. Conditions of authorisation must include risk-mitigation measures, where appropriate.

▼M34

Number	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
34	Cyhalofop butyl CAS No 122008-85-9 CIPAC No 596	Butyl-(R)-2-[4(4-cyano-2-fluorophenoxy) phenoxy]propionate	950 g/kg	1 October 2002	30 September 2012	Only uses as herbicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on cyhalofop butyl, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 19 April 2002 shall be taken into account. In this overall assessment: — Member States must carefully consider the potential impact of aerial applications to non-target organisms and in particular to aquatic species. Conditions of authorisation must include restrictions or risk mitigation measures, where appropriate, — Member States must carefully consider the potential impact of terrestrial applications on aquatic organisms within paddy fields. Conditions of authorisation must include risk-mitigation measures, where appropriate.
35	Famoxadone CAS No 131807-57-3 CIPAC No 594	3-anilino-5-methyl-5-(4-phenoxyphenyl)-1,3-oxazolidine-2,4-dione	960 g/kg	1 October 2002	30 September 2012	Only uses as fungicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on famoxadone, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 19 April 2002 shall be taken into account. In this overall assessment: — Member States must pay particular attention to potential chronic risks of the parent substance or metabolites to earthworms, — Member States must pay particular attention to the protection of aquatic organisms and must ensure that the conditions of authorisation include, where appropriate, risk-mitigation measures, — Member States should pay particular attention to the protection of operators.
36	Florasulam CAS No 145701-23-1 CIPAC No 616	2′, 6′, 8-Trifluoro-5-methoxy-[1,2,4]-triazolo [1,5-c] pyrimidine-2-sulphonanilide	970 g/kg	1 October 2002	30 September 2012	Only uses as herbicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on florasulam, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 19 April 2002 shall be taken into account. In this overall assessment Member States: — should pay particular attention to the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation must include risk-mitigation measures, where appropriate.

▼M34

Number	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
37	Metalaxyl-M CAS No 70630-17-0 CIPAC No 580	Methyl(R)-2-{[(2,6-dimethylphenyl)methoxy-acetyl] amino} propionate	910 g/kg	1 October 2002	30 September 2012	Only uses as fungicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on Metalaxyl-M, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 19 April 2002 shall be taken into account. In this overall assessment: — particular attention should be given to the potential for groundwater contamination by the active substance or its degradation products CGA 62826, and CGA 108906 when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Risk-mitigation measures should be applied, where appropriate.
38	Picolinafen CAS No 137641-05-5 CIPAC No 639	4′-Fluoro-6-[(α,α,α-trifluoro-m-tolyl)oxy] picolinanilide	970 g/kg	1 October 2002	30 September 2012	Only uses as herbicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on picolinafen, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 19 April 2002 shall be taken into account. In this overall assessment Member States: — must pay particular attention to the protection of aquatic organisms. Conditions of authorisation should include risk-mitigation measures, where appropriate.
▼M35 39	Flumioxazine CAS No 103361-09-7 CICAP No 578	N-(7-fluoro-3,4-dihydro-3-oxo-4-prop-2-ynyl-2H-1,4-benzoxazin-6-yl) cyclohex-1-ene-1,2-dicarboximide	960 g/kg	1 January 2003	31 December 2012	Only uses as herbicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on flumioxazine, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 June 2002 shall be taken into account. In this overall assessment Member States: — must carefully consider the risk to aquatic plants and algae. Conditions of authorisation must include risk mitigation measures, where appropriate.

▼M35

Number	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
▼M36 40	Deltamethrin CAS No 52918-63-5 CIPAC No 333	(S)-α-cyano-3-phenoxy-benzyl (1R,3R)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropane carboxylate	980 g/kg	1 November 2003	31 October 2013	Only uses as insecticide may be authorised For the implementation of the uniform principles of Annex VI, the conclusions of the review report on deltamethrin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plant Health on 18 October 2002 shall be taken into account. In this overall assessment Member States: — must pay particular attention to the operator safety and must ensure that the conditions of authorisation include appropriate protective measures, — should observe the acute dietary exposure situation of consumers in view of future revisions of maximum residue levels, — must pay particular attention to the protection of aquatic organisms, bees and non-target arthropods and must ensure that the conditions of authorisation include risk mitigation measures, where appropriate.
▼M37 41	Imazamox CAS No 114311-32-9 CIPAC No 619	(±)-2-(4-isopropyl-4-methyl-5-oxo-2-imidazolin-2-yl)-5-(methoxymethyl) nicotinic acid	950 g/kg	1 July 2003	30 June 2013	Only uses as herbicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on imazamox, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 December 2002 shall be taken into account. In this overall assessment Member States should pay particular attention to the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climate conditions. Risk mitigation measures should be applied where appropriate.
42	Oxasulfuron CAS No 144651-06-9 CIPAC No 626	Oxetan-3-yl 2[(4,6-dimethylpyrimidin-2-yl) carbamoyl-sulfamoyl] benzoate	960 g/kg	1 July 2003	30 June 2013	Only uses as herbicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on oxasulfuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 December 2002 shall be taken into account. — Member States must pay particular attention to the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climate conditions. Risk mitigation measures should be applied, where appropriate.

▼M37

Number	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
43	Ethoxysulfuron CAS No 126801-58-9 CIPAC No 591	3-(4,6-dimethoxypyrimidin-2-yl)-1-(2-ethoxyphenoxy-sulfonyl)urea	950 g/kg	1 July 2003	30 June 2013	Only uses as herbicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on ethoxysulfuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 December 2002 shall be taken into account. Member States should pay particular attention to the protection of non-target aquatic plants and algae in drainage canals. Risk mitigation measures should be applied where appropriate.
44	Foramsulfuron CAS No 173159-57-4 CIPAC No 659	1-(4,6-dimethoxypyrimidin-2-yl)-3-(2-dimethylcarbamoyl-5-formamidophenylsulfonyl)urea	940 g/kg	1 July 2003	30 June 2013	Only uses as herbicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on foramsulfuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 December 2002 shall be taken into account. In this overall assessment Member States should pay particular attention to the protection of aquatic plants. Risk mitigation measures should be applied, where appropriate.
45	Oxadiargyl CAS No 39807-15-3 CIPAC No 604	5-tert-butyl-3-(2,4-dichloro-5-propargyloxyphenyl)-1,3,4 oxadiazol-2-(3H)-one	980 g/kg	1 July 2003	30 June 2013	Only uses as herbicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on oxadiargyl, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 December 2002 shall be taken into account. In this overall assessment Member States should pay particular attention to the protection of algae and aquatic plants. Risk mitigation measures should be applied where appropriate.
46	Cyazofamid CAS No 120116-88-3 CIPAC No 653	4-chloro-2cyano-N,N-dimethyl-5-P-tolylimidazole -1-sulfonamide	935 g/kg	1 July 2003	30 June 2013	Only uses as fungicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on cyazofamid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 December 2002 shall be taken into account. In this overall assessment — Member States must pay particular attention to the protection of aquatic organisms; — Member States must pay particular attention to the degradation kinetics of the metabolite CTCA in soil, especially for Northern European regions. Risk mitigation measures or use restrictions should be applied where appropriate.

▼M37

Number	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
▼M38						
47	2,4-DB CAS No 94-82-6 CIPAC No 83	4-(2,4-dichlorophenoxy) butyric acid	940 g/kg	1 January 2004	31 December 2013	Only use as herbicide may be authorised For the implementation of the uniform principles of Annex VI, the conclusions of the review report on 2,4-DB, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 December 2002 shall be taken into account. In this overall assessment Member States: must pay particular attention to the protection of groundwater when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Risk mitigation measures should be applied, where appropriate.
48	Beta-cyfluthrin CAS No 68359-37-5 (unstated stereochemistry) CIPAC No 482	(1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylic acid (SR)-α-cyano- (4-fluoro-3-phenoxy-phenyl)methyl ester	965 g/kg	1 January 2004	31 December 2013	Only use as insecticide may be authorised Uses other than ornamental in greenhouses and seed treatment are currently not adequately supported and have not shown to be acceptable under the criteria required by Annex VI. To support authorisations for such uses, data and information to prove their acceptability to human consumers and the environment will have to be generated and submitted to the Member States. This will be the case in particular for data to assess in all detail the risks of outdoor foliar uses and the dietary risks of foliar treatment in edible crops. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on beta-cyfluthrin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 December 2002 shall be taken into account. In this overall assessment: Member States must pay particular attention to the protection of non-target arthropods. Conditions of authorisation should include adequate risk mitigation measures.
49	Cyfluthrin CAS No 68359-37-5 (unstated stereochemistry) CIPAC No 385	(RS),-α-cyano-4-fluoro-3-phenoxybenzyl-(1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethycyclopropanecarboxylate	920 g/kg	1 January 2004	31 December 2013	Only use as insecticide may be authorised Uses other than ornamental in greenhouses and seed treatment are currently not adequately supported and have not shown to be acceptable under the criteria required by Annex VI. To support authorisations for such uses, data and information to prove their acceptability to human consumers and the environment will have to be generated and submitted to the Member States. This will be the case in particular for data to assess in all detail the risks of outdoor foliar uses and the dietary risks of foliar treatment in edible crops. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on cyfluthrin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 December 2002 shall be taken into account. In this overall assessment: Member States must pay particular attention to the protection of non-target arthropods. Conditions of authorisation should include adequate risk mitigation measures.

▼M38

Number	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
50	Iprodione CAS No 36734-19-7 CIPAC No 278	3-(3,5-dichlorophenyl)-N-isopropyl-2,4-dioxo-imidazolidine-1-carboximide	960 g/kg	1 January 2004	31 December 2013	Only use as fungicide may be authorised For the implementation of the uniform principles of Annex VI, the conclusions of the review report on iprodione, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 December 2002 shall be taken into account. In this overall assessment, Member States: — should pay particular attention to the potential for ground water contamination when the active substance is applied at high use rates (in particular use in turf) on acidic soils (pH below 6) under vulnerable climatic conditions, — must carefully consider the risk to aquatic invertebrates if the active substance is applied directly adjacent to surface waters. Risk mitigation measures should be applied, where appropriate.
51	Linuron CAS No 330-55-2 CIPAC No 76	3-(3,4-dichlorophenyl)-1-methoxy-1-methylurea	900 g/kg	1 January 2004	31 December 2013	Only use as herbicide may be authorised For the implementation of the uniform principles of Annex VI, the conclusions of the review report on linuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 December 2002 shall be taken into account. In this overall assessment Member States: — must pay particular attention to the protection of wild mammals, non-target arthropods and aquatic organisms. Conditions of authorisation should include risk mitigation measures, where appropriate, — must pay particular attention to the protection of operators.
52	Maleic hydrazide CAS No 123-33-1 CIPAC No 310	6-hydroxy-2H-pyridazin-3-one	940 g/kg The active substance shall comply with Council Directive 79/117/EEC (4), as amended by Council Directive 90/533/EEC (5).	1 January 2004	31 December 2013	Only use as growth regulator may be authorised For the implementation of the uniform principles of Annex VI, the conclusions of the review report on maleic hydrazide, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 December 2002 shall be taken into account. In this overall assessment Member States: — must pay particular attention to the protection of non-target arthropods and must ensure that the conditions of authorisation include risk mitigation measures, where appropriate, — must pay particular attention to the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Risk mitigation measures should be applied, where appropriate.

▼M38

Number	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
53	Pendimethalin CAS No 40487-42-1 CIPAC No 357	N-(1-ethylpropyl)-2,6-dinitro-3,4-xylidene	900 g/kg	1 January 2004	31 December 2013	Only use as herbicide may be authorised For the implementation of the uniform principles of Annex VI, the conclusions of the review report on pendimethalin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health 3 December 2002 shall be taken into account. In this overall assessment Member States: — must pay particular attention to the protection of aquatic organisms and non-target terrestrial plants. Conditions of authorisation must include risk mitigation measures, where appropriate, — must pay particular attention to the possibility of short-range transport of the active substance in air.
▼M40 54	Propineb CAS No: 12071-83-9 (monomer), 9016-72-2 (homopolymer) CIPAC No: 177	Polymeric zinc 1,2-propylenebis(dithiocarbamate)	The technical active substance should comply with the FAO specification	1 April 2004	31 March 2014	Only uses as fungicide may be authorised For the implementation of the uniform principles of Annex VI, the conclusions of the review report on propineb, and in particular Appendices I and II thereto, as finalised in the Standing Committee on the Food Chain and Animal Health on 26 February 2003 shall be taken into account. In this overall assessment: — Member States should pay particular attention to the potential for ground water contamination when the active substance is applied in regions with vulnerable soils and/or extreme climatic conditions — Member States should pay particular attention to the protection of small mammals, aquatic organisms and non-target arthropods. Conditions of authorisation should include risk mitigation measures, where appropriate — Member States should observe the acute dietary exposure situation of consumers in view of future revisions of maximum residue levels
55	Propyzamide CAS No: 23950-58-5 CIPAC No: 315	3,5-dichloro-N-(1,1-dimethyl-prop-2-ynyl) benzamide	920 g/kg	1 April 2004	31 March 2014	Only uses as herbicide may be authorised For the implementation of the uniform principles of Annex VI, the conclusions of the review report on propyzamide, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plant Health 26 February 2003 shall be taken into account. In this overall assessment, Member States: — must pay particular attention to the protection of operators and must ensure that conditions of authorisation include risk mitigation measures, where appropriate — must pay particular attention to the protection of birds and wild mammals in particular if the substance is applied during the breeding season. Conditions of authorisation should include risk mitigation measures, where appropriate

▼M40

Number	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
▼M42						
56	Mecoprop CAS No 7085-19-0 CIPAC No 51	(RS)-2-(4-chloro-o-tolyloxy)-propionic acid	930 g/kg	1 June 2004	31 May 2014	Only uses as herbicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on mecoprop, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 April 2003 shall be taken into account. In this overall assessment: — Member States should pay particular attention to the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation should include risk mitigation measures, where appropriate, — Member States should pay particular attention to the protection of non-target arthropods. Risk mitigation measures should be applied, where appropriate.
57	Mecoprop-P CAS No 16484-77-8 CIPAC No 475	(R)-2-(4-chloro-o-tolyloxy)-propionic acid	860 g/kg	1 June 2004	31 May 2014	Only uses as herbicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on mecoprop-P, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 April 2003 shall be taken into account. In this overall assessment: — Member States should pay particular attention to the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation should include risk mitigation measures, where appropriate.
58	Propiconazole CAS No 60207-90-1 CIPAC No 408	(±)-1-[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole	920 g/kg	1 June 2004	31 May 2014	Only uses as fungicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on propiconazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 April 2003 shall be taken into account. In this overall assessment: — Member States should pay particular attention to the protection of non-target arthropods and aquatic organisms. Conditions of authorisation should include risk mitigation measures, where appropriate, — Member States should pay particular attention to the protection of soil organisms for applications rates exceeding 625 g a.i./ha (e.g. uses in lawn). Conditions of authorisation should include risk mitigation measures (e.g. spotwise application scheme), where appropriate.

▼M42

Number	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
▼M41 59	Trifloxystrobin CAS No 141517-21-7 CIPAC No 617	Methyl (E)-methoxyimino-{(E)-a-[1-a-(a,a,a-trifluoro-m-tolyl)ethylideneaminooxyl]-o-tolyl} acetate	960 g/kg	1 October 2003	30 September 2013	Only use as fungicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on trifloxystrobin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 April 2003 shall be taken into account. In this overall assessment: — Member States should pay particular attention to the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climate conditions. Risk mitigation measures should be applied and/or monitoring programs may be initiated where appropriate.
60	Carfentrazone ethyl CAS No 128639-02.1 CIPAC No 587	Ethyl (RS)-2-chloro-3-[2-chloro-5-(4-difluoromethyl-4,5-dihydro-3-methyl-5oxo-1H 1,2,4-triazol-1-yl)-4-fluorophenyl]propionate	900 g/kg	1 October 2003	30 September 2013	Only use as herbicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on carfentrazone-ethyl, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 April 2003 shall be taken into account. In this overall assessment: — Member States should pay particular attention to the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climate conditions. Risk mitigation measures should be applied where appropriate.
61	Mesotrione CAS No 104206-8 CIPAC No 625	2-(4-mesyl-2-nitrobenzoyl) cyclohexane -1,3-dione	920 g/kg The manufacturing impurity 1-cyano-6-(methylsulfonyl)-7-nitro-9H-xanthen-9-one is considered to be of toxicological concern and must remain below 0.0002 % (w/w) in the technical product.	1 October 2003	30 September 2013	Only use as herbicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on mesotrione, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 April 2003 shall be taken into account.

▼M41

Number	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
62	Fenamidone CAS No 161326-34-7 CIPAC No 650	(S)-5-methyl-2-methylthio-5-phenyl-3-phenylamino-3,5-dihydroimidazol-4-one	975 g/kg	1 October 2003	30 September 2013	Only use as fungicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on fenamidone, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 April 2003 shall be taken into account. In this overall assessment Member States: — should pay particular attention to the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climate conditions, — should pay particular attention to the protection of non-target arthropods, — should pay particular attention to the protection of aquatic organisms. Risk mitigation measures should be applied where appropriate.
63	Isoxaflutole CAS No 141112-29-0 CIPAC No 575	5-cyclopropyl-4-(2-methylsulfonyl-4-trifluoromethylbenzoyl) isoxazole	950 g/kg	1 October 2003	30 September 2013	Only use as herbicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on isoxaflutole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 April 2003 shall be taken into account. In this overall assessment Member States: — must pay particular attention to the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climate conditions. Risk mitigation measures or monitoring programs should be applied where appropriate.
▼M46 64	Flurtamone CAS No 96525-23-4	(RS)-5-methylamino-2-phenyl-4-(a,a,a-trifluoro-m-tolyl) furan-3 (2H)-one	960 g/kg	1 January 2004	31 December 2013	Only uses as herbicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on flurtamone, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 4 July 2003 shall be taken into account. In this overall assessment Member States: — should pay particular attention to the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climate conditions, — should pay particular attention to the protection of algae and other aquatic plants. Risk mitigation measures should be applied where appropriate.

▼M46

Number	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
65	Flufenacet CAS No 142459-58-3 CIPAC No 588	4'-fluoro-N-isopropyl-2-[5-(trifluoromethyl)-1,3,4-thiadiazol-2-yloxy] acetanilide	950 g/kg	1 January 2004	31 December 2013	Only uses as herbicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on flufenacet, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 4 July 2003 shall be taken into account. In this overall assessment Member States: — should pay particular attention to the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climate conditions, — should pay particular attention to the protection of algae and aquatic plants, — should pay particular attention to the protection of operators. Risk mitigation measures should be applied where appropriate.
66	Iodosulfuron CAS No 185119-76-0 (parent) 144550-36-7 (iodosulfuron-methyl-sodium) CIPAC No 634 (parent) 634.501 (iodosulfuron-methyl-sodium)	4-iodo-2-[3-(4-methoxy-6-methyl-1,3,5-triazin-2-yl)-ureidosulfonyl] benzoate	910 g/kg	1 January 2004	31 December 2013	Only uses as herbicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on iodosulfuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 4 July 2003 shall be taken into account. In this overall assessment Member States: — should pay particular attention to the potential of iodosulfuron and its metabolites for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climate conditions, — should pay particular attention to the protection of aquatic plants. Risk mitigation measures should be applied where appropriate.
67	Dimethenamid-p CAS No 163515-14-8 CIPAC No 638	S-2-chloro-N-(2,4-dimethyl-3-thienyl)-N-(2-methoxy-1-methylethyl)-acetamide	890 g/kg (preliminary value based on a pilot plant)	1 January 2004	31 December 2013	Only uses as herbicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on dimethenamid-p, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 4 July 2003 shall be taken into account. In this overall assessment Member States: — should pay particular attention to the potential of the metabolites of dimethenamid-p for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climate conditions, — should pay particular attention to the protection of aquatic ecosystems, especially of aquatic plants. Risk mitigation measures should be applied where appropriate. The Member States shall inform the Commission in accordance with Article 13(5) on the specification of the technical material as commercially manufactured.

▼M46

Number	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
68	Picoxystrobin CAS No 117428-22-5 CIPAC No 628	Methyl (E)-3-methoxy-2-{2-[6-(trifluoromethyl)-2- pyridyloxymethyl] phenyl} acrylate	950 g/kg (preliminary value based on a pilot plant)	1 January 2004	31 December 2013	Only uses as fungicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on picoxystrobin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 4 July 2003 shall be taken into account. In this overall assessment Member States: — should pay particular attention to the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climate conditions, — should pay particular attention to the protection of soil organisms, — should pay particular attention to the protection of aquatic ecosystems. Risk mitigation measures should be applied where appropriate. The Member States shall inform the Commission in accordance with Article 13(5) on the specification of the technical material as commercially manufactured.
69	Fosthiazate CAS No 98886-44-3 CIPAC No 585	(RS)-S-sec-butyl O-ethyl 2-oxo-1,3-thiazolidin-3-ylphosphonothioate	930 g/kg	1 January 2004	31 December 2013	Only uses as nematicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on fosthiazate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 4 July 2003 shall be taken into account. In this overall assessment Member States: — should pay particular attention to the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climate conditions, — should pay particular attention to the protection of birds and wild mammals in particular if the substance is applied during the breeding season, — should pay particular attention to the protection of non-target soil organisms. Risk mitigation measures should be applied where appropriate. In order to mitigate the potential risk to small birds, product authorisations must require that a very high level of incorporation of granules into soil is achieved. The Member States shall inform the Commission in accordance with Article 13(5) on the specification of the technical material as commercially manufactured.

▼M46

Number	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
70	Silthiofam CAS No 175217-20-6 CIPAC No 635	N-allyl-4,5-dimethyl-2-(trimethylsilyl)thiophene-3-carboxamide	950 g/kg	1 January 2004	31 December 2013	Only uses as fungicide may be authorised. Uses other than seed treatments are currently not adequately supported by data. To support authorisations for such uses, data and information to prove their acceptability for consumers, operators and the environment will have to be generated and submitted to the Member States. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on silthiofam, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 4 July 2003 shall be taken into account. In this overall assessment Member States must pay particular attention to the protection of operators. Risk mitigation measures must be applied, where appropriate.
▼M43 71	Coniothyrium minitans Strain CON/M/91-08 (DSM 9660) CIPAC No 614	Not applicable	For details on purity and production control see Review Report	1 January 2004	31 December 2013	Only uses as fungicide may be authorised. When granting authorisations, the conclusions of the review report on *Coniothyrium minitans*, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 4 July 2003 shall be taken into account. In this overall assessment: — Member States must pay particular attention to the operator and worker safety and must ensure that the conditions of authorisation include appropriate protective measures.
▼M44 72	Molinate CAS No 2212-67-1 CIPAC No 235	S-ethyl azepane-1-carbothioate; S-ethyl perhydroazepine-1-carbothioate; S-ethyl perhydroazepine-1-thiocarboxilate	950 g/kg	1 August 2004	31 July 2014	Only uses as herbicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on molinate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 4 July 2003 shall be taken into account. In this overall assessment: — Member States should pay particular attention to the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation should include risk mitigation measures, where appropriate, — Member States should pay particular attention to the possibility of short-range transport of the active substance in air.

▼M44

Number	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
73	Thiram CAS No 137-26-8 CIPAC No 24	tetramethylthiuram disulfide; bis (dimethylthiocarbamoyl)-disulfide	960 g/kg	1 August 2004	31 July 2014	Only uses as fungicide or as repellent may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on thiram, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 4 July 2003 shall be taken into account. In this overall assessment: — Member States should pay particular attention to the protection of aquatic organisms. Risk mitigation measures should be applied, where appropriate, — Member States should pay particular attention to the protection of small mammals and birds when the substance is used as a seed treatment in spring uses. Risk mitigation measures should be applied, where appropriate.
74	Ziram CAS No 137-30-4 CIPAC No 31	Zinc bis (dimethyldithiocarbamate)	950 g/kg (FAO-specification) Arsenic: maximum 250 mg/kg Water: maximum 1,5 %	1 August 2004	31 July 2014	Only uses as fungicide or as repellent may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on ziram, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 4 July 2003 shall be taken into account. In this overall assessment: — Member States should pay particular attention to the protection of non-target arthropods and aquatic organisms. Risk mitigation measures should be applied, where appropriate, — Member States should observe the acute dietary exposure situation of consumers in view of future revisions of Maximum Residue Levels.

▼M44

Number	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
▼M47 75	Paraquat CAS No 4685-14-7 CIPAC No 56	1,1'-dimethyl-4,4'-bipyridinium	500 g/l (expressed as paraquat dichloride)	1 November 2004	31 October 2014	Only uses as herbicide may be authorised. The following uses must not be authorised: — knapsack and handheld applications in home gardening, neither by amateur nor by professional users, — use via broadcast air-assisted application equipment, — ultra low volume applications. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on paraquat, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 October 2003, shall be taken into account. In this overall assessment Member States must pay particular attention to the protection of: — operators, in particular for knapsack and handheld applications, — ground-nesting birds. Where use scenarios indicate the potential for exposure of eggs a risk assessment should be conducted and, where appropriate, risk mitigation applied, — aquatic organisms. Conditions of authorisation should include risk-mitigation measures, where appropriate, — hares. Where use scenarios indicate the potential for exposure of hares, a risk assessment should be conducted and, where appropriate, risk mitigation applied. Member States shall ensure that the authorisation holders report at the latest on 31 March each year until 2008 on incidences of operator health problems and impact on hares in one or more representative areas of use, which should be supplemented by sales data and a survey of use patterns, so that a realistic picture of the toxicological and ecological impact of paraquat can be obtained. Member States must ensure that technical concentrates shall contain an effective emetic. Liquid formulations shall contain an effective emetic, blue/green colorants and stenching or other olfactory alerting agent or agents. Other safeners, such as thickeners, may also be included. In doing so they shall take account of the FAO specification.

▼M47

Number	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
▼M48 76	Mesosulfuron CAS No 400852-66-6 CIPAC No 441	2-[(4,6-dimethoxypyrimidin-2-ylcarbamoyl) sulfamoyl]-α-(methanesulfonamido)-p-toluic acid	930 g/kg	1 April 2004	31 March 2014	Only use as herbicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on mesosulfuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 October 2003 shall be taken into account. In this overall assessment Member States: — should pay particular attention to the protection of aquatic plants; — should pay particular attention to the potential of mesosulfuron and its metabolites for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climate conditions. Risk mitigation measures should be applied where appropriate.
77	Propoxycarbazone CAS No 145026-81-9 CIPAC No 655	2-(4,5-dihydro-4-methyl-5-oxo-3-propoxy-1H-1,2,4-triazol-1-yl)carboxamidosulfonylbenzoicacid-methylester	974 g/kg (expressed as propoxycarbazone-sodium)	1 April 2004	31 March 2014	Only use as herbicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on propoxycarbazone, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 October 2003 shall be taken into account. In this overall assessment Member States: — should pay particular attention to the potential of propoxycarbazone and its metabolites for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climate conditions; — should pay particular attention to the protection of aquatic ecosystems, especially of aquatic plants. Risk mitigation measures should be applied where appropriate. The Member States shall inform the Commission in accordance with Article 13(5) on the specification of the technical material as commercially manufactured.
78	Zoxamide CAS No 156052-68-5 CIPAC No 640	(RS)-3,5-Dichloro-N-(3-chloro-1-ethyl-1-methylacetonyl)-p-toluamide	950 g/kg	1 April 2004	31 March 2014	Only use as fungicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on zoxamide, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 October 2003 shall be taken into account.

▼M48

Number	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
▼M49 79	Chlorpropham CAS No 101-21-3 CIPAC No 43	Isopropyl 3-chlorophenylcarbamate	975 g/kg	1 February 2005	31 January 2015	Only uses as herbicide and sprout suppression may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on chlorpropham, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 November 2003 shall be taken into account. In this overall assessment Member States should pay particular attention to the protection of operators, consumers and non-target arthropods. Conditions of authorisation should include risk mitigation measures, where appropriate.
▼M50 80	Benzoic acid CAS No 65-85-0 CIPAC No 622	benzoic acid	990 g/kg	1 June 2004	31 May 2014	Only uses as disinfectant may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on benzoic acid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 November 2003 shall be taken into account.
81	Flazasulfuron CAS No 104040-78-0 CIPAC No 595	1-(4,6-dimethoxypyrimidin-2-yl)-3-(3-trifluoromethyl-2-pyridylsulphonyl)urea	940 g/kg	1 June 2004	31 May 2014	Only uses as herbicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on flazasulfuron, and in particular Appendices I and II thereto, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 November 2003 shall be taken into account. In this overall assessment Member States — should pay particular attention to the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climate conditions, — should pay particular attention to the protection of aquatic plants. Risk mitigation measures should be applied where appropriate. The Member States shall inform the Commission in accordance with Article 13(5) on the specification of the technical material as commercially manufactured.

▼M50

Number	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
82	Pyraclostrobin CAS No 175013-18-0 CIPAC No 657	methyl N-(2-{[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxymethyl}phenyl) N-methoxy carbamate	975 g/kg The manufacturing impurity dimethylsulfate (DMS) is condidered to be of toxicological concern and must not exceed a concentration of 0,0001 % in the technical product	1 June 2004	31 May 2014	Only uses as fungicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on pyraclostrobin, and in particular Appendices I and II thereto, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 November 2003 shall be taken into account. In this overall assessment Member States — should pay particular attention to the protection of aquatic organisms, especially fish, — should pay particular attention to the protection of terrestrial arthropods and earthworms. Risk mitigation measures should be applied where appropriate. The Member States shall inform the Commission in accordance with Article 13(5) on the specification of the technical material as commercially manufactured.
▼M52 83	Quinoxyfen CAS No 124495-18-7 CIPAC No 566	5, 7-dichloro-4 (ρ-fluorophenoxy) quinoline	970 g/kg	1 September 2004	31 August 2014	Only uses as fungicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on quinoxyfen, and in particular Appendices I and II thereto, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 November 2003, shall be taken into account. Member States should pay particular attention to the protection of aquatic organisms. Risk mitigation measures must be applied and monitoring programmes must be initiated in vulnerable zones where appropriate.

▼M52

Number	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
▼M51 84	Alpha-cypermethrin CAS No 67375-30-8 CIPAC No	Racemate comprising (S)-α- cyano-3 phenoxy-benzyl-(1R)-cis-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylate and (R)-α- cyano-3 phenoxy-benzyl-(1S)-cis-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylate (= cis-2 isomer pair of cypermethrin)	930 g/kg CIS-2	1 March 2005	28 February 2015	Only uses as insecticide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on alpha-cypermethrin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 13 February 2004 shall be taken into account. In this overall assessment: — Member States must pay particular attention to the protection of aquatic organisms, bees and non-target arthropods and must ensure that the conditions of authorisation include risk mitigation measures. — Member States must pay particular attention to the operator safety and must ensure that the conditions of authorisation include appropriate protective measures.
85	Benalaxyl CAS No 71626-11-4 CIPAC No 416	Methyl N-phenylacetyl–N-2, 6–xylyl–DL-alaninate	960 g/kg	1 March 2005	28 February 2015	Only uses as fungicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on benalaxyl, and in particular Appendices I and II thereto, as finalised in the Standing Committee on the Food Chain and Animal Health on 13 February 2004 shall be taken into account. In this overall assessment Member States should pay particular attention to the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation should include risk mitigation measures, where appropriate.
86	Bromoxynil CAS No 1689-84-5 CIPAC No 87	3,5 dibromo – 4- hydroxybenzonitrile	970 g/kg	1 March 2005	28 February 2015	Only uses as herbicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on bromoxynil, and in particular Appendices I and II thereto, as finalised in the Standing Committee on the Food Chain and Animal Health on 13 February 2004 shall be taken into account. In this overall assessment Member States must pay particular attention to the protection of birds and wild mammals, in particular if the substance is applied in winter, and of aquatic organisms. Conditions of authorisation should include risk mitigation measures, where appropriate.

▼M51

Number	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
87	Desmedipham CAS No 13684-56-5 CIPAC No 477	ethyl 3'-phenylcarbamoyloxycarbanilate ethyl 3-phenylcarbamoyloxyphenylcarbamate	Min. 970 g/kg	1 March 2005	28 February 2015	Only uses as herbicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on desmedipham, and in particular Appendices I and II thereto, as finalised in the Standing Committee on the Food Chain and Animal Health on 13 February 2004 shall be taken into account. In this overall assessment Member States should pay particular attention to the protection of aquatic organisms and earthworms. Risk mitigation measures should be applied if appropriate
88	Ioxynil CAS No 13684-83-4 CIPAC No 86	4- hydroxy- 3,5- di-iodobenzonitrile	960 g/kg	1 March 2005	28 February 2015	Only uses as herbicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on ioxynil, and in particular Appendices I and II thereto, as finalised in the Standing Committee on the Food Chain and Animal Health on 13 February 2004 shall be taken into account. In this overall assessment Member States must pay particular attention to the protection of birds and wild mammals in particular if the substance is applied in winter and to aquatic organisms. Conditions of authorisation should include risk mitigation measures, where appropriate.
89	Phenmedipham CAS No 13684-63-4 CIPAC No 77	methyl 3-(3-methylcarbaniloyloxy)carbanilate; 3-methoxycarbonylaminophenyl 3'-methylcarbanilate	Min. 970 g/kg	1 March 2005	28 February 2015	Only uses as herbicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on phenmedipham, and in particular Appendices I and II thereto, as finalised in the Standing Committee on the Food Chain and Animal Health on 13 February 2004 shall be taken into account. In this overall assessment Member States should pay particular attention to the protection of aquatic organisms. Conditions of authorisation should include risk mitigation measures, where appropriate.

▼M51

Number	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
▼M54 90	*Pseudomonas chlororaphis* Strain: MA 342 CIPAC No 574	Not applicable	The amount of the secondary metabolite 2,3-deepoxy-2,3-didehydrorhizoxin (DDR) in the fermentate at the point of formulation of the product must not exceed the LOQ (2 mg/l).	1 October 2004	30 September 2014	Only uses as fungicide for seed dressing in closed seed dressing machinery may be authorised. When granting authorisations, the conclusions of the review report on *Pseudomonas chlororaphis*, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 30 March 2004 shall be taken into account. In this overall assessment, Member States should pay particular attention to the safety of operators and workers. Risk mitigation measures should be applied where appropriate.
▼M53 91	Mepanipyrim CAS No 110235-47-7 CIPAC No 611	N-(4-methyl-6-prop-1-ynylpyrimidin-2-yl) aniline	960 g/kg	1 October 2004	30 September 2014	Only uses as fungicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on mepanipyrim, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 30 March 2004 shall be taken into account. In this overall assessment Member States should pay particular attention to the protection of aquatic organisms. Risk mitigation measures should be applied where appropriate.
▼M56 92	Acetamiprid CAS No 160430-64-8 CIPAC No Not yet allocated	(E)-N^1-[(6-chloro-3-pyridyl)methyl]-N^2-cyano-N^1-methylacetamidine	≥ 990 g/kg	1 January 2005	31 December 2014	Only uses as insecticide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on Acetamiprid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 29 June 2004 shall be taken into account. In this overall assessment Member States — should pay particular attention to worker exposure, — should pay particular attention to the protection of aquatic organisms. Risk mitigation measures should be applied where appropriate.

▼M56

Number	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
93	Thiacloprid CAS No 111988-49-9 CIPAC No 631	(Z)-N-{3-[(6-Chloro-3-pyridinyl)methyl]-1,3-thiazolan-2-yliden} cyanamide	≥ 975 g/kg	1 January 2005	31 December 2014	Only uses as insecticide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on Thiacloprid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 29 June 2004 shall be taken into account. In this overall assessment Member States — should pay particular attention to the protection of non-target arthropods, — should pay particular attention to the protection of aquatic organisms, — should pay particular attention to the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Risk mitigation measures should be applied where appropriate.
▼M57 94	*Ampelomyces quisqualis* Strain: AQ 10 Culture collection No CNCM I-807 CIPAC No Not allocated	Not applicable		1 April 2005	31 March 2015	Only uses as fungicide may be authorised. When granting authorisations, the conclusions of the review report on *Ampelomyces quisqualis*, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 8 October 2004 shall be taken into account.
▼M58 95	Imazosulfuron CAS No: 122548-33-8 CIPAC No: 590	1-(2-chloroimidazo[1,2-α] pyridin-3-ylsul-phonyl)-3-(4,6-dimethoxypyrimidin-2-yl)urea	≥ 980 g/kg	1 April 2005	31 March 2015	Only uses as herbicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on imazosulfuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 8 October 2004 shall be taken into account. In this overall assessment Member States should pay particular attention to the protection of aquatic and terrestrial non-target plants. Risk mitigation measures should be applied where appropriate.
96	Laminarin CAS No: 9008-22-4 CIPAC No: 671	(1→3)-β-D-glucan (according to IUPAC-IUB Joint Commission on Biochemical Nomenclature)	≥ 860 g/kg on dry matter	1 April 2005	31 March 2015	Only uses as elicitor of the crop's self-defence mechanisms may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on laminarin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 8 October 2004 shall be taken into account.

▼M58

Number	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
97	Methoxyfenozide CAS No: 161050-58-4 CIPAC No: 656	N-tert-Butyl-N'-(3-methoxy-o-toluoyl)-3,5-xylohydrazide	≥ 970 g/kg	1 April 2005	31 March 2015	Only uses as insecticide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on methoxyfenozide, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 8 October 2004 shall be taken into account. In this overall assessment Member States should pay particular attention to the protection of terrestrial and aquatic non-target arthropods. Risk mitigation measures should be applied where appropriate.
98	S-metolachlor CAS No: 87392-12-9 (S-isomer) 178961-20-1 (R-isomer) CIPAC No: 607	Mixture of: (aRS, 1 S)-2-chloro-N-(6-ethyl-o-tolyl)-N-(2-methoxy-1-methylethyl) acetamide (80-100 %) and: (aRS, 1 R)-2-chloro-N-(6-ethyl-o-tolyl)-N-(2-methoxy-1-methylethyl) acetamide (20-0 %)	≥ 960 g/kg	1 April 2005	31 March 2015	Only uses as herbicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on s-metolachlor, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 8 October 2004 shall be taken into account. In this overall assessment Member States — should pay particular attention to the potential for groundwater contamination, particularly of the active substance and its metabolites CGA 51202 and CGA 354743, when the active substance is applied in regions with vulnerable soil and/or climatic conditions, — should pay particular attention to the protection of aquatic plants. Risk mitigation measures should be applied where appropriate.
▼M57 99	*Gliocladium catenulatum* Strain: J1446 Culture collection No DSM 9212 CIPAC No Not allocated	Not applicable		1 April 2005	31 March 2015	Only uses as fungicide may be authorised. When granting authorisations, the conclusions of the review report on *Gliocladium catenulatum*, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 30 March 2004 shall be taken into account. In this overall assessment, Member States should pay particular attention to the protection of operators and workers. Risk mitigation measures should be applied where appropriate.

▼M57

Number	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
▼M61 100	Etoxazole CAS No: 153233-91-1 CIPAC No: 623	(RS)-5-*tert*-butyl-2-[2-(2,6-difluorophenyl)-4,5-dihydro-1,3-oxazol-4-yl] phenetole	≥ 948 g/kg	1 June 2005	31 May 2015	Only uses as acaricide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on etoxazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 December 2004 shall be taken into account. In this overall assessment Member States should pay particular attention to the protection of aquatic organisms. Risk mitigation measures should be applied where appropriate.
101	Tepraloxydim CAS No: 149979-41-9 CIPAC No: 608	(EZ)-(RS)-2-{1-[(2E)-3-chloroallyloxyimino] propyl}-3-hydroxy-5-perhydropyran-4-ylcyclohex-2-en-1-one	≥ 920 g/kg	1 June 2005	31 May 2015	Only uses as herbicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on tepraloxydim, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 December 2004 shall be taken into account. In this overall assessment, Member States should pay particular attention to the protection of terrestrial non-target arthropods. Risk mitigation measures should be applied where appropriate.

▼M22

(1) Further details on identity and specification of active substances are provided in their review reports.

►M24 (2) Further details on identity and specification of active substance are provided in the review report (doc. 6797/VI/99 rev. 2). ◄

►M27 (3) Further details on identity and specification of active substances are provided in the review report for DPX KE 459 (flupyrsulfuron-methyl) (5050/VI/97). ◄

►M38 (4) OJ L 33, 8.2.1979, p. 36.

(5) OJ L 296, 27.10.1990 p. 63. ◄

▼B

ANNEX II

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

▼M1

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;

▼M4

1.2. where relevant, be generated using test guidelines, according to the latest adopted version, referred to or described in this Annex; in the case of studies initiated before the entry into force 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;

▼M1

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. ►M4 In particular, when reference is made in this Annex to an EEC Method which consists in the transposal of a method developed by an international organization (e.g. OECD), Member States may accept that the required information is generated according to the latest version of that method if at the initiation of the studies the EEC Method has not yet been updated; ◄

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.

▼M5

2.2. By way of derogation from point 2.1, Member States may provide that tests and analyses, performed on their territory in order to obtain data on the properties and/or safety of the substances with respect to honey-bees and beneficial arthropods other than bees shall be 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 applies to trials actually started on or before 31 December 1999.

2.3. By way of derogation from point 2.1, Member States may provide that supervised residue trials performed on their territory in accordance with the provisions of Section 6 ‘Residues in or on treated products, food and feed’ on plant protection products containing active substances already on the

([1]) OJ No L 15, 17. 1. 1987, p. 29.

▼M5

market two years after notification of the Directive shall be conducted by official or officially-recognized testing facilities or organizations which satisfy at least the requirements under points 2.2 and 2.3 of the introduction to Annex III.

This derogation applies for supervised residue trials actually started on or before 31 December 1997.

▼M25

2.4. By way of derogation from point 2.1, for active substances consisting of micro-organisms or viruses, tests and analyses done to obtain data on the properties and/or safety with respect to other aspects than human health, may have been conducted by official or officially recognised testing facilities or organisations which satisfy at least the requirements under points 2.2 and 2.3 of the introduction of Annex III.

▼B

PART A

Chemical substances [1]

▼M2

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 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

[1] Substance within the meaning of the definition of Article 2, point 3.

▼M2

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.

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,

▼M2

— 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,

— 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,

▼M2

— 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 °C.

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 °C.

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.

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^{-5} 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.

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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 °C 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.

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 °C, or another appropriate temperature.

If degradation is observed at 50 °C, 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 °C. The identity of hydrolysis products formed and the rate constantly

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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 phototrans-formation in purified (e.g. distilled) water at 20 to 25 °C, 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 °C, must be determined and reported according to EEC method A 9; only closed cup methods should be used.

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.

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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)

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.

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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.

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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.

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 °C 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**

Introduction

The provisions of this section only cover analytical methods required for post-registration control and monitoring purposes.

For analytical methods used for generation of data as required in this Directive or for other purposes the applicant has to provide a justification for the method used; where necessary separate guidance will be developed for such methods on the basis of the same requirements as defined for methods for post-registration control and monitoring purposes.

Descriptions of methods must be provided and include details of equipment, materials and conditions used.

As far as practicable these methods must employ the simplest approach, involve the minimum cost, and require commonly available equipment.

For this section the following applies:

Impurities	Any component other than the pure active substance which is present in the active substance as manufactured (including non-active isomers) originating from the manufacturing process or from degradation during storage,
Relevant impurities	Impurities of toxicological and/or ecotoxicological or environmental concern,
Significant impurities	Impurities with a content of ≥ 1 g/kg in the active substance as manufactured,
Metabolites	Metabolites include products resulting from degradation or reaction of the active substance,
Relevant metabolites	Metabolites of toxicological and/or ecotoxicological or environmental concern.

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

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On request the following samples must be provided:

(i) analytical standards of the pure active substance;

(ii) samples of the active substance as manufactured;

(iii) analytical standards of relevant metabolites and all other components included in the residue definition;

(iv) if available, samples of reference substances for the relevant impurities.

4.1. **Methods for the analysis of the active substance as manufactured**

For this point the following definitions apply:

(i) *Specificity*

Specificity is the ability of a method to distinguish between the analyte being measured and other substances.

(ii) *Linearity*

Linearity is defined as the ability of the method, within a given range, to obtain an acceptable linear correlation between the results and the concentration of analyte in samples.

(iii) *Accuracy*

The accuracy of a method is defined as the degree to which the determined value of analyte in a sample corresponds to the accepted reference value (for example ISO 5725).

(iv) *Precision*

Precision is defined as the closeness of agreement between independent test results obtained under prescribed conditions.

Repeatability: Precision under repeatability conditions, i.e. conditions where independent test results are obtained with the same method on identical test material in the same laboratory by the same operator using the same equipment within short intervals of time.

The reproducibility is not required for the active substance as manufactured (for definition of reproducibility see ISO 5725).

4.1.1. Methods, which must be described in full, must be provided for the determination of pure active substance in the active substance as manufactured as specified in the dossier submitted in support of inclusion in Annex I to Directive 91/414/EEC. The applicability of existing Cipac methods must be reported.

4.1.2. Methods must also be provided for the determination of significant and/or relevant impurities and additives (e.g. stabilizers) in the active substance as manufactured.

4.1.3. Specificity, linearity, accuracy and repeatability

4.1.3.1. Specificity of methods submitted, must be demonstrated and reported. In addition the extent of interference by other substances present in the active substance as manufactured (e.g. isomers, impurities or additives), must be determined.

While interferences due to other components may be identified as systematic errors in the assessment of the accuracy of methods proposed for the determination of pure active substance in the active substance as manufactured, an explanation must be provided for any interference occurring which contributes more than ± 3 % to the total quantity determined. The degree of interference for methods for the determination of impurities must also be demonstrated.

4.1.3.2. The linearity of proposed methods over an appropriate range must be determined and reported. For the determination of pure active substance, the calibration range must extend (by at least 20 %) the highest and lowest nominal content of the analyte in relevant analytical solutions. Duplicate calibration determinations must be made at three or more concentrations. Alternatively, five concentrations, each as single measurements, are acceptable. Reports submitted must include the equation of the calibration line and the correlation coefficient and representative and properly labelled documentation from the analysis, e.g. chromatograms.

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4.1.3.3. Accuracy is required for methods for the determination of pure active substance and significant and/or relevant impurities in the active substance as manufactured.

4.1.3.4. For the repeatability in the determination of the pure active substance in principle a minimum of five determinations must be made. The relative standard deviation (% RSD) must be reported. Outliers identified through an appropriate method (e.g. Dixons or Grubbs test), may be discarded. Where outliers have been discarded, that fact must be clearly indicated. An explanation as to the reason for the occurrence of individual outliers, must be attempted.

4.2. **Methods for the determination of residues**

The methods must be capable of determining the active substance and/or relevant metabolites. For each method and for each relevant representative matrix, the specificity, precision, recovery, and limit of determination must be experimentally determined and reported.

In principle, residue methods proposed should be multi-residue methods; a standard multi-residue method must be assessed and reported as to its suitability for residue determination. Where residue methods proposed are not multi-residue methods, or are not compatible with such methods, an alternative method must be proposed. Where this requirement results in an excessive number of methods for individual compounds, a 'common moiety method' may be acceptable.

For this section the following definitions apply:

(i) *Specificity*

Specificity is the ability of a method to distinguish between the analyte being measured and other substances.

(ii) *Precision*

Precision is defined as the closeness of agreement between independent test results obtained under prescribed conditions.

Repeatability: Precision under repeatability conditions, i.e. conditions where independent test results are obtained with the same method on identical test material in the same laboratory by the same operator using the same equipment within short intervals of time.

Reproducibility: As the definition of reproducibility in relevant publications (for example, in ISO 5725) is in general not practicable for residue analytical methods, reproducibility in the context of this Directive is defined as a validation of repeatability of recovery, from representative matrices and at representative levels, by at least one laboratory which is independent from that which initially validated the study (this independent laboratory may be within the same company) (independent laboratory validation).

(iii) *Recovery*

The percentage of the amount of active substance or relevant metabolite originally added to a sample of the appropriate matrix which contains no detectable level of the analyte.

(iv) *Limit of determination*

The limit of determination (often referred to as limit of quantification) is defined as the lowest concentration tested, at which an acceptable mean recovery is obtained (normally 70 to 110 % with a relative standard deviation of preferably $\leq$ 20 %; in certain justified cases lower or higher mean recovery rates as well as higher relative standard deviations may be acceptable).

4.2.1. Residues in and/or on plants, plant products, foodstuffs (of plant and animal origin), feedingstuffs

Methods submitted must be suitable for the determination of all components included in the residue definition as submitted according to the provisions of section 6, points 6.1 and 6.2 in order to enable Member States to determine compliance with established MRL's or to determine dislodgeable residues.

The specificity of the methods must enable all components included in the residue definition to be determined, using an additional confirmatory method if appropriate.

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The repeatability must be determined and reported. The replicate analytical portions for test can be prepared from a common field treated sample, containing incurred residues. Alternatively the replicate analytical portions for test can be prepared from a common untreated sample with aliquots fortified at the required level(s).

The results from an independent laboratory validation must be reported.

The limit of determination including the individual and mean recovery must be determined and reported. The overall relative standard deviation, as well as the relative standard deviation for each fortification level must be experimentally determined and reported.

4.2.2. Residues in soil

Methods for analysis of soil for parent compound and/or relevant metabolites must be submitted.

The specificity of the methods must enable the parent compound and/or relevant metabolites to be determined, using an additional confirmatory method if appropriate.

The repeatability, recovery and the limit of determination including the individual and mean recovery must be determined and reported. The overall relative standard deviation, as well as the relative standard deviation for each fortification level must be experimentally determined and reported.

The proposed limit of determination must not exceed a concentration which is of concern with regard to exposure of non-target organisms or because of phytotoxic effects. Normally the proposed limit of determination should not exceed 0,05 mg/kg.

4.2.3. Residues in water (including drinking water, ground water and surface water)

Methods for analysis in water for parent compound and/or relevant metabolites must be submitted.

The specificity of the methods must enable the parent compound and/or relevant metabolites to be determined, using an additional confirmatory method if appropriate.

The repeatability, recovery and the limit of determination including the individual and mean recovvery must be determined and reported. The overall relative standard deviation, as well as the relative standard deviation for each fortification level must be experimentally determined and reported.

For drinking water the proposed limit of determination must not exceed 0,1 μg/l. For surface water the proposed limit of determination must not exceed a concentration which has an impact on non-target organisms deemed to be unacceptable according to the requirements of Annex VI.

4.2.4. Residues in air

Methods for the analysis in air of the active substance and/or relevant metabolites formed during or shortly after application must be submitted unless it can be justified that exposure of operators, workers or bystanders is not likely to occur.

The specificity of the methods must enable the parent compound and/or relevant metabolites to be determined, using an additional confirmatory method if appropriate.

The repeatability, recovery and the limit of determination including the individual and mean recovery must be determined and reported. The overall relative standard deviation, as well as the relative standard deviation for each fortification level must be experimentally determined and reported.

The proposed limit of determination must take into account relevant health based limit values or relevant exposure levels.

4.2.5. Residues in body fluids and tissues

Where an active substance is classified as toxic or highly toxic appropriate analytical methods must be submitted.

The specificity of the methods must enable the parent compound and/or relevant metabolites to be determined, using an additional confirmatory method if appropriate.

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The repeatability; recovery and the limit of determination including the individual and mean recovery must be determined and reported. The overall relative standard deviation, as well as the relative standard deviation for each fortification level must be experimentally determined and reported.

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5. Toxicological and metabolism studies

Introduction

(i) The information provided, taken together with that provided for one or more preparations containing the active substance, must be sufficient to permit an evaluation to be made as to the risks for man, associated with the handling and use of plant protection products containing the active substance, and the risk for man arising from residual traces remaining in food and water. In addition, the information provided must be sufficient to:

— permit a decision to be made as to whether, or not, the active substance can be included in Annex I,

— specify appropriate conditions or restrictions to be associated with any inclusion in Annex I,

— classify the active substance as to hazard,

— establish a relevant acceptable daily intake (ADI) level for man,

— establish acceptable operator exposure level(s) (AOEL),

— specify the hazard symbols, the indications of danger, and the risk and safety phrases for the protection of man, animals and the environment to be included in packaging (containers),

— identify relevant first aid measures as well as appropriate diagnostic and therapeutic measures to be followed in the event of poisoning in man, and

— permit an evaluation to be made as to the nature and extent of the risks for man, animals (species normally fed and kept or consumed by man) and of the risks for other non-target vertebrate species.

(ii) There is a need to investigate and report all potentially adverse effects found during routine toxicological investigations (including effects on organs and special systems such as immunotoxicity and neurotoxicity) and to undertake and report such additional studies which may be necessary to investigate the probable mechanism involved, to establish Noaels (no observed adverse effect levels), and to assess the significance of these effects. All available biological data and information which is relevant to the assessment of the toxicological profile of the substance tested, must be reported.

(iii) In the context of the influence that impurities can have on toxicological behaviour, it is essential that for each study submitted, a detailed description (specification) of the material used, as mentioned under section 1 point 11 be provided. Tests should be conducted using active substance of that specification to be used in the manufacture of preparations to be authorized, except where radiolabelled material is required or permitted.

(iv) Where studies are conducted using an active substance produced in the laboratory or in a pilot plant production system, the studies must be repeated using the active substance as manufactured, unless it can be justified that the test material used is essentially the same, for the purposes of toxicological testing and assessment. In cases of uncertainty, appropriate bridging studies must be submitted to serve as a basis for a decision as to the possible need for repetition of the studies.

(v) In the case of studies in which dosing extends over a period, dosing should preferably be done using a single batch of active substance if stability permits.

(vi) For all studies actual achieved dose in mg/kg body weight, as well as in other convenient units, must be reported. Where dosing via the diet is utilized the test compound must be distributed uniformly in the diet.

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(vii) Where, as a result of metabolism or other processes in or on treated plants, or as a result of processing of treated products, the terminal residue (to which consumers or workers as defined in Annex III, point 7.2.3 will be exposed) contains a substance which is not the active substance itself and is not identified as a metabolite in mammals, it will be necessary to carry out toxicity studies on these components of the terminal residue unless it can be demonstrated that consumer or worker exposure to these substances does not constitute a relevant risk to health. Toxicokinetic and metabolism studies relating to metabolites and degradation products should only be conducted if toxicity findings of the metabolite cannot be evaluated by the available results relating to the active substance.

(viii) The way of administration of the test substance depends on the main exposure routes. In cases where exposure is mainly by the gas phase, it can be more appropriate to perform inhalation studies instead of oral studies.

5.1. **Studies on absorption, distribution, excretion and metabolism in mammals**

Quite limited data, as described below and restricted to one test species (normally the rat) may be all that is required in this area. These data can provide information useful in the design and interpretation of subsequent toxicity tests. However, it must be remembered that information on interspecies differences may be crucial in extrapolation of animal data to man and information on percutaneous penetration, absorption, distribution, excretion and metabolism may be useful in operator risk assessments. It is not possible to specify detailed data requirements in all areas, since the exact requirements will be dependant upon the results obtained for each particular test substance.

Aim of the test:

The tests should provide sufficient data to permit:

— an evaluation of the rate and extent of absorption,

— the tissue distribution and the rate and extent of excretion of the test substance and the relevant metabolites,

— the identification of metabolites and the metabolic pathway.

The effect of dose level on these parameters and whether results are different after single versus repeated doses, should also be investigated.

Circumstances in which required

A single dose toxicokinetic study in rats (oral route of administration) in at least two dose levels as well as a repeated dose toxicokinetic study in rats (oral route of administration) at a single dose level, must be conducted and reported. It may be necessary in some cases to perform additional studies on another species (such as goat or chicken).

Test guideline

Commission Directive 87/302/EEC of 18 November 1987 adapting to technical progress for the ninth time Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances ([1]), part B, Toxicokinetics.

5.2. **Acute toxicity**

The studies, data and information to be provided and evaluated must be sufficient to permit the identification of effects following a single exposure to the active substance, and in particular to establish, or indicate:

— the toxicity of the active substance;

([1]) OJ No L 133, 30. 5. 1988, p. 1.

▼M4

— the time course and characteristics of the effects with full details of behavioural changes and possible gross pathological findings at post-mortem;

— where possible mode of toxic action; and

— the relative hazard associated with the different routes of exposure.

While the emphasis must be on estimating the toxicity ranges involved, the information generated must also permit the active substance to be classified in accordance with Council Directive 67/548/EEC. The information generated through acute toxicity testing is of particular value in assessing hazards likely to arise in accident situations.

5.2.1. *Oral*

Circumtances in which required

The acute oral toxicity of the active substance must always be reported.

Test guideline

The test must be carried out in accordance with the Annex to Commission Directive 92/69/EEC of 31 July 1992 adapting to technical progress for the seventeenth time Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances ([1]), Method B1 or B1 bis.

5.2.2. *Percutaneous*

Circumstances in which required

The acute percutaneous toxicity of the active substance must always be reported.

Test guideline

Both local and systemic effects must be investigated. The test must be carried out in accordance with Directive 92/69/EEC method B3.

5.2.3. *Inhalation*

Circumstances in which required

The inhalation toxicity of the active substance must be reported where the active substance is:

— a gas or liquified gas,

— is to be used as a fumigant,

— is to be included in a smoke generating, aerosol or vapour releasing preparation,

— is to be used with fogging equipment,

— has a vapour pressure > 1 × 10−2 Pa and is to be included in preparations to be used in enclosed spaces such as warehouses or glasshouses,

— is to be included in preparations which are powders containing a significant proportion of particles of diameter ►C3 < 50μm ◄ (> 1 % on a weight basis), or

— is to be included in preparations to be applied in a manner which generates a significant proportion of particles or droplets of diameter < 50μm (> 1 % on a weight basis).

Test guideline

The test must be carried out in accordance with Directive 92/69/EEC Method B2.

([1]) OJ No L 383A, 29. 12. 1992, p. 1.

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5.2.4. *Skin irritation*

Aim of the test

The test will provide the potential of skin irritancy of the active substance including the potential reversibility of the effects observed.

Circumstances in which required

The skin irritancy of the active substance must be determined except where it is likely, as indicated in the test guideline, that severe skin effects may be produced or that effects can be excluded.

Test guideline

The acute skin irritation must be carried out in accordance with Directive 92/69/EEC Method B4.

5.2.5. *Eye irritation*

Aim of test

The test will provide the potential of eye irritancy of the active substance including the potential reversibility of the effects observed.

Circumstances in which required

Eye irritation tests must be conducted except where it is likely, as indicated in the test guideline, that severe effects on the eyes may be produced.

Test guidelines

The acute eye irritation must be determined in accordance with Directive 92/69/EEC Method B5.

5.2.6. *Skin sensitization*

Aim of test

The test will provide sufficient information to assess the potential of the active substance to provoke skin sensitization reactions.

Circumstances in which required

The test must always be carried out except where the substance is a known sensitizer.

Test guideline

The test must be carried out in accordance with Directive 92/69/EEC Method B6.

5.3. **Short-term toxicity**

Short-term toxicity studies must be designed to provide information as to the amount of the active substance that can be tolerated without toxic effects under the conditions of the study. Such studies provide useful data on the risks for those handling and using preparations containing the active substance. In particular, short-term studies provide an essential insight into possible cumulative actions of the active substance and the risks to workers who may be intensively exposed. In addition short-term studies provide information useful in the design of chronic toxicity studies.

The studies, data and information to be provided and evaluated, must be sufficient to permit the identification of effects following repeated exposure to the active substance, and in particular to further establish, or indicate:

— the relationship between dose and adverse effects,

— toxicity of the active substance including where possible the Noael,

— target organs, where relevant,

— the time course and characteristics of poisoning with full details of behavioural changes and possible pathological findings at post-mortem,

— specific toxic effects and pathological changes produced,

— where relevant the persistence and reversibility of certain toxic effects observed, following discontinuation of dosing,

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— where possible, the mode of toxic action, and

— the relative hazard associated with the different routes of exposure.

5.3.1. *Oral 28-day study*

Circumstances in which required

Although it is not mandatory to perform 28-day short term studies, they can be useful as range finding tests. Where conducted they must be reported, since the results could be of particular value in the identification of adaptive responses which can be masked in chronic toxicity studies.

Test guideline

The test must be carried out in accordance with Directive 92/69/EEC Method B7.

5.3.2. *Oral 90-day study*

Circumstances in which required

The short-term oral toxicity (90 day) of the active substance to both rat and dog, must always be reported. Where there is evidence that the dog is significantly more sensitive and where such data are likely to be of value in extrapolating results obtained to man, a 12-month toxicity study in dogs must be conducted and reported.

Test guidelines

Directive 87/302/EEC, Part B, sub-chronic oral toxicity test.

5.3.3. *Other routes*

Circumstances in which required

For the assessment of operator exposure additional percutaneous studies may be useful.

For volatile substances (vapour pressure $>10^{-2}$ Pascal) expert judgment is required to decide whether the short term studies have to be performed by oral or inhalation exposure.

Test guidelines

— 28-day dermal: Directive 92/69/EEC Method B9,

— 90-day dermal: Directive 87/302/EEC, Part B, sub-chronic dermal toxicity study,

— 28-day inhalation: Directive 92/69/EEC Method B8,

— 90-day inhalation: Directive 87/302/EEC, Part B, sub-chronic inhalation toxicity study.

5.4. **Genotoxicity testing**

Aim of the test

These studies are of value in:

— the prediction of genotoxic potential

— the early identification of genotoxic carcinogens

— the elucidation of the mechanism of action of some carcinogens

To avoid responses that are artifacts of the test system, excessively toxic doses must not be used in either *in vitro* or *in vivo* assays for mutagenicity. This approach should be regarded as general guidance. It is important that a flexible approach is adopted, with selection of further tests being' dependant upon interpretation of results at each stage.

5.4.1. *In vitro studies*

Circumstances in which required

In vitro mutagenicity tests (bacterial assay for gene mutation, test for clastogenicity in mammalian cells and test for gene mutation in mammalian cells) must always be performed.

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Test guidelines

Acceptable test guidelines are:

Directive 92/69/EEC Method B14 — *Salmonella Typhimurium* reverse mutation assay

Directive 92/69/EEC Method B10 — *in vitro* mammalian cytogenetic test

Directive 87/302/EEC, Part B — *in vitro* mammalian cell gene mutation test

5.4.2. *In vivo studies in somatic cells*

Circumstances in which required

If all the results of the *in vitro* studies are negative further resting must be done with consideration of other relevant information available (including toxicokinetic, toxicodynamic and physico-chemical data and data on analogous substances). The test can be an *in vivo* study or an *in vitro* study using a different metabolizing system from that/those previously used.

If the *in vitro* cytogenetic test is positive, an *in vivo* test using somatic cells (metaphase analysis in rodent bone marrow or micronucleus test in rodents) must be conducted.

If either of the *in vitro* gene mutation tests are positive, an *in vivo* test to investigate unscheduled DNA synthesis or a mouse spot test must be conducted.

Test guidelines

Acceptable test guidelines are:

Directive 92/69/EEC Method B12 — Micronucleus test,

Directive 87/302/EEC Part B — Mouse spot test,

Directive 92/69/EEC Method B11 — *In vivo* Mammalian Bone-Marrow cytogenetic test, Chromosomal analysis.

5.4.3. *In vivo studies in germ cells*

Circumstances in which required

When any result of an *in vivo* study in somatic cells is positive, *in vivo* testing for germ cell effects may be justified. The necessity for conducting these tests will have to be considered on a case by case basis, taking into account information regarding toxicokinetics, use and anticipated exposure. Suitable tests would need to examine interaction with DNA (such as the dominant lethal assay), to look at the potential for inherited effects and possibly make a quantitative assessment of heritable effects. It is recognized that in view of their complexity, the use of quantitative studies would require strong justification.

5.5. **Long term toxicity and carcinogenicity**

Aim of the test

The long-term studies conducted and reported, taken together with other relevant data and information on the active substance, must be sufficient to permit the identification of effects, following repeated exposure to the active substance, and in particular must be sufficient to:

— identify adverse effects resulting from exposure to the active substance,

— identify target organs, where relevant,

— establish the dose-response relationship,

— identify changes in toxic signs and manifestations observed, and

— establish the Noael.

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Similarly, the carcinogenicity studies taken together with other relevant data and information on the active substance, must be sufficient to permit the hazards for humans, following repeated exposure to the active substance, to be assessed, and in particular must be sufficient:

— to identify carcinogenic effects resulting from exposure to the active substance,

— to establish the species and organ specificity of tumours induced,

— to establish the dose-response relationship, and

— for non-genotoxic carcinogens, to identify the maximum dose eliciting no adverse effect (threshold dose).

Circumstances in which required

The long-term toxicity and carcinogenicity of all active substances must be determined. If in exceptional circumstances, it is claimed that such testing is unnecessary, that claim must be fully justified, *viz.* toxicokinetic data demonstrates that absorption of the active substance does not occur from the gut, through the skin or via the pulmonary system.

Test conditions

A long-term oral toxicity and carcinogenicity study (two years) of the active substance must be conducted using the rat as test species; these studies can be combined.

A carcinogenicity study of the active substance must be conducted using the mouse as test species.

Where a non-genotoxic mechanism for carcinogenicity is suggested, a well argued case, supported with relevant experimental data, including that necessary to elucidate the possible mechanism involved, must be provided.

While the standard reference points for treatment responses are concurrent control data, historical control data, may be helpful in the interpretation of particular carcinogenicity studies. Where submitted, historical control data should be from the same species and strain, maintained under similar conditions and should be from contemporaneous studies. The information on historical control data provided must include:

— identification of species and strain, name of the supplier, and specific colony identification, if the supplier has more than one geographical location,

— name of the laboratory and the dates when the study was performed,

— description of the general conditions under which animals were maintained, including the type or brand of diet and, where possible, the amount consumed,

— approximate age, in days, of the control animals at the beginning of the study and at the time of killing or death,

— description of the control group mortality pattern observed during or at the end of the study, and other pertinent observations (e.g. diseases, infections),

— name of the laboratory and the examining scientists responsible for gathering and interpreting the pathological data from the study, and

— a statement of the nature of the tumours that may have been combined to produce any of the incidence data.

The doses tested, including the highest dose tested, must be selected on the basis of the results of short-term testing and where available at the time of planning the studies concerned, on the basis of metabolism and toxicokinetic data. The highest dose level in the carcinogenicity study should elicit signs of minimal toxicity such as slight depression in body-weight gain (less than 10 %), without causing tissue necrosis or metabolic saturation and without substantially altering normal lifespan due to effects other than tumours. If the long-term toxicity study is carried out separately, the highest dose level should elicit definite signs of toxicity without causing excessive lethality. Higher doses, causing excessive toxicity are not considered relevant to evaluations to be made.

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In the collection of data and compilation of reports, incidence of benign and malignant tumours must not be combined, unless there is clear evidence of benign tumours becoming malignant with time. Similarly, dissimilar, un-associated tumours, whether benign or malignant, occurring in the same organ, must not be combined, for reporting purposes. In the interests of avoiding confusion, terminology such as that developed by American Society of Toxicologic Pathologists [1], or the Hannover Tumour Registry (RENI) should be used in the nomenclature and reporting of tumours. The system used must be identified.

It is essential that biological material selected for histopathological examination includes material selected to provide further information on lesions identified during gross pathological examination. Where relevant to the elucidation of mechanism of action and available, special histological (staining) techniques, histochemical techniques and electron microscopic examinations, must be conducted and reported.

Test guideline

The studies must be carried out in accordance with Directive 87/302/EEC, part B, Chronic toxicity test, Carcinogenicity test or combined chronic toxicity/carcinogenicity test.

5.6. **Reproductive toxicity**

Adverse reproductive effects are of two main types:

— impairment of male or female fertility, and

— impacts on the normal development of progeny (developmental toxicity).

Possible effects on all aspects of reproductive physiology in both males and females, as well as possible effects on pre-natal and post-natal development, must be investigated and reported. If in exceptional circumstances, it is claimed that such testing is unnecessary, that claim must be fully justified.

While the standard reference point for treatment responses are concurrent control data, historical control data may be helpful in the interpretation of particular reproductive studies. Where submitted, historical control data should be from the same species and strain, maintained under similar conditions and should be from contemporaneous studies. The information on historical control data provided must include:

— identification of species and strain, name of the supplier, and specific colony identification, if the supplier has more than one geographical location,

— name of the laboratory and the dates when the study was performed,

— description of the general conditions under which animals were maintained, including the type or brand of diet and, where possible, the amount consumed,

— approximate age, in days, of the control animals at the beginning of the study and at the time of killing or death,

— description of the control group mortality pattern observed during or at the end of the study, and other pertinent observations (e.g. diseases, infections), and

— name of the laboratory and the examining scientist responsible for gathering and interpreting the toxicological data from the study.

[1] *Standardized System of Nomenclature and Diagnostic Criteria — Guides for Toxicologic Pathology*

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5.6.1. *Multi-generation studies*

Aim of the test

The studies reported, taken together with other relevant data and information on the active substance, must be sufficient to permit the identification of effects for reproduction, following repeated exposure to the active substance, and in particular must be sufficient:

— to identify direct and indirect effects on reproduction resulting from exposure to the active substance,

— to identify any enhancement of general toxic effects (noted during short-term and chronic toxicity testing),

— to establish the dose-response relationship, to identify changes in toxic signs and manifestations observed, and

— to establish the Noael.

Circumstances in which required

A reproduction toxicity study in rats over at least two generations must always be reported.

Test guideline

The tests must be carried out in accordance with Directive 87/302/EEC, Part B, two-generation reproduction toxicity test. In addition organ weight of reproductive organs must be reported.

Supplementary studies

Where necessary for a better interpretation of the effects on reproduction and as far as this information is not yet available it could be necessary to perform supplementary studies in order to provide the following information:

— separate male and female studies,

— three segment designs,

— dominant lethal assay for male fertility,

— cross-matings of treated males with untreated females and vice versa,

— effects on spermatogenesis,

— effects on oogenesis,

— sperm motility, mobility and morphology, and

— investigation of hormonal activity.

5.6.2. *Developmental toxicity studies*

Aim of the test

The studies reported, taken together with other relevant data and information on the active substance, must be sufficient to permit effects on embryonic and foetal development, following repeated exposure to the active substance, to be assessed, and in particular must be sufficient:

— to identify direct and indirect effects on embryonic and foetal development resulting from exposure to the active substance,

— to identify any maternal toxicity,

— to establish the relationship between observed responses and dose in both dam and offspring,

— to identify changes in toxic signs and manifestations observed, and

— to establish the Noael.

Furthermore, the tests will give additional information on any enhancement of general toxic effects of pregnant animals.

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Circumstances in which required

The tests must always be carried out.

Test conditions

Developmental toxicity must be determined both to rat and rabbit by the oral route. Malformations and variations should be reported separately. A glossary of terminology and diagnostic principles for malformations and variations must be given in the report.

Test guideline

The tests must be carried out in accordance with Directive 87/302/EEC, Part B, teratogenicity test — rodent and non-rodent.

5.7. **Delayed neurotoxicity studies**

Aim of the test

The test shall provide sufficient data to evaluate if the active substance could provoke delayed neurotoxicity after acute exposure.

Circumstances in which required

These studies have to be performed for substances of similar or related structures to those capable of inducing delayed neurotoxicity such as organophosphates.

Test guidelines

The test must be carried out in accordance with OECD Guideline 418.

5.8. **Other toxicological studies**

5.8.1. *Toxicity studies of metabolites as referred to in the introduction point (vii)*

Supplementary studies, where they relate to substances other than the active substance, are not a routine requirement.

Decisions as to the need for supplementary studies must be made on a case by case basis.

5.8.2. *Supplementary studies on the active substance*

In certain cases it can be necessary to carry out supplementary studies to further clarify observed effects. These studies could include:

— studies on absorption, distribution, excretion and metabolism,

— studies on the neurotoxic potential,

— studies on the immunotoxicological potential,

— studies on other routes of administration.

Decisions as to the need for supplementary studies must be made on a case by case basis, taking into account the results of the available toxicological and metabolism studies and the most important exposure routes.

Studies required must be designed on an individual basis, in the light of the particular parameters to be investigated and the objectives to be achieved.

5.9. **Medical data**

Where available, and without prejudice to the provisions of Article 5 of Council Directive 80/1107/EEC of 27 November 1980 on the protection of workers from the risks related to chemical, physical and biological agents at work ([1]), practical data and information relevant to the recognition of the symptoms of poisoning, and on the effectiveness of first aid and therapeutic measures have to be submitted. More specific references to the investigation for antidotal pharmacology or safety pharmacology using animals should be provided. Where

([1]) OJ No L 327, 3. 12. 1980, p. 8.

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relevant, the effectiveness of potential antagonists to poisoning, should be investigated and reported.

Data and information relevant to the effects of human exposure, where available and of the necessary quality, are of particular value, in confirming the validity of extrapolations made and conclusions reached with respect to target organs, dose-response relationships, and the reversibility of toxic effects. Such data can be generated following accidental or occupational exposure.

5.9.1. *Medicinal surveillance on manufacturing plant personnel*

Reports of occupational health surveillance programmes, supported with detailed information on the design of the programme, on exposure to the active substance and exposure to other chemicals, must be submitted. Such reports should, where feasible, include data relevant to the mechanism of action of the active substance. These reports shall, where available, include data from persons exposed in manufacturing plants or after application of the active substance (e.g.: in efficacy trials).

Available information on the sensitization including allergenic response of workers and others exposed to the active substance, must be provided, and include where relevant details of any incidence of hypersensitivity. The information provided should include details of frequency, level and duration of exposure, symptoms observed and other relevant clinical information.

5.9.2. *Direct observation, e.g.: clinical cases and poisoning incidents*

Available reports from the open literature, relating to clinical cases and poisoning incidents, where they are from refereed journals or official reports, must be submitted together with reports of any follow-up studies undertaken. Such reports should contain complete descriptions of the nature, level and duration of exposure, as well as the clinical symptoms observed, first aid and therapeutic measures applied and measurements and observations made. Summary and abstract information is not of value.

Where supported with the necessary level of detail, such documentation can be of particular value in confirming the validity of extrapolations from animal data to man and in identifying unexpected adverse effects which are specific to humans.

5.9.3. *Observations on exposure of the general population and epidemiological studies if appropriate*

Where available, and supported with data on levels and duration of exposure, and conducted in accordance with recognized standards ([1]), epidemiological studies are of particular value and must be submitted.

5.9.4. *Diagnosis of poisoning (determination of active substance, metabolites), specific signs of poisoning, clinical tests*

A detailed description of the clinical signs and symptoms of poisoning, including the early signs and symptoms and full details of clinical tests useful for diagnostic purposes, where available, must be provided and include full details of the time courses involved relevant to the ingestion, dermal exposure or inhalation of varying amounts of the active substance.

5.9.5. *Proposed treatment: first aid measures, antidotes, medical treatment*

The first aid measures to be used in the event of poisoning (actual and suspected) and in the event of contamination of eyes must be provided.

Therapeutic regimes for use in the event of poisoning or contamination of eyes, including where available the use of antidotes, must be described in full. Information based on practical experience, where it exists and is available, in other cases on theoretical grounds, as to the effectiveness of alternative treatment regimes, where relevant, must be provided. Contraindications associated with particular regimes, particu-

([1]) *Guidelines for Good Epidemiology Practices for Occupational and Environmental Research, developed by the Chemical Manufacturers Association's Epidemiology Task Group, as part of the Epidemiology Resource and Information Centre (ERIC),* Pilot Project, 1991

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larly those relating to 'general medical problems' and conditions, must be described.

5.9.6. *Expected effects of poisoning*

Where known, the expected effects and the duration of these effects following poisoning must be described and include the impact of:

— the type, level and duration of exposure, or ingestion, and

— varying time periods between exposure, or ingestion, and commencement of treatment.

5.10. **Summary of mammalian toxicity and overall evaluation**

A summary of all data and information provided under paragraphs 5.1 through 5.10, must be submitted, and include a detailed and critical assessment of those data in the context of relevant evaluative and decision making criteria and guidelines, with particular reference to the risks for man and animals that may or do arise, and the extent, quality and reliability of the data base.

Where relevant, in the light of findings with respect to the analytical profile of batches of the active substance (paragraph 1.11) and any bridging studies conducted (paragraphs 5 (iv)), the relevance of the data as submitted to the assessment of the toxicological profile of the active substance as manufactured, must be argued.

On the basis of an assessment of the data base, and the relevant decision making criteria and guidelines, justifications must be submitted for the Noaels proposed for each relevant study.

On the basis of these data scientifically reasoned proposals for the establishment of ADI and AOEL(s) for the active substance must be submitted.

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6. Residues in or on treated products, food and feed

Introduction

(i) The information provided, taken together with that provided for one or more preparations containing the active substance, must be sufficient to permit an evaluation to be made as to the risks for man, arising from residues of the active substance and relevant metabolites, degradation and reaction products remaining in food. In addition, the information provided must be sufficient to:

— permit a decision to be made as to whether, or not, the active substance can be included in Annex I,

— specify appropriate conditions or restrictions to be associated with any inclusion in Annex I.

(ii) A detailed description (specification) of the material used, as provided under Section 1, point 11 must be provided.

(iii) Studies should be performed according to the guidance available on regulatory testing procedures for residues of plant protection products in food ([1]).

(iv) Where relevant, data should be analyzed using appropriate statistical methods. Full details of the statistical analysis should be reported.

(v) Stability of residues during storage.

If may be necessary to perform studies on the stability of residues during storage. Provided samples are frozen within generally 24 hours after sampling and unless a compound is otherwise known to be volatile or labile, data are not normally required for samples extracted and analysed within 30 days from sampling (six months in the case of radio-labelled material).

Studies with non-radio-labelled substances should be carried out with representative substratets and preferably on samples from treated crops or animals with incurred residues. Alternatively, if

([1]) Guidance under development.

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this is not possible, aliquots of prepared control samples should be spiked with a known amount of chemical before storage under normal storage conditions.

Where the degradation during storage is significant (more than 30 %) it may be necessary to change the storage conditions or not to store the samples prior to analysis and repeat and studies where the unsatisfactory storage conditions were used.

Detailed information with respect to the sample preparation and storage conditions (temperature and duration) of samples and extracts must be submitted. Storage stability data using sample extracts will also be required unless samples are analysed within 24 hours of extraction.

6.1. **Metabolism, distribution and expression of residue in plants**

Aim of the tests

The objectives of these studies are:

— to provide an estimate of total terminal residues in the relevant portion of crops at harvest following treatment as proposed,

— to identify the major components of the total terminal residue,

— to indicate the distribution of residues between relevant crops parts,

— to quantify the major components of the residue and to establish the efficiency of extraction procedures for these components,

— to decide on the definition and expression of a residue.

Circumstances in which required

These studies must always be performed unless it can be justified that no residues will remain on plants/plant products which are used as food or feedingstuffs.

Test conditions

Metabolism studies have to involve crops or categories of crops in which plant protection products containing the active substance in question would be used. If a wide range of uses in different crop categories or in the category fruits is envisaged, studies have to be carried out on at least three crops unless it can be justified that a different metabolism is unlikely to occur. In cases where use is envisaged in different categories of crops, the studies must be representative for the relevant categories. For this purpose crops can be considered as falling into one of five categories: root vegetables, leafy crops, fruits, pulses and oilseeds, cereals. If studies are available for crops from three of these categories and the results indicate that the route of degradation is similar in all three categories then it is unlikely that any more studies will be needed unless it could be expected that a different metabolism will occur. The metabolism studies have also to take into account the different properties of the active substance and the intended method of application.

An evaluation of the results from different studies has to be submitted on the point and path of uptake (e.g. via leaves or roots), and on the distribution of residues between relevant parts of the crop at harvest (with particular emphasis on edible parts for man or animals). If the active substance or relevant metabolites are not taken up by the crop, this must be explained. Information on the mode of action and the physico-chemical properties of the active substance may be helpful in assessing trial data.

6.2. **Metabolism, distribution and expression of residue in livestock**

Aim of tests

The objectives of these studies are:

— to identify the major components of the total terminal residue in edible animal products,

— to quantify the rate of degradation and excretion of the total residue in certain animal products (milk or eggs) and excreta,

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— to indicate the distribution of residues between relevant edible animal products,

— to quantify the major components of the residue and to show the efficiency of extraction procedures for these components,

— to generate data from which a decision on the need for livestock feeding studies as provided for in point 6.4 can be made,

— to decide on the definition and expression of a residue.

Circumstances in which required

Metabolism studies on animals, such as lactating ruminants (e.g. goat or cow) or laying poultry, are only required when pesticide use may lead to significant residues in livestock feed (≥ 0,1 mg/kg of the total diet as received, except special cases e.g. active substances which accumulate). Where it becomes apparent that metabolic pathways differ significantly in the rat as compared to ruminants a pig study must be conducted unless the expected intake by pigs is not significant.

6.3. **Residue trials**

Aim of the tests

The objectives of these studies are:

— to quantify the highest likely residue levels in treated crops at harvest or outloading from store following the propopsed good agricultural practice (GAP),

and

— to determine, when appropriate, the rate of decline of plant protection product deposits.

Circumstances in which required

These studies must always be performed where the plant protection product will be applied to plants/plant products which are used as food or feedingstuffs or where residues from soil or other substrates can be taken up by such plants except where extrapolation from adequate data on another crop is possible.

Residue trial data shall be submitted in the Annex II dossier for those uses of plant protection products for which authorization is sought at the moment of introduction of a dossier for inclusion of the active substance in Annex I.

Test conditions

Supervised trials should corrspond to proposed critical GAP. The test conditions must take into account the highest residues which may reasonably arise (e.g. maximum number of proposed applications, use of the maximum envisaged quantity, shortest pre-harvest intervals, withholding periods or storage periods) but which remain representative of the realistic worst case conditions in which the active substance would be used.

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.

When establishing a supervised trial programme, normally factors such as climatic differences existing between production areas, differences in production methods (e.g. outdoor versus glasshouse uses), seasons of production, type of formulations, etc. should be taken into account.

In general, for a comparable set of conditions, trials should be carried out over a minimum of two growing seasons. All exceptions should be fully justified.

The precise number of trials necessary is difficult to determine in advance of a preliminary evaluation of the trial results. Minimum data requirements only apply where comparability can be established between production areas, e.g. concerning climate, methods and growing seasons of production, etc. Assuming all other variables (climate, etc.) are comparable, a minimum of eight trials representative of the proposed growing area is required for major crops. For minor

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crops normally four trials representative of the proposed growing area are required.

Due to the inherently higher level of homogeneity in residues arising from post-harvest treatments or protected crops, trials from one growing season will be acceptable. For post-harvest treatments, in principle a minimum of four trials are required, carried out preferably at different locations with different cultivars. A set of trials has to be carried out for each application method and store type unless the worst case residue situation can be clearly identified.

The number of studies per growing season to be performed can be reduced if it can be justified that the residue levels in plants/plant products will be lower than the limit of determination.

Where a significant part of the consumable crop is present at the time of application, half of the supervised residue trials reported should include data to show the effect of time on the level of residue present (residue decline studies) unless it can be justified that the consumable crop is not affected by the application of the plant protection product under the proposed conditions of use.

6.4. **Livestock feeding studies**

Aim of the tests

The objective of these studies is to determine the residue in products of animal origin which will result from residues in feedingstuffs or fodder crops.

Circumstances in which required

Feeding studies are only required:

— when significant residues (≥ 0,1 mg/kg of the total diet as received, except special cases, such as active substances which accumulate) occur in crops or part of the crop (e.g. trimmings, waste) fed to animals, and

— when metabolism studies indicate that significant residues (0,01 mg/kg or above the limit of determination if this would be higher than 0,01 mg/kg) may occur in any edible animal tissue taking into account the residue levels in potential feedingstuffs obtained at the 1 × dose rate.

Where appropriate separate feeding studies for lactating ruminant and/or laying poultry should be submitted. Where it appears from the metabolism studies submitted in accordance with the provisions of point 6.2 that metabolic pathways differ significantly in the pig as compared to ruminants, a pig feeding study must be conducted unless the expected intake by pigs is not significant.

Test conditions

In general, the feed is administered in three dosages (expected residue level, three to five times, and 10 times the expected residue level). When setting the 1 × dose, a theoretical feed ration must be compiled.

6.5. **Effects of industrial processing and/or household preparations**

Circumstances in which required

The decision as to whether it is necessary to carry out processing studies will depend on:

— the importance of a processed product in the human or animal diet,

— the level of residue in the plant or plant product to be processed,

— the physico-chemical properties of the active substance or relevant metabolites, and

— the possibility that degradation products of toxicological significance may be found after processing of the plant or plant product.

Processing studies are not normally necessary if no significant or no analytically determinable residues occur in the plant or plant product which would be processed, or if the total theoretical maximum daily intake (TMDI) is less than 10 % of the ADI. In addition, processing studies are not normally required for plants or plant products mostly

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eaten raw except for those with inedible portions such as citrus, banana or kiwi fruit where data on the distribution of the residue in peel/pulp may be required.

'Significant residues' generally refer to residues above 0,1 mg/kg. If the pesticide concerned has a high acute toxicity and/or a low ADI, consideration must be given to conducting processing studies for determinable residues below 0,1 mg/kg.

Studies on the effects on the nature of the residue are not normally required where only simple physical operations, not involving a change in temperature of the plant or the plant product, are involved such as washing, trimming or pressing.

6.5.1. *Effects on the nature of the residue*

Aim of the tests

The objective of these studies is to establish whether or not breakdown or reaction products arise from residues in the raw products during processing which may require a separate risk assessment.

Test conditions

Depending upon the level and chemical nature of the residue in the raw commodity, a set of representative hydrolysis situations (simulating the relevant processing operations) should be investigated, where appropriate. The effects of process other than hydrolysis, may also have to be investigated, where the properties of the active substance or metabolites indicate that toxicologically significant degradation products may occur as a result of these processes. The studies are normally conducted with a radio-labelled form of the active substance.

6.5.2. *Effects on the residue levels*

Aim of the tests

The main objectives of these studies are:

— to determine the quantitative distribution of residues in the various intermediate and end products, and to estimate transfer factors,

— to enable a more realistic estimate to be made of dietary intake of residues.

Test conditions

Processing studies should represent household processing and/or actual industrial processes.

In the first instance it is usually only necessary to carry out a core set of 'balance studies' representative of the common processes relevant to the plants or plant products containing significant residues. Justification should be given for the selection made of these representative process(es). The technology to be used in processing studies should always correspond as closely as possible to the actual conditions that are normally used in practice. A balance sheet should be made in which the mass balance of residues in all intermediate and end products is investigated. In drawing up such a balance sheet any concentrations or reductions in residues in individual products can be recognized and the corresponding transfer factors can also be determined.

If the processed plant products play an important part in the diet, and if the 'balance study' indicates that a significant transfer of residue into the processed products could occur, then three 'follow-up studies' to determine residue concentration or dilution factors must be carried out.

6.6. **Residues in succeeding crops**

Aim of the test

The objective of these studies is to permit an evaluation of possible residues in succeeding crops.

Circumstances in which required

Where data generated in accordance with Annex II, Section 7, point 7.1 or Annex III, Section 9, point 9.1, shows that significant residues (> 10 % of the applied active substance as a total of unchanged active

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substance and its relevant metabolites or degradation products) remain in soil or in plant materials, such as straw or organic material up to sowing or planting time of possible succeeding crops, and which could lead to residues above the limit of determination in succeeding crops at harvest, consideration should be given to the residue situation. This should include consideration of the nature of the residue in the succeeding crops and involve at least a theoretical estimation of the level of these residues. If the likelihood of residues in succeeding crops can not be excluded, metabolism and distribution studies should be carried out, if necessary followed by field trials.

Test conditions

If a theoretical estimation of residues in succeeding crops is done, full details and a justification shall be be given.

Metabolism and distribution studies and field trials, if necessary, shall be carried out on representative crops chosen to represent normal agricultural practice.

6.7. **Proposed maximum residue levels (MRLs) and residue definiton**

A full justification for the propsoed MRLs must be provided, including, where relevant, full details of the statistical analysis used.

When judging which compounds are to be included in the residue definition, account has to be taken of the toxicological significance of the compounds, amounts likely to be present and the practicality of the analytical methods proposed for post-registration control and monitoring purposes.

6.8. **Proposed pre-harvest intervals for envisaged uses, or withholding periods or storage periods, in the case of post-harvest uses**

A full justification for the proposals must be provided.

6.9. **Estimation of the potential and actual exposure through diet and other means**

Consideration will be given to the calculation of a realistic prediction of dietary intake. This may be done in a step-wise fashion leading to an increasingly realistic predictions of intake. Where relevant, other sources of exposure such as residues arising from the use of medicines or veterinary drugs have to be taken into acocunt.

6.10. **Summary and evaluation of residue behaviour**

A summary and evaluation of all data presented in this Section should be carried out according to the guidance given by the competent authorities of the Member States concerning the format of such summaries and evaluations. It should include a detailed and critical assessment of those data in the context of relevant evaluative and decision-making criteria and guidelines, with particular reference to the risks for man and animals that may or do arise, and the extent, quality and reliablity of the data base.

In particular, the toxicological significance of any non-mammalian metabolites must be addressed.

A schematic diagram should be prepared of the metabolic pathway in plants and animals with a brief explanation of the distribution and chemical changes involved.

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7. **Fate and behaviour in the environment**

Introduction

(i) The information provided, taken together with that for one or more preparations containing the active substance, must be sufficient to pemit an assessment of the fate and behaviour of the active substance in the environment, and of the non-target species likely to be at risk from exposure to the active substance, its metabolites, degradation and reaction products, where they are of toxicological or environmental significance.

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(ii) In particular, the information provided for the active substance, together with other relevant information, and that provided for one or more preparations containing it, should be sufficient to:

— decide whether, or not, the active substance can be included in Annex I,

— specify appropriate conditions or restrictions to be associated with any inclusion in Annex I,

— classify the active substance as to hazard;

— specify the hazard symbols, the indications of danger, and relevant risk and safety phrases for the protection of the environment, which are to be included on packaging (containers),

— predict the disribution, fate, and behaviour in the environment of the active substance and relevant metabolites, degradation and reaction products as well as the times courses involved,

— identify non-target species and populations for which hazards a rise because of potential exposure, and

— identify measures necesary to minimize contamination of the environment and impact on non-target species.

(iii) A detailed description (specification) of the material used, as provided for under Section 1, point 11 must be provided. Where testing is done using active substance the material used should be of that specification that will be used in the manufacture of preparations to be authorized except where radio-labelled material is used.

Where studies are conducted using active substance produced in the laboratory or in a pilot plant production system, the studies must be repeated using active substance as manufactured, unless it can be justified that the test material used is essentially the same for the purposes of environmental testing and assessment.

(iv) Where radio-labelled test material is used, radio-labels should be positioned at sites (one or more as necessary), to facilitate elucidation of metabolic and degradative pathways and to facilitate investigation of the distribution of the active substance and of its metabolite, reaction and degradation products in the environment.

(v) It may be necessary to conduct separate studies for metabolites, degradation or reaction products, where these products can constitute a relevant risk to non-target organisms or to the quality of water, soil and air and where their effects cannot be evaluated by the available results relating to the active substance. Before such studies are performed the information from the Sections 5 and 6 has to be taken into account.

(vi) Where relevant, tests should be designed and data analysed using appropriate statistical methods.

Full details of the statistical anaylsis should be reported (e.g. all point estimates should be given with confidence intervals, exact p-values should be given rather than stating significant/non significant).

7.1. **Fate and behaviour in soil**

All relevant information on the type and the properties of the soil used in the studies, including pH, organic carbon content, cation exchange capacity, particle size distribution and water holding capacity, particle size distribution and water holding capacity at pF = 0 and pF = 2,5 has to be reported in accordance with relevant ISO or other international standards.

The microbial biomass of soils used for laboratory degradation studies must be determined just prior to the commencement and at the end of the study.

It is recommended to use as much as possible the same soils throughout all laboratory soil studies.

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The soils used for degradation or mobility studies must be selected such that they are representative of the range of soils typical of the various Community regions where use exists or is anticipated, and be such that:

— they cover a range of organic carbon content, particle size distribution and pH values; and

— where on the basis of other information, degradation or mobility are expected to be pH dependent (e.g. solubility and hydrolysis rate — paragraphs 2.7 and 2.8), they cover the following pH ranges:

  — 4,5 to 5,5

  — 6 to 7, and

  — 8 (approximately).

Soils used must, wherever possible, be freshly sampled. If use of stored soils is unavoidable, storage should be properly carried out for a limited time under defined and reported conditions. Soils stored for longer periods of time can only be used for adsorption/desorption studies.

The soil chosen to begin studying should not have extreme characteristics with respect to parameters such as particle size distribution, organic carbon content and pH.

Soils should be collected and handled in accordance with ISO 10381-6 *(Soil quality — Sampling — Guidance on the collection, handling and storage of soil for the assessment of microbial processes in the laboratory)*. Any deviations must be reported and justified.

Field studies should be carried out in conditions as close to normal agricultural practice as possible on a range of soil types and climatic conditions representative of the area(s) of use. Weather conditions shall be reported in cases where field studies are conducted.

7.1.1. *Route and rate of degradation*

7.1.1.1. Route of degradation

Aim of the tests

The data and information provided, together with other relevant data and information, should be sufficient to:

— identify, where feasable, the relative importance of the types of process involved (balance between chemical and biological degradation),

— identify the individual components present which at any time account for more than 10 % of the amount of active substance added, including, where feasible, non-extractable residues,

— identify where possible also individual components present which account for less than 10 % of the amount of active substance added,

— establish the relative proportions of the components present (mass balance), and

— permit the soil residue of concern and to which non-target species are or may be exposed, to be defined.

Where a reference is made to non-extractable residues these 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.

7.1.1.1.1. Aerobic degradation

Circumstances in which required

The degradation pathway or pathways must always be reported except where the nature and manner of use of preparations containing the active substance, preclude soil contamination such as uses on stored products or wound healing treatments for trees.

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Test conditions

The degradation pathway or pathways must be reported for one soil.

Results obtained must be presented in the form of schematic drawings showing the pathways involved, and in the form of balance sheets which show the distribution of radio-label as a function of time, as between:

— active substance,

— CO_2,

— volatile compounds other than CO_2,

— individual identified transformation products,

— extractable substances not identified, and

— non-extractable residues in soil.

The investigation of degradation pathways must include all feasible steps to characterise and quantify non-extractable residues formed after 100 days when exceeding 70 % of the applied dose of the active substance. The techniques and methodologies applied are best selected on a case-by-case basis. A justification must be provided where the compounds involved are not characterized.

The duration of the study is normally 120 days, except where after a shorter period the levels of non-extractable residues and CO_2 are such that they can be extrapolated in a reliable way to 100 days.

Test guideline

Setac — Procedures for assessing the environmental fate and ecotoxicity of pesticides ([1]).

7.1.1.1.2. Supplementary studies

— Anaerobic degradation

Circumstances in which required

An anaerobic degradation study must be reported unless it can be justified that exposure of the plant protection products containing the active substance to anaerobic conditions is unlikely to occur.

Test conditions and test guideline

The same provisions as provided for under the corresponding paragraph of point 7.1.1.1.1 apply.

— Soil photolysis

Circumstances in which required

A soil photolysis study must be reported unless it can be justified that deposition of the active substance at the soil surface is unlikely to occur.

Test guideline

Setac — Procedures for assessing the Environmental fate and ecotoxicity of pesticides.

7.1.1.2. Rate of degradation

7.1.1.2.1. Laboratory studies

Aim of the tests

The soil degradation studies should provide best possible estimates of the time taken for degradation of 50 % and 90 % (DT_{50lab} and DT_{90lab}), of the active substance, and of relevant metabolites, degradation and reaction products under laboratory conditions.

— Aerobic degradation

Circumstances in which required

The rate of degradation in soil must always be reported, except where the nature and manner of use of plant protection products containing

([1]) Society of Environmental Toxicology and Chemistry (SETAC), 1995. Procedures for assessing the environmental fate and ecotoxicity of pesticides, ISBN 90-5607-002-9.

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the active substance preclude soil contamination such as uses on stored products or wound healing treatments for trees.

Test conditions

The rate of aerobic degradation of the active substance in three soil types additional to that referred to in paragraph 7.1.1.1.1. must be reported.

In order to investigate the influence of temperature on degradation, one additional study at 10 °C has to be performed on one of the soils used for the investigation of degradation at 20 °C until a validated Community calculation model for the extrapolation of degradation rates at low temperatures is available.

The duration of the study is normally 120 days except if more than 90 % of the active substance is degraded before that period expires.

Similar studies for three soil types must be reported for all relevant metabolites, degradation and reaction products which occur in soil and which at any time during the studies account for more than 10 % of the amount of active substance added, except where their DT_{50} values were able to be determined from the results of the degradation studies with the active substance.

Test guideline

Setac — Procedures for assessing the environmental fate and ecotoxicity of pesticides.

— Anaerobic degradation

Circumstances in which required

The rate of anaerobic degradation of the active substance must be reported where an anaerobic study has to be performed according to point 7.1.1.1.2.

Test conditions

The rate of anaerobic degradation of the active substance must be carried out in the soil used in the anaerobic study performed according to point 7.1.1.1.2.

The duration of the study is normally 120 days except if more than 90 % of the active substance is degraded before that period expires.

Similar studies for one soil must be reported for all relevant metobolites, degradation and reaction products which occur in soil and which at any time during the studies account for more than 10 % of the amount of active substance added, except where their DT_{50} values were able to be determined from the results of the degradation studies with the active substance.

Test guideline

Setac — Procedures for assessing the environmental fate and ecotoxicity of pesticides.

7.1.1.2.2. Field studies

— Soil dissipation studies

Aim of the test

The soil dissipation studies should provide estimates of the time taken for dissipation of 50 % and 90 % (DT_{50f} and DT_{90f}), of the active substance under field conditions. Where relevant, information on relevant metabolites, degradation and reaction products must be reported.

Circumstances in which required

The tests have to be conducted in those conditions where DT_{50lab} determined at 20 °C and at a moisture content of the soil related to a pF value of 2 to 2,5 (suction pressure) is greater than 60 days.

Where plant protection products containing the active substance are intended to be used in cold climatic conditions, the tests have to be conducted where DT_{50lab}, determined at 10 °C and at a moisture content of the soil related to a pF value of 2 to 2,5 (suction pressure) is greater than 90 days.

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Test conditions

Individual studies on a range of representative soils (normally four different types) must be continued until > 90 % of the amount applied have dissipated. The maximum duration of the studies is 24 months.

Test guideline

SETAC — Procedures for assessing the environmental fate and ecotoxicity of pesticides.

— Soil residue studies

Aim of the test

Soil residue studies should provide estimates of the soil residue levels at harvest or at time of cowing or planting succeeding crops.

Circumstances in which required

Soil residue studies must be reported where DT_{50lab} is greater than one-third of the period between the application and harvest and where absorption by the succeeding crop is possible, except where soil residues at sowing or planting of a succeeding crop can be reliably estimated from the data of the soil dissipation studies or where it can be justified that these residues can not be phytotoxic to or leave unacceptable residues in rotational crops.

Test conditions

Individual studies must be continued until harvest or time of sowing or planting succeeding crops, unless > 90 % of the amount applied have dissipated.

Test guideline

SETAC — Procedures for assessing the environmental fate and ecotoxicity of pesticides.

— Soil accumulation studies

Aim of the tests

The tests should provide sufficient data to evaluate the possibility of accumulation of residues of the active substance and of relevant metabolites, degradation and reaction products.

Circumstances in which required

Where on the basis of soil dissipation studies it is established that DT_{90f} > one year and where repeated application is envisaged, whether in the same growing season or in succeeding years, the possibility of accumulation of residues in soil and the level at which a plateau concentration is achieved must be investigated except where reliable information can be provided by a model calculation or another appropriate assessment.

Test conditions

Long term field studies must be done on two relevant soils and involve multiple applications.

Before performing these studies the applicant shall seek the agreement of the competent authorities on the type of study to be performed.

7.1.2. *Adsorption and desorption*

Aim of the test

The data and information provided, together with other relevant data and information, should be sufficient to establish the absorption coefficient of the active substance and of relevant metabolites, degradation and reaction products.

Circumstances in which required

The studies must always be reported except where the nature and manner of use of preparations containing the active substance, preclude soil contamination such as uses on stored products or wound healing trees.

Testo conditions

Studies on the active substance must be reported for four soil types.

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Similar studies, for at least three soil types, must be reported for all relevant metabolites, degradation and reaction products which in soil degradation studies account at any time for more than 10 % of the amount of active substance added.

Test guideline

OECD method 106

7.1.3. *Mobility in the soil*

7.1.3.1. Column leaching studies

Aim of the test

The test should provide sufficient data to evaluate the mobility and leaching potential of the active substance and if possible of relevant metabolities, degradation and reaction products.

Circumstances in which required

Studies in four soils must be carried out where in the absorption and desorption studies provided for under point 7.1.2 it is not possible to obtain reliable absorption coefficient values.

Test guideline

SETAC — Procedures for assessing the environmental fate and ecotoxicity of pesticides.

7.1.3.2. Aged residue column leaching

Aim of the test

The test should provide sufficient data to estimate the mobility and leaching potential of relevant metabolites, degradation and reaction products.

Circumstances in which required

The studies must be performed except:

— where the nature and manner of use of preparations containing the active substance, preclude soil contamination such as uses on stored products or wound healing treatments for trees, or

— where a separate study for the metabolite, degradation or reaction product in accordance to point 7.1.2 or 7.1.3.1 was performed.

Test conditions

The period(s) of ageing should be determined from inspection of the degradation patterns of active substance and metabolites to ensure that a relevant spectrum of metabolites is present at the time of leaching.

Test guideline

SETAC — Procedures for assessing the environmental fate and ecotoxicity of pesticides.

7.1.3.3. Lysimeter studies or field leaching studies

Aim of the tests

The test should provide data on:

— the mobility in soil,

— the potential for leaching to ground water,

— The potential distribution in soil.

Circumstances in which requried

Expert judgement will be necessary to decide whether lysimeter studies or field leaching studies should be carried out, taking into account the results of degradation and other mobility studies and the predicted environmental concentrations in groundwater (PEC_{GW}), calculated in accordance with the provisions of Annex III, Section 9. The type and conditions of the study to be conducted should be discussed with the competent authorities.

Test conditions

Great care is necessary in design of both experimental installations and individual studies, to ensure that results obtained can be used for

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assessment purposes. Studies should cover the realistic worst case situation, taking into account the soil type, climatic conditions, the application rate and the frequency and period of application.

Water percolating from soil columns must be analyzed at suitable intervals, while residues in plant material must be determined at harvest. Residues in the soil profile in at least five layers must be determined on termination of experimental work. Intermediate sampling must be avoided, since removal of plants (except for harvesting according to normal agricultural practice) and soil cross influences the leaching process.

Precipitation, soil and air temperatures have to be recorded at regular intervals (at least on a weekly base).

— *Lysimeter* studies

Test conditions

The minimal depth of the lysimeters should be 100 cm; their maximal depth should be 130 cm. The soil cross must be undisturbed. Soil temperatures must be similar to those pertaining in the field. Where necessary, supplementary irrigation must be provided to ensure optimal plant growth and to ensure that the quantity of infiltration water is similar to that in the regions for which authorization is sought. When during the study the soil has to be disturbed for agricultural reasons it must not be disturbed deeper than 25 cm.

— Field leaching studies

Test conditions

Information on the groundwater table in the experimental fields must be submitted. If soil cracking is observed during the study this must be fully described.

Great attention should be given to the number and the location of water collection devices. The placement of these devices in the soil should not result in preferential flow paths.

Test guideline

SETAC — Procedures for assessing the environmental fate and ecotoxicity of pesticides.

7.2. **Fate and behaviour in water and air**

Aim of the tests

The information and data provided, taken together with that provided for one or more preparations containing the active substance, and other relevant information, should be sufficient to establish, or permit estimation of:

— persistence in water systems (bottom sediment and water, including suspended particles),

— the extent to which water, sediment organisms and air are at risk,

— potential for contamination of surface water and groundwater.

7.2.1. *Route and rate of degradation in aquatic systemes (as far as not covered by point 2.9)*

Aim of the tests

The data and information provided, together with other relevant data and information, should be sufficient to:

— identify the relative importance of the types of processes involved (balance between chemical and biological degradation),

— where possible, identify the individual components present,

— establish the relative proportions of the components present and their distribution as between water, including suspended particles, and sediment, and

— permit the residue of concern and to which non-target species are or may be exposed, to be defined.

7.2.1.1. Hydrolytic degradation

Circumstances in which required

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The test must always be performed for relevant metabolites, degradation and reaction products which account at any time for more than 10 % of the amount of active substance added unless sufficient information on their degradation is available from the test performed in accordance with point 2.9.1.

Test conditions and test guideline

The same provisions as provided under the corresponding paragraphs of point 2.9.1 apply.

7.2.1.2. Photochemical degradation

Circumstances in which required

The test must always be performed for relevant metabolites, degradation and reaction products which account at any time for more than 10 % of the amount of active substance added unless sufficient information on their degradation is available from the test performed in accordance with points 2.9.2 and 2.9.3.

Test conditions and test guideline

The same provisions as provided under the corresponding paragraphs of points 2.9.2 and 2.9.3 apply.

7.2.1.3. Biological degradation

7.2.1.3.1. 'Ready biodegradability'

Circumstances in which required

The test must always be performed unless it is not required under the provisions of Annex VI to Directive 67/548/EEC for the classification of the active substance.

Test guideline

EEC method C4.

7.2.1.3.2. Water/sediment study

Circumstances in which required

The test must be reported unless it can be justified that contamination of surface water will not occur.

Test guideline

SETAC — Procedures for assessing the environmental fate and ecotoxicity of pesticides.

7.2.1.4. Degradation in the saturated zone

Circumstances in which required

Transformation rates in the saturated zone of active substances and of relevant metabolites, degradation and reaction products can provide useful information on the fate of these substances in the groundwater.

Test conditions

Expert judgement is required to decide whether this information is necessary. Before performing these studies the applicant shall seek the agreement of the competent authorities on the type of study to be performed.

7.2.2. *Route and rate of degradation in air (as far as not covered by point 2.10)*

Guidance under development.

7.3. **Definition of the residue**

In the light of the chemical composition of residues occurring in soil, water or air, resulting from use, or proposed use, of a plant protection product containing the active substance a proposal for the definition of the residue must be submitted, taking account of both the levels found and their toxicological and environmental significance.

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7.4. **Monitoring data**

Available monitoring data concerning fate and behaviour of the active substance and relevant metabolites, degradation and reaction products must be reported.

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8. **Ecotoxicological studies**

Introduction

(i) The information provided, taken together with that for one or more preparations containing the active substance, must be sufficient to permit an assessment of the impact on non-target species (flora and fauna), likely to be at risk from exposure to the active substance, its metabolites, degradation and reaction products, where they are of environmental significance. Impact can result from single, prolonged or repeated exposure and can be reversible or irreversible.

(ii) In particular, the information provided for the active substance, together with other relevant information, and that provided for one or more preparations containing it, should be sufficient to:

— decide whether, or not, the active substance can be included in Annex I,

— specify appropriate conditions or restrictions to be associated with any inclusion in Annex I,

— permit an evaluation of short- and long-term risks for non-target species — populations, communities, and processes — as appropriate,

— classify the active substance as to hazard,

— specify the precautions necessary for the protection of non-target species, and

— specify the hazard symbols, the indications of danger, and relevant risk and safety phrases for the protection of the environment, to be mentioned on packaging (containers).

(iii) There is a need to report all potentially adverse effects found during routine ecotoxicological investigations and to undertake and report, where required by the competent authorities, such additional studies which may be necessary to investigate the probable mechanisms involved and assess the significance of these effects. All available biological data and information which is relevant to the assessment of the ecotoxicological profile of the active substance must be reported.

(iv) The information on fate and behaviour in the environment, generated and submitted in accordance with points 7.1 to 7.4, and on residue levels in plants generated and submitted in accordance with point 6 is central to the assessment of impact on non-target species, in that together with information on the nature of the preparation and its manner of use, it defines the nature and extent of potential exposure. The toxicokinetic and toxicological studies and information submitted in accordance with points 5.1 to 5.8 provide essential information as to toxicity to vertebrate species and the mechanisms involved.

(v) Where relevant, tests should be designed and data analysed using appropriate statistical methods. Full details of the statistical analysis should be reported (e. g. all point estimates should be given with confidence intervals, exact p-values should be given rather than stating significant/non significant).

Test substance

(vi) A detailed description (specification) of the material used, as provided for under point 1.11 must be provided. Where testing is done using active substance the material used should be of that specification that will be used in the manufacture of preparations to be authorized except where radiolabelled material is used.

(vii) Where studies are conducted using active substance produced in the laboratory or in a pilot plant production system, the studies must be repeated using active substance as manufactured, unless

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it can be justified that the test material used is essentially the same, for the purposes of ecotoxicological testing and assessment. In cases of uncertainty, appropriate bridging studies must be submitted to serve as a basis for a decision as to the possible need for repetition of the studies.

(viii) In the case of studies in which dosing extends over a period, dosing should preferably be done using a single batch of active substance if stability permits.

Whenever a study implies the use of different doses, the relationship between dose and adverse effect must be reported.

(ix) For all feeding studies, average achieved dose must be reported, including where possible the dose in mg/kg body weight. Where dosing via the diet is utilized the test compound must be distributed uniformly in the diet.

(x) It may be necessary to conduct separate studies for metabolites, degradation or reaction products, where these products can constitute a relevant risk to non-target organisms and where their effects cannot be evaluated by the available results relating to the active substance. Before such studies are performed the information from points 5, 6 and 7 has to be taken into account.

Test organisms

(xi) In order to facilitate the assessment of the significance of test results obtained, including the estimation of intrinsic toxicity and the factors affecting toxicity, the same strain (or recorded origin) of each relevant species should, where possible, be used in the various toxicity tests specified.

8.1. **Effects on birds**

8.1.1. Acute oral toxicity

Aim of the test

The test should provide, where possible, LD_{50} values, the lethal threshold dose, time courses of response and recovery and the NOEL, and must include relevant gross pathological findings.

Circumstances in which required

The possible effects of the active substance on birds must be investigated except where the active substance is intended solely to be included in preparations for exclusive use in enclosed spaces (e.g. in glasshouses or in food storage practice).

Test conditions

The acute oral toxicity of active substance to a quail species (Japanese quail *(Coturnix coturnix japonica)* or Bobwhite quail *(Colinus virginianus)* or to mallard duck *(Anas platyrhynchos)* must be determined. The highest dose used in tests need not exceed 2 000 mg/kg body weight.

Test guideline

Setac — Procedures for assessing the environmental fate and ecotoxicity of pesticides [1].

8.1.2. Short-term dietary toxicity

Aim of the test

The test should provide the short term dietary toxicity (LC_{50} values, lowest lethal concentration (LLC), where possible no observed effect concentrations (NOEC), time courses of response and recovery) and include relevant gross pathological findings.

Circumstances in which required

The dietary (five-day) toxicity of the active substance to birds must always be investigated on one species except where a study in accordance with the provisions of point 8.1.3 is reported. Where its

[1] Society of Environmental Toxicology and Chemistry (Setac), 1995. *Procedures for Assessing the Environmental Fate and Ecotoxicity of Pesticides,* ISBN 90-5607-002-9.

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acute oral NOEL is ≤ 500 mg/kg body weight or where the short-term NOEC < 500 mg/kg food the test must be performed on a second species.

Test conditions

The first species to be studied must be either a quail species or mallard duck. If a second species must be tested it should not be related to the first species tested.

Test guideline

The test must be carried out in accordance with OECD Method 205.

8.1.3. Subchronic toxicity and reproduction

Aim of the test

The test should provide the subchronic toxicity and reproductive toxicity of the active substance to birds.

Circumstances in which required

The subchronic and reproductive toxicity of the active substance to birds must be investigated, unless it can be justified that continued or repeated exposure of adults, or exposure of nest sites during the breeding season is unlikely to occur.

Test guideline

The test must be carried out in accordance with OECD Method 206.

8.2. **Effects on aquatic organisms**

The data of the tests referred to in points 8.2.1, 8.2.4 and 8.2.6 have to be submitted for every active substance even when it is not expected that plant protection products containing it could reach surface water following the proposed conditions of use. These data are required under the provisions of Annex VI to Directive 67/548/EEC for the classification of the active substance.

Data reported must be supported with analytical data on concentrations of the test substance in the test media.

8.2.1. Acute toxicity to fish

Aim of the test

The test should provide the acute toxicity (LC_{50}), and details of observed effects.

Circumstances in which required

The test must always be carried out.

Test conditions

The acute toxicity of the active substance must be determined for rainbow trout *(Oncorhynchus mykiss)* and for a warm water fish species. Where tests with metabolites, degradation or reaction products have to be performed the species used must be the more sensitive of the two species tested with the active substance.

Test guideline

The test must be carried out in accordance with the Annex to Commission Directive 92/69/EEC [1] adapting to technical progress for the 17th time Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification and labelling of dangerous, substances, Method C1.

8.2.2. Chronic toxicity to fish

Circumstances in which required

A chronic toxicity study must be carried out unless it can be justified that continued or repeated exposure of fish is unlikely to occur or unless a suitable microsom or mesocosm study is available.

Expert judgment is required to decide which test has to be performed. In particular for active substance for which there are indications of particular concerns (related to the toxicity of the active substance for

[1] OJ No L 383, 29. 12. 1992, p. 113.

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fish or the potential exposure) the applicant shall seek the agreement of the competent authorities on the type of test to be performed.

A fish early life stage toxicity test might be appropriate where bioconcentration factors (BCF) are between 100 and 1 000 or where EC_{50} of the active substance < 0,1 mg/l.

A fish life cycle test might be appropriate in cases where

— the bioconcentration factor is greater tan 1 000 and the elimination of the active substance during a depuration phase of 14 days is lower than 95 %,

or

— the substance is stable in water or sediment (DT_{90} > 100 days).

It is not necessary to perform a chronic toxicity test on juvenile fish when a fish early life stage toxicity test or a fish life cycle test has been performed; it is likewise not necessary to perform a fish early life stage toxicity test when a fish life cycle test has been performed.

8.2.2.1. Chronic toxicity test on juvenile fish

Aim of the test

The test should provide effects on growth, the threshold level for lethal effects and for observed effects, the NOEC and details of observed effects.

Test conditions

The test must be conducted on juvenile rainbow trout, following exposure of 28 days to the active substance. Data on the effects on growth and behaviour must be generated.

8.2.2.2. Fish early life stage toxicity test

Aim of the test

The test should provide effects on development, growth and behaviour, the NOEC and details of observed effects on fish early life stages.

Test guideline

The test must be carried out in accordance with OECD Method 210.

8.2.2.3. Fish life cycle test

Aim of the test

The test will provide effects on reproduction of the parental and the viability of the filial generation.

Test conditions

Before performing these studies the applicant shall seek the agreement of the competent authorities on the type and conditions of the study to be performed.

8.2.3. Bioconcentration in fish

Aim of the test

The test should provide the steady-state bioconcentration factors, uptake rate constants and depuration rate constants, calculated for each test compound, as well as relevant confidence limits.

Circumstances in which required

The bioconcentration potential of active substances, of metabolites and of degradation and reaction products, likely to partition into fatty tissues (such as log $p_{ow} \geq 3$ — see point 2.8 or other relevant indications of bioconcentration), must be investigated and be reported, unless it can be justified that exposure leading to bioconcentration is not likely to occur.

Test guideline

The test must be carried out in accordance with OECD Method 305E.

8.2.4. Acute toxicity to aquatic invertebrates

Aim of the test

The test should provide the 24 and 48-hour acute toxicity of the active substance, expressed as the median effective concentration (EC_{50}) for

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immobilization, and where possible the highest concentration causing no immobilization.

Circumstances in which required

The acute toxicity must always be determined for *Daphnia* (preferably *Daphnia magna)*. Where plant protection products containing the active substance are intended to be used directly on surface water additional data have to be reported on at least one representative species from each of the following groups: aquatic insects, aqautic crustaceans (on a species not related to *Daphnia)* and aquatic gastropod molluscs.

Test guideline

The test must be carried out in accordance with Directive 92/69/EEC, Method C2.

8.2.5. Chronic toxicity to aquatic invertebrates

Aim of the test

The test should provide where possible EC_{50} values for effects such as immobilization and reproduction and the highest concentration at which no effect such as on martality or reproduction occurs (NOEC) and details of observed effects.

Circumstances in which required

A test on *Daphnia* and on at least one representative aquatic insect species and an aquatic gastropod mollusc species must be carried out unless it can be justified that continued or repeated exposure is not likely to occur.

Test conditions

The test with *Daphnia* must be continued for 21 days.

Test guideline

The test must be carried out in accordance with OECD Method 202, Part II.

8.2.6. Effects on algal growth

Aim of the test

The test should procide EC_{50} values for growth and growth rate, NOEC values, and details of observed effects.

Circumstances in which required

Possible effects on algal growth of active substances must always be reported.

For herbicides a test on a second species from a different taxonomic group has to be performed.

Test guideline

The test must be carried out in accordance with Directive 92/69/EEC, Method C3.

8.2.7. Effects on sediment dwelling organisms

Aim of test

The test will measure effects on survival and development (including effects on emergence of adults for *Chironomus),* the relevant EC_{50} values and the NOEC values.

Circumstances in which required

Where environmental fate and behaviour data required in point 7 report that an active substance is likely to partition to and persist in aquatic sediments, expert judgement should be used to decide whether an acute or a chronic sediment toxicity test in required. Such expert judgement should take into account whether effects on sediment dwelling invertebrates are likely by comparing the aquatic invertebrate toxicity EC_{50} data from points 8.2.4 and 8.2.5 with the predicted levels of the active substances in sediment from data in Annex III, point 9.

Test conditions

Before performing these studies the applicant shall seek the agreement of the competent authorities on the type and conditions of the study to be performed.

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8.2.8. Aquatic plants

A test on aquatic plants has to be performed for herbicides.

Before performing these studies the applicant shall seek the agreement of the competent authorities on the type and conditions of the study to be performed.

8.3. **Effect on arthropods**

8.3.1. Bees

8.3.1.1. Acute toxicity

Aim of the test

The test should provide the acute oral and contact LD_{50} value of the active substance.

Circumstances in which required

Potential impact on bees must be investigated, except where preparations containing the active substance are for exclusive use in situations where bees are not likely to be exposed such as:

— food storage in enclosed spaces,

— non-systemic seed dressings,

— non-systemic preparations for application to soil,

— non-systemic dipping treatments for transplanted crops and bulbs,

— wound sealing and healing treatments,

— rodenticidal baits,

— use in glasshouses without pollinators.

Test guideline

The test must be carried out in accordance with EPPO Guideline 170.

8.3.1.2. Bee brood feeding test

Aim of the test

The test should provide sufficient information to evaluate possible risks from the plant protection product on honeybee larvae.

Circumstances in which required

The test must be carried out when the active substance may act as an insect growth regulator unless it can be justified that it is not likely that bee brood would be exposed to it.

Test guideline

The test must be carried out in accordance with ICPBR Method (e.g. P. A. Oomen, A. de Riujter and J. van der Steen. Method for honeybee brood feeding tests with insect growth-regulating insecticides. *EPPO Bulletin,* Volume 22, pp 613 to 616, 1992.)

8.3.2. Other arethropods

Aim of the test

The test should provide sufficient information to evaluate the toxicity (mortality and sublethal effects) of the active substance to selected arthropod species.

Circumstances in which required

Effects on non-target terrestrial arthropods (e.g. predators or parasitoids of harmful organisms) must be investigated. The information obtained for these species can also be used to indicate the potential for toxicity to other non-target species inhabiting the same environment. This information is required for all active substances except where preparations containing the active substance are for exclusive use in situations where non-target arthropods are not exposed such as:

— food storage in enclosed spaces,

— wound sealing and healing treatments,

— rodenticidal baits.

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Test conditions

The test must be performed initially in the laboratory on an artificial substrate (i.e. glass plate or quartz sand, as appropriate) unless adverse effects can be clearly predicted from other studies. In these cases, more realistic substrates may be used.

Two sensitive standard species, a parasitoid and predatory mite (e.g. *Aphidius rhopalosiphi* and *Typhlodromus pyri)* should be tested. In addition to these, two additional species must also be tested, which should be relevant to the intended use of the substance. Where possible and if appropriate, they should represent the other two major functional groups, ground dwelling predators and foliage dwelling predators. Where effects are observed with species relevant to the proposed use of the product, further testing may be carried out at the extended laboratory/semi-field level. Selection of the relevant test species should follow the proposals outlined in Setac — Guidance document on regulatory testing procedures for pesticides with non-target arthropods ([1]). Testing must be conducted at rates equivalent to the highest rate of field application to be recommended.

Test guideline

Where relevant, testing should be done according to appropriate guidelines which satisfy at least the requirements for testing as included in Setac — Guidance document on regulatory testing procedures for pesticides with non-target arthropods.

8.4. **Effects on earthworms**

8.4.1. Acute toxicity

Aim of the test

The test should provide the LC_{50} value of the active substance to earthworms, where possible the highest concentration causing no mortality and the lowest concentration causing 100 % mortality, and must include observed morphological and behavioural effects.

Circumstances in which required

Effects on earthworms must be investigated, where preparations containing the active substance are applied to soil, or can contaminate soil.

Test guideline

The test must be carried out in accordance with Commission Directive 88/302/EEC ([2]) adapting to technical progress for the ninth time Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, Part C, Toxicity for earthworms: Artificial soil test.

8.4.2. Sublethal effects

Aim of the test

The test should provide the NOEC and the effects on growth, reproduction and behaviour.

Circumstances in which required

Where on the basis of the proposed manner of use of preparations containing the active substance or on the basis of its fate and behaviour in soil (DT_{90} > 100 days), continued or repeated exposure of earthworms to the active substance, or to significant quantities of metabolites, degradation or reaction products, can be anticipated expert judgement is required to decide whether a sublethal test can be useful.

([1]) From the Workshop European Standard Characteristics of beneficials Regulatory Testing (Escort), 28 to 30 March 1994, ISBN 0-95-22535-2-6.
([2]) OJ No L 133, 30. 5. 1988, p. 1.

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Test conditions

The test must be carried out on *Eisenia foetida.*

8.5. **Effects on soil non-target micro-organisms**

Aim of the test

The test should provide sufficient data to evaluate the impact of the active substance on soil microbial activity, in terms of nitrogen transformation and carbon mineralization.

Circumstances in which required

The test must be carried out where preparations containing the active substance are applied to soil or can contaminate soil under practical conditions of use. In the case of active substances intended for use in preparations for soil sterilization, the studies must be designed to measure rates of recovery following treatment.

Test conditions

Soils used must be freshly sampled agricultural soils. The sites from which soil is taken must not have been treated during the previous two years with any substance that could substantially alter the diversity and levels of microbial populations present, other than in a transitory manner.

Test guideline

Setac — Procedures for assessing the environmental fate and ecotoxicity of pesticides.

8.6. **Effects on other non-target organisms (flora and fauna) believed to be at risk**

A summary of available data from preliminary tests used to assess the biological activity and dose range finding, whether positive or negative, which may provide information with respect to possible impact on other non-target species, both flora and fauna, must be provided, together with a critical assessment as to its relevance to potential impact on non-target species.

8.7. **Effects on biological methods for sewage treatment**

Effects on biological methods for sewage treatment must be reported where the use of plant protection products containing the active substance can give rise to adverse effects on sewage treatment plants.

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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*

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PART B

Introduction

(i) Active substances are defined in Article 2(4) and include chemical substances and micro-organisms including viruses.

This Part provides data requirements for active substances consisting of micro-organisms, including viruses.

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For the purposes of Annex II, Part B, the term 'micro-organism' is used and is defined as follows: 'A microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material'.

The definition applies to, but is not limited to, bacteria, fungi, protozoa, viruses and viroids.

(ii) For all micro-organisms that are subject to application all available relevant knowledge and information in literature should be provided.

The most important and informative information is obtained by the characterisation and identification of a micro-organism. Such information is found in sections 1 to 3 (identity, biological properties and further information) which form the basis for an assessment of human health and environmental effects.

Newly generated data from conventional toxicological and/or pathological experiments on laboratory animals are normally required unless the applicant can justify, on the basis of the previous information, that the use of the micro-organism, under the proposed conditions of use, does not have any harmful effects on human and animal health or on groundwater or any unacceptable influence on the environment.

(iii) Pending the acceptance of specific guidelines at international level, the information required shall be generated using available test guidelines accepted by the competent authority (e.g. USEPA guideline [1]); where appropriate test guidelines as described in Annex II, Part A, should be adapted in such a way that they are appropriate for micro-organisms. Testing should include viable and, if appropriate, non-viable micro-organisms, and a blank control.

(iv) Where testing is done, a detailed description (specification) of the material used and its impurities, according to the provisions of section 1, point 1.4, must be provided. The material used should be of that specification that will be used in the manufacture of preparations to be authorised.

Where studies are conducted using micro-organisms produced in the laboratory or in a pilot plant production system, the studies must be repeated using micro-organisms as manufactured, unless it can be demonstrated that the test material used is essentially the same for the purposes of the testing and assessment.

(v) Where the micro-organism has been genetically modified, as defined in Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms [2], a copy of the evaluation of the data concerning the assessment of risk to the environment, as stated in Article 1(3) of Directive 91/414/EEC, has to be submitted.

(vi) Where relevant, data should be analysed using appropriate statistical methods. Full details of the statistical analysis should be reported (e.g. all point estimates should be given with confidence intervals, exact p-values should be given rather than stating significant/non significant).

(vii) In the case of studies in which dosing extends over a period, dosing should preferably be done using a single batch of the micro-organism, if stability permits.

If the studies are not performed using a single batch of the micro-organism, the similarity of the different batches has to be stated.

Whenever a study implies the use of different doses, the relationship between dose and adverse effect must be reported.

(viii) If the plant protection action is known to be due to the residual effect of a toxin/metabolite or if significant residues of toxins/metabolites are to be expected not related to the effect of the active substance, a dossier for the toxin/metabolite has to be submitted in accordance with the requirements of Annex II, Part A.

1. IDENTITY OF THE MICRO-ORGANISM

The identification together with the characterisation of the micro-organism provides the most important information and is a key point for decision-making.

([1]) *USEPA Microbial Pesticide Test Guidelines, OPPTS Series 885, February 1996*(http://www.epa.gov/oppbppd1/biopesticides/guidelines/series885.htm).

([2]) OJ L 117, 8.5.1990, p. 15.

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1.1. **Applicant**

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

1.2. **Producer**

The name and address of the producer or producers of the micro-organism must be provided as must the name and address of each plant in which the micro-organism is produced. A contact point (preferably a central contact point, to include name, telephone and fax number) must be provided, with a view to providing updating information and responding to queries arising, regarding production technology, processes and the quality of product (including where relevant, individual batches). Where, following inclusion of the micro-organism in Annex I, there are changes in the location or number of producers, the information required must again be notified to the Commission and the Member States.

1.3. **Name and species description, strain characterisation**

(i) The micro-organism should be deposited at an internationally recognised culture collection and given an accession number and these details must be submitted.

(ii) Each micro-organism that is subject to the application should be identified and named at the species level. The scientific name and taxonomic grouping, i.e. family, genus, species, strain, serotype, pathovar or any other denomination relevant to the micro-organism, must be stated.

It must be indicated whether the micro-organism:

— is indigenous or non-indigenous at the species level to the intended area of application,

— is a wild type,

— is a spontaneous or induced mutant,

— has been modified, using techniques described in Annex IA, Part 2, and Annex IB to Directive 90/220/EEC.

In the latter two cases, all known differences between the modified micro-organism and the parent wild strain must be provided.

iii) Best available technology should be used to identify and characterise the micro-organism at the strain level. The appropriate test procedures and criteria used for identification (e.g. morphology, biochemistry, serology, molecular identification) must be provided.

iv) Common name or alternative and superseded names and code names used during the development, if any, must be provided.

(v) Relationships to known pathogens should be indicated.

1.4. **Specification of the material used for manufacturing of formulated products**

1.4.1. *Content of the micro-organism*

The minimum and maximum content of the micro-organism in the material used for manufacturing of formulated products, must be reported. The content should be expressed in appropriate terms, such as number of active units per volume or weight or any other manner that is relevant to the micro-organism.

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 stabilised, if production changes result in a changed specification of purity.

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1.4.2. *Identity and content of impurities, additives, contaminating micro-organisms*

It is desirable to have a plant protection product without contaminants (including contaminating micro-organisms), if possible. The level and nature of acceptable contaminants should be judged from a risk assessment point of view, by the competent authority.

If possible and appropriate, the identity and maximum content of all contaminating micro-organisms, expressed in the appropriate unit, must be reported. The information on identity must be provided where possible as outlined in Annex II, Part B, section1, point 1.3.

Relevant metabolites (i.e. if expected to be of concern to human health and/or the environment) known to be formed by the micro-organism should be identified and characterised at different states or growth stages of the micro-organism (see Annex IIB, Introduction, (viii)).

Where relevant detailed information on all components such as condensates, culture medium, etc. must be provided.

In the case of chemical impurities that are relevant for human health and/or the environment, the identity and maximum content, expressed in appropriate terms, must be provided.

In the case of additives, the identity and content in g/kg must be provided.

The information on identity of chemical substances such as additives must be provided as outlined in Annex II, Part A, section 1, point 1.10.

1.4.3. *Analytical profile of batches*

Where relevant, the same data as outlined in Annex II, Part A, section 1, point 1.11, have to be reported, using the appropriate units.

2. BIOLOGICAL PROPERTIES OF THE MICRO-ORGANISM

2.1. **History of the micro-organism and its uses. Natural occurrence and geographical distribution**

Familiarity, interpreted as the availability of relevant knowledge of the micro-organism, should be presented.

2.1.1. *Historical background*

The historical background of the micro-organism and its use (tests/ research projects or commercial use) must be provided.

2.1.2. *Origin and natural occurrence*

The geographical region and the place in the ecosystem (e.g. host plant, host animal, or soil from which the micro-organism was isolated) must be stated. The method of isolation of the micro-organism should be reported. The natural occurrence of the micro-organism in the relevant environment shall be given if possible at strain level.

In the case of a mutant, or a genetically modified micro-organism (as defined in Annex IA, Part 2, and Annex IB to Directive 90/220/EEC), detailed information should be provided on its production and isolation and on the means by which it can be clearly distinguished from the parent wild strain.

2.2. **Information on target organism(s)**

2.2.1. *Description of the target organism(s)*

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

2.2.2. *Mode of action*

The principal mode of action should be indicated. In connection with the mode of action it should also be stated if the micro-organism produces a toxin with a residual effect on the target organism. In that case, the mode of action of this toxin should be described.

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If relevant, information on the site of infection and mode of entry into the target organism and its susceptible stages should be given. The results of any experimental studies must be reported.

It should be stated by which way an uptake of the micro-organism, or its metabolites (especially toxins) may occur (e.g. contact, stomach, inhalation). It must also be stated whether or not the micro-organism or its metabolites are translocated in plants and, where relevant, how this translocation takes place.

In case of pathogenic effect on the target organism, infective dose (the dose needed to cause infection with the intended effect on a target species) and transmissibility (possibility of spread of the micro-organism in the target population, but also from one target species to another (target) species) after application under the proposed condition of use shall be indicated.

2.3. **Host specificity range and effects on species other than the target harmful organism**

Any available information on the effects on non-target organisms within the area to which the micro-organism may spread shall be given. The occurrence of non-target organisms being either closely related to the target species or being especially exposed shall be indicated.

Any experience of the toxic effect of the active substance or its metabolic products on humans or animals, of whether the organism is capable of colonising or invading humans or animals (including immunosuppressed individuals) and whether it is pathogenic shall be stated. Any experience of whether the active substance or its products may irritate skin, eyes or respiratory organs of humans or animals and whether it is allergenic in contact with skin or when inhaled shall be stated.

2.4. **Development stages/life cycle of the micro-organism**

Information on the life cycle of the micro-organism, described symbiosis, parasitism, competitors, predators, etc., including host organisms, as well as vectors for viruses, must be presented.

The generation time and the type of reproduction of the micro-organism must be stated.

Information on the occurrence of resting stages and their survival time, their virulence and infection potential must be provided.

The potential of the micro-organism to produce metabolites, including toxins that are of concern for human health and/or the environment, in its different development stages after the release, must be indicated.

2.5. **Infectiveness, dispersal and colonisation ability**

The persistence of the micro-organism and information on its life cycle under the typical environmental conditions of use must be indicated. In addition, any particular sensitivity of the micro-organism to certain compartments of the environment (e.g. UV light, soil, water) must be stated.

The environmental requirements (temperature, pH, humidity, nutrition requirements, etc.) for survival, reproduction, colonisation, damage (including human tissues) and effectiveness of the micro-organism must be stated. The presence of specific virulence factors should be indicated.

The temperature range at which the micro-organism grows must be determined, including minimum, maximum and optimum temperatures. This information is of particular value as a trigger for studies of effects on human health (section 5).

The possible effect of factors such as temperature, UV light, pH, and the presence of certain substances on the stability of relevant toxins must also be stated.

Information on possible dispersal routes of the micro-organism (via air as dust particles or aerosols, with host organisms as vectors, etc.), under typical environmental conditions relevant to the use, must be provided.

2.6. **Relationships to known plant or animal or human pathogens**

The possible existence of one or more species of the genus of the active and/or, where relevant, contaminating micro-organisms known to be

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pathogenic to humans, animals, crops or other non-target species and the type of disease caused by them shall be indicated. It shall be stated whether it is possible, and if so, by which means to clearly distinguish the active micro-organism from the pathogenic species.

2.7. **Genetic stability and factors affecting it**

Where appropriate, information on genetic stability (e.g. mutation rate of traits related to the mode of action or uptake of exogenous genetic material) under the environmental conditions of proposed use must be provided.

Information must also be provided on the micro-organism's capacity to transfer genetic material to other organisms as well as its capacity to being pathogenic for plants, animals or man. If the micro-organism carries relevant additional genetic elements, the stability of the encoded traits should be indicated.

2.8. **Information on the production of metabolites (especially toxins)**

If other strains belonging to the same microbial species as the strain subject to the application are known to produce metabolites (especially toxins) with unacceptable effects on human health and/or the environment during or after application, the nature and structure of this substance, its presence inside or outside the cell and its stability, its mode of action (including external and internal factors of the micro-organism necessary to action) as well as its effect on humans, animals or other non-target species shall be provided.

The conditions under which the micro-organism produces the metabolite (s) (especially toxin(s)) must be described.

Any available information on the mechanism by which the micro-organisms regulate the production of the(se) metabolite(s) should be provided.

Any available information on the influence of the produced metabolites on the micro-organism's mode of action should be provided.

2.9. **Antibiotics and other anti-microbial agents**

Many micro-organisms produce some antibiotic substances. Interference with the use of antibiotics in human or veterinary medicine must be avoided at any stage of the development of a microbial plant protection product.

Information on the micro-organism's resistance or sensitivity to antibiotics or other anti-microbial agents must be provided, in particular the stability of the genes coding for antibiotic resistance, unless it can be justified that the micro-organism has no harmful effects on human or animal health, or that it can not transfer its resistance to antibiotics or other anti-microbial agents.

3. FURTHER INFORMATION ON THE MICRO-ORGANISM

Introduction

(i) The information provided must describe the intended purposes for which preparations containing the micro-organism 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 micro-organism.

(iii) The studies, data and information submitted, must demonstrate the suitability of measures proposed for use in emergency situations.

(iv) The information and data referred to are required for each micro-organism, except where otherwise specified.

3.1. **Function**

The biological function must be specified from among the following:

— control of bacteria,

— control of fungi,

— control of insects,

— control of mites,

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— control of molluscs,

— control of nematodes,

— control of weeds,

— other (must be specified).

3.2. **Field of use envisaged**

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

— field use, such as agriculture, horticulture, forestry, and viticulture,

— protected crops (e.g. in greenhouses),

— amenity,

— weed control on non-cultivated areas,

— home gardening,

— house plants,

— stored products,

— other (specify).

3.3. **Crops or products protected or treated**

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

3.4. **Method of production and quality control**

Full information on how the micro-organism is produced in bulk must be provided.

Both production method/process and product must be subject to a continuous quality control by the applicant. In particular, the occurrence of spontaneous changing of major characteristics of the micro-organism and of the absence/presence of significant contaminants should be monitored. The quality assurance criteria for the production should be submitted.

The techniques used to ensure a uniform product, and the assay methods for its standardisation, maintenance and purity of the micro-organism must be described and specified (e.g. HACCP).

3.5. **Information on the occurrence or possible occurrence of the development of resistance of the target organism(s)**

Available information on the possible occurrence of the development of resistance or cross-resistance of the target organism(s) must be provided. Where possible, appropriate management strategies should be described.

3.6. **Methods to prevent loss of virulence of seed stock of the micro-organism**

Methods to prevent loss of virulence of starting cultures are to be provided.

In addition, any method, if available, that could prevent the micro-organism from losing its effects on the target species must be described.

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

A safety data sheet similar to that required for chemical active substances in Article 27 of Directive 67/548/EEC [1] must be provided for each micro-organism.

[1] See doc. 6853/VI/98, Concise outline report of the first peer review meeting on micro-organisms.

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3.8. **Procedures for destruction or decontamination**

In many cases the preferred or sole means of safe disposal of micro-organisms, contaminated materials, or contaminated packaging, is through controlled incineration in a licensed incinerator.

Methods to dispose safely of the micro-organism or, where necessary, to kill it prior to disposal, and methods to dispose of contaminated packaging and contaminated materials, must be fully described. Data must be provided for such methods to establish their effectiveness and safety.

3.9. **Measures in case of an accident**

Information on procedures for rendering the micro-organism harmless in the environment (e.g. water or soil) in case of an accident must be provided.

4. ANALYTICAL METHODS

Introduction

The provisions of this section only cover analytical methods required for post-registration control and monitoring purposes.

Post-approval monitoring might be considered for all areas of risk assessment. This is particularly the case when (strains of) micro-organisms that are non-indigenous to the intended area of application are considered for approval. For analytical methods used for generation of data as required in this Directive or for other purposes the applicant has to provide a justification for the method used; where necessary separate guidance will be developed for such methods on the basis of the same requirements as defined for methods for post-registration control and monitoring purposes.

Descriptions of methods must be provided and include details of equipment, materials and conditions used. The applicability of any internationally recognised method must be reported.

As far as practicable these methods must employ the simplest approach, involve the minimum cost, and require commonly available equipment.

Data on specifity, linearity, accuracy and repeatability, as defined in Annex II, Part A, points 4.1 and 4.2, are also required for methods used to analyse micro-organisms and their residues.

For this section the following applies:

Impurities	Any component (including contaminating micro-organisms and/or chemical substances) other than the specified micro-organism, originating from the manufacturing process or from degradation during storage
Relevant impurities	Impurities, as defined above, that are of concern for human or animal health and/or the environment
Metabolites	Metabolites include products resulting from degradative and biosynthetic reactions taking place within the micro-organism or other organisms used to produce the micro-organism of interest
Relevant metabolites	Metabolites that are of concern for human or animal health and/or the environment
Residues	Viable micro-organisms and substances produced in significant quantities by these micro-organisms which persist after the disappearance of the micro-organisms and are of concern for human or animal health and/or the environment.

On request the following samples must be provided:

(i) samples of the micro-organism as manufactured;

(ii) analytical standards of relevant metabolites (especially toxins) and all other components included in the residue definition;

(iii) if available, samples of reference substances for the relevant impurities.

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4.1. **Methods for the analysis of the micro-organism as manufactured**

— Methods for the identification of the micro-organism.

— Methods for providing information on possible variability of seed stock/active micro-organism.

— Methods to differentiate a mutant of the micro-organism from the parent wild strain.

— Methods for the establishment of purity of seed stock from which batches are produced and methods to control that purity.

— Methods to determine the content of the micro-organism in the manufactured material used for the production of formulated products and methods to show that contaminating micro-organisms are controlled to an acceptable level.

— Methods for the determination of relevant impurities in the manufactured material.

— Methods to control the absence and to quantify (with appropriate limits of determination) the possible presence of any human and mammalian pathogens.

— Methods to determine storage stability, shelf-life of the micro-organism, if appropriate.

4.2. **Methods to determine and quantify residues (viable or non-viable)**

of:

— the active micro-organism(s),

— relevant metabolites (especially toxins),

on and/or in crop, in foodstuffs and feeding stuffs, in animal and human body tissues and fluids, in soil, in water (including drinking water, ground water and surface water) and in air where relevant.

Analytical methods for amount or activity of proteinaceous products should also be included, e.g. by testing exponential cultures and culture supernatants in an animal cell bioassay.

5. EFFECTS ON HUMAN HEALTH

Introduction

(i) Available information based on the properties of the micro-organism and corresponding organisms (sections 1 to 3), including health and medical reports may be sufficient for a decision whether the micro-organism would cause health effects (infectious/pathogenic/toxic) in humans or not.

(ii) The information provided, taken together with that provided for one or more preparations containing the micro-organism, must be sufficient to permit an evaluation to be made as to the risks for man, directly and/or indirectly associated with the handling and use of plant protection products containing the micro-organism, and the risk for man handling treated products, and the risk for man arising from residual traces or contaminants remaining in food and water. In addition, the information provided must be sufficient to:

— permit a decision to be made as to whether, or not, the micro-organism can be included in Annex I,

— specify appropriate conditions or restrictions to be associated with any inclusion in Annex I,

— specify risk and safety phrases (once introduced) for the protection of man, animals and the environment to be included on packaging (containers),

— identify relevant first aid measures as well as appropriate diagnostic and therapeutic measures to be followed in the event of infection or another adverse effect in man.

(iii) All effects found during investigations should be reported. Investigations which may be necessary in order to evaluate the probable mechanism involved, and to assess the significance of these effects, must also be performed.

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(iv) For all studies actual achieved dose in colony forming units per kg body weight (cfu/kg), as well as in other appropriate units, must be reported.

(v) Evaluation of the micro-organism should be carried out in a tier-wise manner.

The first tier (Tier I) includes available basic information and basic studies, which have to be performed for all micro-organisms. Expert judgment will be necessary to decide about the appropriate test programme on a case-by-case basis. Newly generated data from conventional toxicological and/or pathological experiments on laboratory animals are normally required unless the applicant can justify, on the basis of the previous information, that the use of the micro-organism, under the proposed conditions of use, does not have any harmful effects on human and animal health. Pending the acceptance of specific guidelines at international level, the information required shall be generated using available test guidelines (e.g. USEPA OPPTS Guidelines).

Tier II studies must be conducted if tests under Tier I have shown adverse health effects. The type of study to be performed depends on the effects observed in the Tier I studies. Before performing such studies, the applicant shall seek agreement of the competent authorities on the type of study to be performed.

TIER I

5.1. **Basic information**

Basic information is required about the micro-organism's potential to cause adverse effects such as ability to colonise, to cause damage and to produce toxins and other relevant metabolites.

5.1.1. *Medical data*

Where available, and without prejudice to the provisions of Article 5 of Council Directive 80/1107/EEC of 27 November 1980 on the protection of workers from the risks related to chemical, physical and biological agents at work ([1]) and Articles 5 to 17 of Council Directive 90/679/EEC of 26 November 1990 on the protection of workers from the risks related to biological agents at work ([2]), practical data and information relevant to the recognition of the symptoms of infection or pathogenicity and on the effectiveness of first aid and therapeutic measures have to be submitted. Where relevant, the effectiveness of potential antagonists, should be investigated and reported. Where relevant, methods to kill or render the micro-organism uninfective must be indicated (see section 3, point 3.8).

Data and information relevant to the effects of human exposure, where available and of the necessary quality, are of particular value, in confirming the validity of extrapolations made and conclusions reached with respect to target organs, virulence, and the reversibility of adverse effects. Such data can be generated following accidental or occupational exposure.

5.1.2. *Medical surveillance on manufacturing plant personnel*

Available reports of occupational health surveillance programmes, supported with detailed information on the design of the programme and on exposure to the micro-organism must be submitted. Such reports should, where feasible, include data relevant to the mechanism of action of the micro-organism. These reports shall, where available, include data from persons exposed in manufacturing plants or after application of the micro-organism (e.g. in efficacy trials).

Special attention should be devoted to those whose susceptibility may be affected, e.g. pre-existing disease, medication, compromised immunity, pregnancy or breast feeding.

5.1.3. *Sensitisation/allergenicity observations, if appropriate*

Available information on the sensitisation and allergenic response of workers, including workers in manufacturing plants, agricultural and research workers and others exposed to the micro-organism must be

([1]) OJ L 327, 3.12.1980, p. 8.
([2]) OJ L 374, 31.12.1990, p. 1.

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provided, and include, where relevant, details of any incidences of hypersensitivity and chronic sensitisation. The information provided should include details of frequency, level and duration of exposure, symptoms observed and other relevant clinical observation. Information should be given about whether workers have been subjected to any allergy tests or interviewed about allergenic symptoms.

5.1.4. *Direct observation, e.g. clinical cases*

Available reports from the open literature on the micro-organism or closely related members of the taxonomic group (relating to clinical cases), where they are from reference journals or official reports, must be submitted together with reports of any follow-up studies undertaken. Such reports are of particular value and should contain complete descriptions of the nature, level and duration of exposure, as well as the clinical symptoms observed, first aid and therapeutic measures applied and measurements and observations made. Summary and abstract information is of limited value.

If there are animal studies performed, reports relating to clinical cases can be of particular value in confirming the validity of interpretations from animal data to man and in identifying unexpected adverse effects which are specific to humans.

5.2. **Basic studies**

In order to make it possible to correctly interpret the obtained results, it is of greatest importance that the suggested test methods are relevant regarding species sensitivity, administration route, etc., and relevant from a biological and toxicological point of view. The way of administration of the test micro-organism depends on the main exposure routes to humans.

To evaluate medium- and long-term effects after acute, sub-acute or semi-chronic exposure to micro-organisms, it is necessary to use the options provided in most of the OECD guidelines, to extend the studies concerned with a recovery period (after which full macroscopic and microscopic pathology is to be performed, including an exploration for micro-organisms in the tissues and organs). This facilitates the interpretation of certain effects and provides the possibility to recognise infectiveness and/or pathogenicity, which in turn helps taking decisions on other issues such as the necessity to perform long-term studies (carcinogenicity etc., see point 5.3), and whether or not to perform residue studies (see point 6.2).

5.2.1. *Sensitisation* ([1])

Aim of the test

The test will provide sufficient information to assess the potential of the micro-organism to provoke sensitisation reactions by inhalation as well as with dermal exposure. A maximised test has to be performed.

Circumstances in which required ([2])

Information on sensitisation must be reported.

5.2.2. *Acute toxicity, pathogenicity and infectiveness*

The studies, data and information to be provided and evaluated must be sufficient to permit the identification of effects following a single exposure to the micro-organism, and in particular to establish, or indicate:

— the toxicity, pathogenicity and infectiveness of the micro-organism,

([1]) The available methods for testing dermal sensitisation are not suitable for testing micro-organisms. Sensitisation by inhalation is most probably a greater problem compared with dermal exposure to micro-organisms but so far, there are no validated test methods. Development of these kinds of methods is therefore of great importance. Until then, all micro-organisms should be regarded as potential sensitisers. This approach also takes into consideration immuno-compromised or other sensitive individuals in the population (e.g. pregnant women, new-born children or elderly).

([2]) As a consequence of the absence of proper test methods all micro-organisms will be labelled as potential sensitisers, unless the applicant wants to demonstrate the non-sensitising potential by submitting data. Therefore, this data requirement should be regarded as not obligatory but optional, on a provisional base.

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— the time course and characteristics of the effects with full details of behavioural changes and possible gross pathological findings at post-mortem,

— where possible mode of toxic action,

— the relative hazards associated with the different routes of exposure, and

— blood analyses throughout the studies in order to evaluate the clearance of the micro-organism.

Acute toxic/pathogenic effects may be accompanied by infectiveness and/or more long-term effects which cannot be observed immediately. With a view to health evaluation, it is therefore necessary to carry out studies on the ability to infect in connection with oral intake, inhalation and intraperitoneal/subcutaneous injection by test mammals.

During the acute toxicity, pathogenicity and infectiveness studies, an estimation of the micro-organism and/or the active toxin clearance in the organs deemed to be relevant for microbial examination (e.g. liver, kidneys, spleen, lungs, brain, blood and site of administration) must be performed.

The observations to be made should reflect expert scientific judgement and may include the micro-organism numeration in all the tissues likely to be affected (e.g. showing lesions) and in the main organs: kidneys, brain, liver, lungs, spleen, bladder, blood, lymphatic ganglia, gastrointestinal tract, thymus gland and lesions at the inoculation site in the dead or moribund animals and at interim and final sacrifice.

The information generated through acute toxicity, pathogenicity and infectiveness testing is of particular value in assessing hazards likely to arise in accident situations and consumer risks due to exposure to possible residues.

5.2.2.1. Acute oral toxicity, pathogenicity and infectiveness

Circumstances in which required

The acute oral toxicity, pathogenicity and infectiveness of the micro-organism must be reported.

5.2.2.2. Acute inhalation toxicity, pathogenicity and infectiveness

Circumstances in which required

The inhalation toxicity ([1]), pathogenicity and infectiveness of the micro-organism must be reported.

5.2.2.3. Intraperitoneal/subcutaneous single dose

The intraperitoneal/subcutaneous test is considered a highly sensitive assay to elicit in particular infectiveness.

Circumstances in which required

The intraperitoneal injection is always required for all micro-organisms, however, expert judgement may be exercised to evaluate whether subcutaneous injection is preferred instead of intraperitoneal injection if the maximum temperature for growth and multiplication is lower than 37 °C.

5.2.3. *Genotoxicity testing*

Circumstances in which required

If the micro-organism produces exotoxins according to point 2.8, then these toxins and any other relevant metabolites in the culture medium must also be tested for genotoxicity. Such tests on toxins and metabolites should be performed using the purified chemical if possible.

If basic studies do not indicate that toxic metabolites are formed, studies on the micro-organism itself should be considered depending on expert judgement on the relevance and validity of the basic data. In the case of

([1]) An inhalation study may be replaced by an intratracheal study.

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a virus the risk of insertional mutagenesis in mammal cells or the risk of carcinogenicity has to be discussed.

Aim of the test

These studies are of value in:

— the prediction of genotoxic potential,

— the early identification of genotoxic carcinogens,

— the elucidation of the mechanism of action of some carcinogens.

It is important that a flexible approach is adopted, with selection of further tests being dependent upon interpretation of results at each stage.

Test conditions ([1])

Genotoxicity of cellular micro-organisms will be studied after breaking of the cells, wherever possible. Justification should be provided on the method of sample preparation used.

Genotoxicity of viruses should be studied on infectious isolates.

5.2.3.1. *In vitro* studies

Circumstances in which required

Results of *in vitro* mutagenicity tests (bacterial assay for gene mutation, test for clastogenicity in mammalian cells and test for gene mutation in mammalian cells) must be provided.

5.2.4. *Cell culture study*

This information must be reported for intracellular replicating micro-organisms, such as viruses, viroids or specific bacteria and protozoa, unless the information from sections 1 to 3 clearly demonstrates that the micro-organism does not replicate in warm-blooded organisms. A cell culture study should be performed in human cell or tissue cultures of different organs. Selection can be based on expected target organs after infection. If human cell or tissue cultures of specific organs are not available, other mammal cell and tissue cultures can be used. For viruses, the ability to interact with the human genome is a key consideration.

5.2.5. *Information on short-term toxicity and pathogenicity*

Aim of the test

Short-term toxicity studies must be designed to provide information as to the amount of the micro-organism that can be tolerated without toxic effects under the conditions of the study. Such studies provide useful data on the risks for those handling and using preparations containing the micro-organism. In particular, short-term studies provide an essential insight into possible cumulative actions of the micro-organism, and the risks to workers who may be intensively exposed. In addition short-term studies provide information useful in the design of chronic toxicity studies.

The studies, data and information to be provided and evaluated, must be sufficient to permit the identification of effects following repeated exposure to the micro-organism, and in particular to further establish, or indicate:

— the relationship between dose and adverse effects,

— toxicity of the micro-organism including where necessary the NOAEL for toxins,

— target organs, where relevant,

— the time course and characteristics of the effects with full details of behavioural changes and possible gross pathological findings at post-mortem,

— specific toxic effects and pathological changes produced,

([1]) As the present test methods are designed to be performed on soluble chemicals, it is necessary that the methods are developed so as to become relevant for micro-organisms.

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— where relevant the persistence and reversibility of certain toxic effects observed, following discontinuation of dosing,

— where possible, the mode of toxic action, and

— the relative hazard associated with the different routes of exposure.

During the short-term toxicity study, an estimation of the micro-organism clearance in the main organs must be performed.

Investigations should be included for pathogenicity and infectiveness end points.

Circumstances in which required

The short-term toxicity (minimum 28 days) of the micro-organism must be reported.

The choice of test species has to be justified. The choice of study length depends on acute toxicity and clearance data.

Expert judgement is required to decide what route of administration is preferable.

5.2.5.1. Health effects after repeated inhalatory exposure

Information on the health effects after repeated inhalatory exposure is considered necessary, particularly for the risk assessment of the occupational setting. Repeated exposure might influence the clearance capacity (e.g. resistance) of the host (human). Furthermore, for proper risk assessment the toxicity after repeated exposure to contaminants, growth medium, co-formulants and the micro-organism needs to be addressed. It should be kept in mind that the formulants in the plant protection product can influence the toxicity and infectiveness of a micro-organism.

Circumstances in which required

Information on the short-term infectiveness, pathogenicity and toxicity (respiratory route) of a micro-organism is required, unless the information already provided is sufficient to assess human health effects. This can be the case if it is demonstrated that the test material has no inhalable fraction and/or repeated exposure is not expected.

5.2.6. *Proposed treatment: first aid measures, medical treatment*

The first aid measures to be used in the event of infection and in the event of contamination of eyes must be provided.

Therapeutic regimes for use in the event of ingestion or contamination of eyes and skin must be described in full. Information based on practical experience, where it exists and is available, in other cases on theoretical grounds, as to the effectiveness of alternative treatment regimes, where relevant, must be provided.

Information on resistance to antibiotics must be provided.

(END OF TIER I)

TIER II

5.3. **Specific toxicity, pathogenicity and infectiveness studies**

In certain cases, it can be necessary to carry out supplementary studies to further clarify the adverse human effects.

In particular, if results from earlier studies indicate that the micro-organism may cause long-term health effects, studies on chronic toxicity, pathogenicity and infectiveness, carcinogenicity and reproductive toxicity must be carried out. Furthermore, where a toxin is produced, kinetic studies must be performed.

Studies required must be designed on an individual basis, in the light of the particular parameters to be investigated and the objectives to be achieved. Before performing such studies, the applicant shall seek agreement of the competent authorities on the type of study to be performed.

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5.4. ***In vivo* studies in somatic cells**

Circumstances in which required

If all the results of the *in vitro* studies are negative further testing must be done with consideration of other relevant information available. The test can be an *in vivo* study or an *in vitro* study using a different metabolising system from that/those previously used.

If the *in vitro* cytogenetic test is positive, an *in vivo* test using somatic cells (metaphase analysis in rodent bone marrow or micronucleus test in rodents) must be conducted.

If either of the *in vitro* gene mutation tests are positive, an *in vivo* test to investigate unscheduled DNA synthesis or a mouse spot test must be conducted.

5.5. **Genotoxicity — *In vivo* studies in germ cells**

Aim of the test and test conditions

See point 5.4.

Circumstances in which required

When any result of an *in vivo* study in somatic cells is positive, *in vitro* testing for germ cell effects may be justified. The necessity for conducting these tests will have to be considered on a case-by-case basis, taking into account other relevant information available including use and expected exposure. Suitable tests would need to examine interaction with DNA (such as the dominant lethal assay), to look at the potential for inherited effects and possibly make a quantitative assessment of heritable effects. It is recognised that in view of their complexity, the use of quantitative studies would require strong justification.

(END OF TIER II)

5.6. **Summary of mammalian toxicity, pathogenicity and infectiveness and overall evaluation**

A summary of all data and information provided under points 5.1 through 5.5, must be submitted, and include a detailed and critical assessment of those data in the context of relevant evaluative and decision making criteria and guidelines, with particular reference to the risks for man and animals that may or do arise, and the extent, quality and reliability of the data base.

It must be explained whether exposure of animals or humans has any implications for vaccination or serological monitoring.

6. RESIDUES IN OR ON TREATED PRODUCTS, FOOD AND FEED

Introduction

(i) The information provided, taken together with that for one or more preparations containing the micro-organism, must be sufficient to permit an evaluation to be made as to the risk for man and/or animals, arising from exposure to the micro-organism and its residual traces and metabolites (toxins) remaining in or on plants or plant products.

(ii) In addition, the information provided must be sufficient to:

— permit a decision to be made as to whether or not the micro-organism can be included in Annex I to Directive 91/414/EEC,

— specify appropriate conditions or restrictions to be associated with any inclusion in Annex I to Directive 91/414/EEC,

— where relevant, set maximum residue levels, preharvest intervals to protect consumers and waiting periods, to protect workers handling the treated crops and products.

(iii) For the evaluation of risk arising from residues, experimental data on levels of exposure to the residue may not be required where it can be justified, that the micro-organism and its metabolites are not hazardous to humans in the concentrations that could occur as a result of authorised use. This justification can be based on open

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literature, on practical experience and on information submitted in sections 1 through 3 and section 5.

6.1. **Persistance and likelihood of multiplication in or on crops, feedingstuffs or foodstuffs**

A substantiated estimation of persistance/competitiveness of the micro-organism and relevant secondary metabolites (especially toxins) in or on the crop under the environmental conditions prevailing at and after the intended use, taking into account in particular the information provided in section 2, has to be delivered.

Moreover, the application shall state to which extent and on which basis it is considered that the micro-organism can (or cannot) multiply in or on the plant or plant product or during processing of raw products.

6.2. **Further information required**

Consumers may be exposed to micro-organisms for a considerable time as a result of the consumption of treated food commodities; potential effects on the consumers must, therefore, be derived from chronic or semi-chronic studies, so that a toxicological end point, such as the ADI, can be established for risk management.

6.2.1. *Non-viable residues*

A non viable micro-organism is a micro-organism that is not capable of replication or of transferring genetic material.

If relevant quantities of the micro-organism or of produced metabolites, especially toxins, have been found to be persistant in section 2, points 2.4 and 2.5, full experimental residue data as provided for in Annex II, Part A, section 6, is required, if concentrations of the micro-organism and/or its toxins in or on the treated foodstuffs or feedingstuffs are expected to occur in concentrations higher than under natural conditions or in a different phenotypic state.

In agreement with Directive 91/414/EEC, the conclusion concerning the difference between natural concentrations and an elevated concentration due to treatment with the micro-organism, is to be based on experimentally obtained data, and not on extrapolations or calculations using models.

Before performing such studies, the applicant shall seek agreement of the competent authorities on the type of study to be performed.

6.2.2. *Viable residues*

If the information submitted according to point 6.1 suggests persistance of relevant amounts of the micro-organism in or on treated products, food or feed, possible effects on humans and/or animals must be investigated, unless it can be justified from section 5, that the micro-organism and its metabolites and/or degradation products are not hazardous to humans in the concentrations and of the nature that could occur as a result of authorised use.

In agreement with Directive 91/414/EEC, the conclusion concerning the difference between natural concentrations and an elevated concentration due to treatment with the micro-organism, is to be based on experimentally obtained data, and not on extrapolations or calculations using models.

The persistence of viable residues needs special attention if infectiveness or pathogenicity to mammals have been found in sections 2.3, 2.5 or 5 and/or if any other information suggests a hazard to consumers and/or workers. In this case the competent authorities may require studies similar to those provided for in Part A.

Before performing such studies, the applicant shall seek agreement of the competent authorities on the type of study to be performed.

6.3. **Summary and evaluation of residue behaviour resulting from data submitted under points 6.1 and 6.2**

7. FATE AND BEHAVIOUR IN THE ENVIRONMENT

Introduction

(i) Information on the origin, the properties, and the survival of the micro-organism and its residual metabolites as well as its intended

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use form the basis for an assessment of environmental fate and behaviour.

Experimental data are normally required unless it can be justified that an assessment of its fate and behaviour in the environment can be performed with the information already available. This justification can be based on open literature, on practical experience and, on information submitted in sections 1 through 6. The function of the micro-organism in environmental processes (as defined in section 2, point 2.1.2) is of particular interest.

(ii) The information provided, taken together with other relevant information, and that for one or more preparations containing the micro-organism, must be sufficient to permit an assessment of its fate and behaviour as well as that of its residual traces and toxins, where they are of significance for human health and/or the environment.

(iii) In particular, the information provided should be sufficient to:

— decide whether, or not, the micro-organism can be included in Annex I,

— specify appropriate conditions or restrictions to be associated with any inclusion in Annex I,

— specify the hazard symbols (once introduced), the indications of danger, and relevant risk and safety phrases for the protection of the environment, which are to be included on packaging (containers),

— predict the distribution, fate, and behaviour in the environment of the micro-organism and its metabolites as well as the time courses involved,

— identify measures necessary to minimise contamination of the environment and impact on non-target species.

(iv) Any relevant metabolites (i.e. of concern for human health and/or the environment) formed by the test organism under any relevant environmental conditions should be characterised. If relevant metabolites are present in or produced by the micro-organism, data as outlined under Annex II, Part A, point 7 may be required, if all of the following conditions are met:

— the relevant metabolite is stable outside the micro-organism, see point 2.8, and

— a toxic effect of the relevant metabolite is independent of the presence of the micro-organism, and

— the relevant metabolite is expected to occur in the environment in concentrations considerably higher than under natural conditions.

(v) Available information on the relationship with naturally occurring wild type relatives should be taken into account.

(vi) Before performing studies as referred to below, the applicant shall seek agreement of the competent authorities on whether studies need to be performed and, if so, the type of study to be conducted. The information from the other sections has, also, to be taken into account.

7.1. **Persistence and multiplication**

Where relevant, appropriate information on the persistence and multiplication of the micro-organism, in all environmental compartments has to be given, unless it can be justified that exposure of the particular environmental compartment to the micro-organism is unlikely to occur. Special attention shall be given to

— competitiveness under the environmental conditions prevailing at and after the intended use, and

— population dynamics in seasonally or regionally extreme climates (particularly hot summer, cold winter and rainfall) and to agricultural practices applied after intended use.

Estimated levels of the specified micro-organism in a time course after use of the product under the proposed conditions of use shall be given.

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7.1.1. *Soil*

Information on viability/population dynamics should be reported in several cultivated and uncultivated soils representative of soils typical of the various Community regions where use exists or is anticipated. The provisions on choice of soil and its collection and handling, as referred to in Part A, point 7.1, Introduction, have to be followed. If the test organism is to be used in association with other media, e.g. rockwool, this must be included in the test range.

7.1.2. *Water*

Information should be reported on viability/population dynamics in natural sediment/water systems under both dark and illuminated conditions.

7.1.3. *Air*

In case of particular concerns for operator, worker or bystander exposure, information on the concentrations in air might be necessary.

7.2. **Mobility**

The possible spread of the micro-organism and its degradation products in relevant environmental compartments has to be evaluated, unless it can be justified that exposure of the particular environmental compartments to the micro-organism is unlikely to occur. In this context, the intended use (e.g. field or greenhouse, application to soil or to crops), life cycle stages, including occurrence of vectors, persistence and the ability of the organism to colonise adjacent habitats are of particular interest.

The spread, the persistence and probable transport ranges need special attention if toxicity, infectiveness or pathogenicity have been reported or if any other information suggests possible hazard to humans, animals or to the environment. In this case the competent authorities may require studies similar to those provided for in Part A. Before performing such studies, the applicant shall seek agreement of the competent authorities on the type of study to be performed.

8. EFFECTS ON NON-TARGET ORGANISMS

Introduction

(i) The information on identity, biological properties and further information in sections 1 to 3 and 7 is central to the assessment of impact on non-target species. Additional useful information may be found on fate and behaviour in the environment in section 7 and on residue levels in plants in section 6 which, together with information on the nature of the preparation and its manner of use, defines the nature and extent of potential exposure. The information submitted in accordance with section 5 will provide essential information as to effects to mammals and the mechanisms involved.

Experimental data are normally required, unless it can be justified that an assessment of effects on non-target organisms can be performed with the information already available.

(ii) The choice of the appropriate non-target organisms for testing of environmental effects should be based on the identity of the micro-organism (including the host specificity, mode of action and ecology of the organism). From such knowledge it would be possible to choose the appropriate test-organisms, such as organisms closely related to the target organism.

(iii) The information provided, taken together with that for one or more preparations containing the micro-organism, must be sufficient to permit an assessment of the impact on non-target species (flora and fauna), likely to be at risk from exposure to the micro-organism, where they are of environmental significance. Impact can result from single, prolonged or repeated exposure and can be reversible or irreversible.

(iv) In particular, the information provided for the micro-organism, together with other relevant information, and that provided for one or more preparations containing it, should be sufficient to:

— decide whether, or not, the micro-organism can be included in Annex I,

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— specify appropriate conditions or restrictions to be associated with any inclusion in Annex I,

— permit an evaluation of short- and long-term risks for non-target species — populations, communities, and processes — as appropriate,

— classify the micro-organism as to biological hazard,

— specify the precautions necessary for the protection of non-target species, and

— specify the hazard symbols (once introduced), the indications of danger, and relevant risk and safety phrases for the protection of the environment, to be mentioned on packaging (containers).

(v) There is a need to report all potentially adverse effects found during routine investigations on environmental effects, to undertake and report, where required by the competent authorities, such additional studies which may be necessary to investigate the probable mechanisms involved and to assess the significance of these effects. All available biological data and information which is relevant to the assessment of the ecology profile of the micro-organism must be reported.

(vi) For all studies, average achieved dose in cfu/kg body weight as well as in other appropriate units must be reported.

(vii) It may be necessary to conduct separate studies for relevant metabolites (especially toxins), where these products can constitute a relevant risk to non-target organisms and where their effects cannot be evaluated by the available results relating to the micro-organism. Before such studies are performed, the applicant shall seek agreement of the competent authorities on whether such studies need to be performed and, if so, the type of study to be conducted. The information from sections 5, 6 and 7 has to be taken into account.

(viii) In order to facilitate the assessment of the significance of test results obtained, the same strain (or recorded origin) of each relevant species should, where possible, be used in the various tests specified.

(ix) Tests must be performed unless it can be justified that the non-target organism will not be exposed to the micro-organism. If it is justified that the micro-organism does not cause toxic effects or is not pathogenic or infective to vertebrates or plants, only reaction to appropriate non-target organisms must be investigated.

8.1. **Effects on birds**

Aim of the test

Information on toxicity, infectiveness and pathogenicity to birds must be reported.

8.2. **Effects on aquatic organisms**

Aim of the test

Information on toxicity, infectiveness and pathogenicity to aquatic organisms must be reported.

8.2.1. *Effects on fish*

Aim of the test

Information on toxicity, infectiveness and pathogenicity to fish must be reported.

8.2.2. *Effects on freshwater invertebrates*

Aim of the test

Information on toxicity, infectiveness and pathogenicity to freshwater invertebrates must be reported.

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8.2.3. *Effects on algae growth*

Aim of the test

Information on effects on algal growth, growth rate and capacity to recover must be reported.

8.2.4. *Effects on plants other than algae*

Aim of the test

Information on effects on plants other than algae must be reported.

8.3. **Effects on bees**

Aim of the test

Information on toxicity, infectiveness and pathogenicity to bees must be reported.

8.4. **Effects on arthropods other than bees**

Aim of the test

Information on toxicity, infectiveness and pathogenicity to arthropods other than bees must be reported. The selection of the test species should be related to the potential use of the plant protection products (e.g. foliar or soil application). Special attention should be given to organisms used for biological control and organisms playing an important role in integrated pest management.

8.5. **Effects on earthworms**

Aim of the test

Information on toxicity, infectiveness and pathogenicity to earthworms must be reported.

8.6. **Effects on non-target soil micro-organisms**

Impact on relevant non-target micro-organisms and on their predators (e. g. protozoa for bacterial inoculants) should be reported. Expert judgement is required to decide whether additional studies are necessary. Such decision will take into consideration the available information in this and other sections, in particular data on the specificity of the micro-organism, and the expected exposure. Useful information may also be available from the observations carried out in efficacy testing. Special attention should be given to organisms used in integrated crop management (ICM).

8.7. **Additional studies**

The additional studies might include further acute studies on additional species or processes (such as sewage systems) or higher tier studies such as chronic, sub-lethal or reproductive studies on selected non-target organisms.

Before performing such studies, the applicant shall seek agreement of the competent authorities on the type of study to be performed.

9. SUMMARY AND EVALUATION OF ENVIRONMENTAL IMPACT

A summary and evaluation of all data relevant to the environmental impact, should be carried out according to the guidance given by the competent authorities of the Member States concerning the format of such summaries and evaluations. It should include a detailed and critical assessment of those data in the context of relevant evaluative and decision making criteria and guidelines, with particular reference to the risks for the environment and non-target species that may or do arise, and the extent, quality and reliability of the data base. In particular the following issues should be addressed:

— distribution and fate in the environment, and the time courses involved,

— identification of non-target species and populations at risk, and the extent of their potential exposure,

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— identification of precautions necessary to avoid or minimise contamination of the environment, and for the protection of non-target species.

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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;

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1.2. where relevant, be generated using test guidelines, according to the latest adopted version, referred to or described in this Annex; in the case of studies initiated before the entry into force 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;

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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. ►M4 In particular, when reference is made in this Annex to an EEC Method which consists in the transposal of a method developed by an international organization (e.g. OECD), Member States may accept that the required information is generated according to the latest version of that method if at the initiation of the studies the EEC Method has not yet been updated; ◄

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,

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

— 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.

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2.4. By way of derogation from point 2.1, Member States may apply the provisions of points 2.2 and 2.3, by extension, to tests and analyses performed on their territory in order to obtain data on the properties and/or safety of the preparations with respect to honey-bees and beneficial arthropods other than bees and actually started on or before 31 December 1999.

2.5. By way of derogation from point 2.1, Member States may apply the provisions of points 2.2 and 2.3, by extension, to supervised residue trials performed on their territory in accordance with the provisions of Section 8 ‘Residues in or on treated products, food and feed’ with plant protection products containing active substances already on the market two years after notification of the Directive and actually started on or before 31 December 1997.

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2.6. By way of derogation from point 2.1, for active substances consisting of micro-organisms or viruses, tests and analyses done to obtain data on the properties and/or safety with respect to other aspects than human health, may have been conducted by official or officially recognised testing facilities or organisations which satisfy at least the requirements under points 2.2 and 2.3 of the introduction of Annex III.

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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.

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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.

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,

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— dye,

— emetic,

— emulsifier,

— fertilizer,

— preservative,

— odourant,

— perfume,

— propellant,

— repellent,

— safener,

— solvent,

— stabilizer,

— synergist,

— thickener,

— wetting agent,

— miscellaneous (specify).

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.

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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).

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 °C 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 °C or 12 weeks at 35 °C or 18 weeks at 30 °C) 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.

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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.

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.

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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*

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.

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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 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.

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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 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.

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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 °C 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**

Introduction

The provisions of this section only cover analytical methods required for post-registration control and monitoring purposes.

For analytical methods used for generation of data as required in this Directive or for other purposes the applicant has to provide a justification for the method used; where necessary separate guidance will be developed for such methods on the basis of the same requirements as defined for methods for post-registration control and monitoring purposes.

Descriptions of methods must be provided and include details of equipment, materials and conditions used.

As far as practicable these methods must employ the simplest approach, involve the minimum cost, and require commonly available equipment.

For this section the following applies:

Impurities	Any component other than the pure active substance which is present in the active substance as manufactured (including non-active isomers) originating from the manufacturing process or from degradation during storage
Relevant impurities	Impurities of toxicological and/or ecotoxicological or environmental concern
Metabolites	Metabolites include products resulting from degradation or reaction of the active substance
Relevant metabolites	Metabolites of toxicological and/or ecotoxicological or environmental concern

On request the following samples must be provided:

(i) samples of the preparation;

(ii) analytical standards of the pure active substance;

(iii) samples of the active substance as manufactured;

(iv) analytical standards of relevant metabolites and all other components included in the residue definition;

(v) if available, samples of reference substances for the relevant impurities.

For definitions see Annex II, Section 4, points 4.1 and 4.2.

5.1. **Methods for the analysis of the preparation**

5.1.1. Methods, which must be described in full, must be provided for the determination of the active substance in the preparation. In the case of

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a preparation containing more than one active substance a method capable of determining each, in the presence of the other, should be provided. If a combined method is not submitted, the technical reasons must be stated. The applicability of existing Cipac methods must be reported.

5.1.2. Methods must also be provided for the determination in the preparation of relevant impurities, if the composition of the preparation is such that — on the basis of theoretical consideration — such impurities may be formed by its manufacturing process or from degradation during storage.

If required, methods for the determination of formulants or constituents of formulants in the preparation must be submitted.

5.1.3. Specificity, linearity, accuracy and repeatability

5.1.3.1. Specificity of methods submitted, must be demonstrated and reported. In addition the extent of interference by other substances present in the preparation must be determined.

While interferences due to other components may be identified as systematic errors in the assessment of the accuracy of methods proposed, an explanation must be provided for any interference occurring which contribute more than ± 3 % to the total quantity determined.

5.1.3.2. The linearity of proposed methods over an appropriate range, must be determined and reported. The calibration range must extend (by at least 20 %) the highest and lowest nominal content of the analyte in relevant analytical solutions of the preparation. Duplicate calibration determinations must be made at three or more concentrations. Alternatively, five concentrations, each as single measurements, are acceptable. Reports submitted must include the equation of the calibration line and the correlation coefficient and representative and properly labelled documentation from the analysis, e.g. chromatograms.

5.1.3.3. Accuracy will normally only be required for methods for the determination of pure active substance and relevant impurities in the preparation.

5.1.3.4. For the repeatability in principle a minimum of five determinations must be made. The relative standard deviation (% RSD) must be reported. Outliers identified through an appropriate method (e.g. Dixons or Grubbs test), may be discarded. Where outliers have been discarded, that fact must be clearly indicated. An explanation as to the reason for the occurrence of individual outliers, must be attempted.

5.2. **Analytical methods for the determination of residues**

Analytical methods for the determination of residues must be submitted unless it is justified that the methods already submitted according to the requirements of Annex II, Section 4, point 4.2 can be applied.

The same provisions as provided in Annex II, Section 4, point 4.2 apply.

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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 agricultural 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

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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 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.

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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.

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

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— 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.

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.

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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.

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.

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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.

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7. Toxicological studies

For proper evaluation of the toxicity of preparations sufficient information should be available on acute toxicity, irritation and sensitization of the active substance. If possible, additional information on mode of toxic action, toxicological profile and all other known toxicological aspects of the active substance should be submitted.

In the context of the influence that impurities and other components can have on toxicological behaviour, it is essential that for each study submitted, a detailed description (specification) of the material used, be provided. Tests must be conducted using the plant protection product to be authorized.

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

▼M4

7.1. **Acute toxicity**

The studies, data and information to be provided and evaluated, must be sufficient to permit the identification of effects following a single exposure to the plant protection product, to be assessed, and in particular to establish, or indicate:

— the toxicity of the plant protection products,

— toxicity of the plant protection product relative to the active substance,

— the time course and characteristics of the effect with full details of behavioural changes and possible gross pathological findings at post-mortem,

— where possible the mode of toxic action, and

— the relative hazard associated with the different routes of exposure.

While the emphasis must be on estimating the toxicity ranges involved, the information generated must also permit the plant protection product to be classified in accordance with Council Directive 78/631/EEC. The information generated through acute toxicity testing is of particular value in assessing hazards likely to arise in accident situations.

7.1.1. *Oral*

Circumstances in which required

An acute oral test should always be carried out unless the applicant can justify to the satisfaction of the competent authority that Article 3.2 of Council Directive 78/631/EEC can be invoked.

Test guidelines

The test must be carried out in accordance with Directive 92/69/EEC Method B1 or B1 bis.

7.1.2. *Percutaneous*

Circumstances in which required

An acute percutaneous test should always be carried out unless the applicant can justify to the satisfaction of the competent authority that Article 3.2 of Council Directive 78/631/EEC can be invoked.

Test guideline

The test must be carried out in accordance with Directive 92/69/EEC Method B3.

7.1.3. *Inhalation*

Aim of the test

The test will provide the inhalation toxicity to rats of the plant protection product or of the smoke it generates.

Circumstances in which required

The test must be carried out where the plant protection product:

— is a gas or liquified gas,

— is a smoke generating formulation or fumigant,

— is used with fogging equipment,

— is a vapour releasing preparation,

— is an aerosol,

— is a powder containing a significant proportion of particles of diameter <50 μm (> 1 % on a weight basis),

— is to be applied from aircraft in cases where inhalation exposure is relevant,

— contains an active substance with a vapour pressure $> 1 \times 10^{-2}$ Pa and is to be used in enclosed spaces such as warehouses or glasshouses,

— is to be applied in a manner which generates a significant proportion of particles or droplets of diameter <50 μm (> 1 % on a weight basis).

▼M4

Test guideline

The test must be carried out in accordance with Directive 92/69/EEC Method B2.

7.1.4. *Skin irritation*

Aim of the test

The test will provide the potential of skin irritancy of the plant protection product including the potential reversibility of the effects observed.

Circumstances in which required

The skin irritancy of the plant protection product must be determined except where it is likely, as indicated in the test guideline, that severe skin effects may be produced or that effects can be excluded.

Test guideline

The test must be carried out in accordance with Directive 92/69/EEC Method B4.

7.1.5. *Eye irritation*

Aim of the test

The test will provide the protential for eye irritation of the plant protection product, including the potential reversibility of the effects observed.

Circumstances in which required

Eye irritation tests must be conducted except where it is likely, as indicated in the test guideline, that severe effects on the eyes may be produced.

Test guideline

The eye irritation must be determined in accordance with Directive 92/69/EEC Method B5.

7.1.6. *Skin sensitization*

Aim of the test

The test will provide sufficient information to assess the potential of the plant protection product to provoke skin sensitization reactions.

Circumstances in which required

The tests must always be carried out except where the active substance (s) or co-formulants are known to have sensitizing properties.

Test guideline

The tests have to be carried out in accordance with Directive 92/69/EEC Method B6.

7.1.7. *Supplementary studies for combinations of plant protection products*

Aim of the test

In certain cases it may be necessary to carry out the studies as referred to under points 7.1.1 to 7.1.6 for a combination of plant protection products 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. Decisions as to the need for supplementary studies must be made on a case by case basis, taking into account the results of the acute toxicity studies of the individual plant protection products, the possibility for exposure to the combination of the products concerned and available information or practical experience with the products concerned or similar products.

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7.2. **Data on exposure**

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When measuring exposure to a plant protection product in the air within the breathing area of operators, bystanders or workers the requirements for measuring procedures described in Annex II A to 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] have to be taken into account.

▼M4

7.2.1. *Operator exposure*

The risks for those using plant protection products depend on the physical, chemical and toxicological properties of the plant protection product as well as the type of the product (undiluted/diluted), and on the route, the degree and duration of exposure. Sufficient information and data must be generated and reported to permit an assessment of the extent of exposure to the active substance(s) and/or toxicologically relevant compounds in the plant protection product likely to occur under the proposed conditions of use. It must also provide a basis for the selection of the appropriate protective measures including personal protective equipment to be used by operators and to be specified on the label.

7.2.1.1. *Estimation of operator exposure*

Aim of the estimation

An estimation shall be made, using where available a suitable calculation model, in order to permit an evaluation of the operator exposure likely to arise under the proposed conditions of use.

Circumstances in which required

An estimation of operator exposure must always be completed.

Estimation conditions

An estimation shall be made for each type of application method and application equipment proposed for use of the plant protection product taking account of the requirements resulting from the implementation of the classification and labelling provisions of Directive 78/631/EEC for handling the undiluted or diluted product as well as the different types and sizes of containers to be used, mixing, loading operations, application of the plant protection product, the climatic conditions and cleaning and routine maintenance of application equipment.

At first an estimation shall be made with the assumption that the operator is not using any personal protective equipment.

Where appropriate, a second estimation shall be made with the assumption that the operator is using effective and readily obtainable protective equipment which is feasible to be used by the operator. Where protective measures are specified on the label, the estimation will take these into account.

7.2.1.2. *Measurement of operator exposure*

Aim of the test

The test shall provide sufficient data to permit an evaluation of the operator exposure likely to arise under the proposed conditions of use.

Circumstances in which required

Actual exposure data for the relevant exposure route(s) must be reported where the risk assessment indicates that a health-based limit value is exceeded. This will, for example, be the case when the results of the estimation of operator exposure provided for under point 7.2.1.1 indicate that:

— the Acceptable Operator Exposure Level(s) (AOEL) established in the context of inclusion of the active substance(s) in Annex I, and/or

— the Limit Values established for the active substance and/or toxicologically relevant compound(s) of the plant protection product in accordance with Council Directive 80/1107/EEC and Council

[1] OJ No L 327, 3. 12. 1980, p. 8.

▼M4

Directive 90/394/EEC of 28 June 1990 on the protection of workers from the risks related to exposure to carcinogens at work [1],

may be exceeded.

Actual exposure data must also be reported when no appropriate calculation model or no appropriate data are available to do the estimation provided for under point 7.2.1.1.

In cases where dermal exposure is the most important exposure route, a dermal absorption test or the results of a sub-acute dermal study, if not already available, may be a useful alternative test to provide data in order to refine the estimate provided for under point 7.2.1.1.

Test conditions

The test must be done under realistic exposure conditions taking into account the proposed conditions of use.

7.2.2. *Bystander exposure*

Bystanders can be exposed during the application of plant protection products. Sufficient information and data must be reported to provide a basis for the selection of appropriate conditions of use, including the exclusion of bystanders from treatment areas and separation distances.

Aim of the estimation

An estimation shall be made, using where available a suitable calculation model in order to permit an evaluation of the bystander exposure likely to arise under the proposed conditions of use.

Circumstances in which required

An estimation of bystander exposure must always be completed.

Estimation conditions

An estimation of bystander exposure must be made for each type of application method. The estimation shall be made with the assumption that bystanders do not use any personal protective equipment.

Measurement of bystander exposure may be required when estimates indicate a cause for concern.

7.2.3. *Worker exposure*

Workers can be exposed following application of plant protection products, when entering treated fields or premises or handling treated plants or plant products on which residues remain. Sufficient information and data must be reported to provide a basis for the selection of appropriate protective measures, including waiting and re-entry periods.

7.2.3.1. Estimation of worker exposure

Aim of the estimation

An estimation shall be made using where available a suitable calculation model, in order to permit an evaluation of the worker exposure likely to arise under the proposed conditions of use.

Circumstances in which required

The estimation of worker exposure must always be completed.

Estimation conditions

An estimation of worker exposure must be made for each crop and task to be carried out.

At first the estimation shall be made using available data on the exposure to be expected with the assumption that the worker is not using any personal protective equipment.

Where appropriate, a second estimation shall be made with the assumption that the worker is using effective and readily obtainable protective equipment which is feasible to be used.

Where appropriate, a further estimation shall be made using data generated on the amount of dislodgeable residues under the proposed conditions of use.

[1] OJ No L 196, 26. 7. 1990, p. 1.

▼M4

7.2.3.2. Measurement of worker exposure

Aim of the test

The test shall provide sufficient data to permit an evaluation of the worker exposure likely to arise under the proposed conditions of use.

Circumstances in which required

Actual exposure data for the relevant exposure route(s) must be reported where the risk assessment indicates that a health-based limit value is exceeded. This will, for example, be the case where the results of the estimation of worker exposure provided for under point 7.2.3.1 indicate that:

— the AOEL(s) established in the context of inclusion of the active substance(s) in Annex I,

and/or

— the Limit Values established for the active substance and/or toxicologically relevant compound(s) of the plant protection product in accordance with Council Directives 80/1107/EEC and 90/394/EEC,

may be exceeded.

Actual exposure data must also be reported when no appropriate calculation model or no appropriate data are available to do the estimation provided for under point 7.2.3.1.

Where dermal exposure is the most important exposure route, a dermal absorption test, if not already available, may be a useful alternative test to provide data in order to refine the estimate provided for under point 7.1.3.1.

Test conditions

The test must be done under realistic exposure conditions taking into account the proposed conditions of use.

7.3. **Dermal absorption**

Aim of the test

The test shall provide a measurement of the absorption of the active substance and toxicologically relevant compounds through the skin.

Circumstances in which required

The study must be conducted when dermal exposure is a significant exposure route and where the risk assessment indicates that a health-based limit value is exceeded. This will, for example, be the case where the results of the estimation or measurement of operator exposure provided for under points 7.2.1.1 or 7.2.1.2 indicate that:

— the AOEL(s) established in the context of inclusion of the active substance(s) in Annex I,

and/or

— the limit values established for the active substance and/or toxicologically relevant compound(s) of the plant protection product in accordance with Council Directives 80/1107/EEC and 90/394/EEC may be exceeded.

Test conditions

In principle data of an *in vivo* rat skin absorption study must be reported. If, when the results of the estimation using these *in vivo* skin absorption data are incorporated in the risk assessment, there remains an indication of excessive exposure, it may be necessary to perform an *in vivo* comparative absorption study on rat and human skin.

Test guideline

Appropriate elements of OECD guideline 417 are to be used. For the design of the studies it may be necessary to take into account the results of the skin absorption studies with the active substance(s).

7.4. **Available toxicological data relating to non-active substances**

Where available, a copy of the notification and the safety data sheet submitted in the context of Directive 67/548/EEC and Commission Directive 91/155/EEC of 5 March 1991 defining and laying down the detailed arrangements for the system of specific information relating to dangerous preparations in implementation of Article 10 of Council

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Directive 88/379/EEC [1] must be submitted for each formulant. All other available information should be submitted.

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8. Residues in or on treated products, food and feed

Introduction

The provisions of Annex II, Section 6, Introduction apply.

8.1. **Metabolism, distribution and expression of residue in plants or livestock**

Aim of the tests

The objectives of these studies are:

— to provide an estimate of total terminal residues in the relevant portion of crops at harvest following treatment as proposed,

— to quantify the rate of degradation and excretion of the total residue in certain animal products (milk or eggs) and excreta,

— to identify the major components of the total terminal residue in crops and in edible animal products respectively,

— to indicate the distribution of residues between relevant crop parts and between relevant edible animal products respectively,

— to quantify the major components of the residue and to show the efficiency of extraction procedures for these components,

— to generate data from which a decision on the need for livestock feeding studies as provided for in point 8.3 can be made,

— to decide on the definition and expression of a residue.

Circumstances in which required

Supplementary metabolism studies only need to be performed where it is not possible to extrapolate from data obtained on the active substance in accordance to the requirements of Annex II, Section 6, points 6.1 and 6.2. This might be the case for crops or for livestock for which data were not submitted in the framework of inclusion of the active substance in Annex I or were not necessary for amending the conditions of its inclusion in Annex I or where it could be expected that a different metabolism will occur.

Test conditions

The same provisions as provided under the corresponding paragraphs of Annex II, Section 6, points 6.1 and 6.2 apply.

8.2. **Residue trials**

Aim of the tests

The objectives of these studies are:

— to quantify the highest likely residue levels in treated crops at harvest or outloading from store following the proposed good agricultural practice (GAP),

and

— to determine, when appropriate, the rate of decline of pesticide deposits.

Circumstances in which required

Supplementary residue trials only need to be performed where it is not possible to extrapolate from data obtained on the active substance in accordance to the requirements of Annex II, Section 6, point 6.3. This might be the case for special formulations, for special application methods or for crops for which data were not submitted in the framework of inclusion of the active substance in Annex I or were not necessary for amending the conditions of its inclusion in Annex I.

[1] OJ No L 76, 22. 3. 1991, p. 35.

▼M9

Test conditions

The same provisions as provided under the corresponding paragraphs of Annex II, Section 6, point 6.3 apply.

8.3. **Livestock feeding studies**

Aim of the tests

The objective of these studies is to determine the residue in products of animal origin which will result from residues in feedingstuffs or fodder crops.

Circumstances in which required

Supplementary feeding studies for the purpose of assessing maximum residue levels for products of animal origin are only required where it is not possible to extrapolate from data obtained on the active substance in accordance to the requirements of Annex II, Section 6, point 6.4. This might be the case where additional fodder crops are to be authorized which leads to an increased intake of residues of livestock for which data were not submitted in the framework of inclusion of the active substance in Annex I or were not necessary for amending the conditions of its inclusion in Annex I.

Test conditions

The same provisions as provided under the corresponding paragraphs of Annex II, Section 6, point 6.4 apply.

8.4. **Effects of industrial processing and/or household preparations**

Aim of the tests

The main objectives of these studies are:

— to establish whether or not breakdown or reaction products arise from residues in the raw products during processing which may require a separate risk assessment,

— to determine the quantitative distribution of residues in the various intermediate and end products, and to estimate transfer factors,

— to enable a more realistic estimate to be made of dietary intake of residues.

Circumstances in which required

Supplementary studies only need to be performed where it is not possible to extrapolate from data obtained on the active substance in accordance to the requirements of Annex II, Section 6, point 6.5. This might be the case for crops for which data were not submitted in the framework of inclusion of the active substance in Annex I or were not necessary for amending the conditions of its inclusion in Annex I.

Test conditions

The same provisions as provided under the corresponding paragraphs of Annex II, Section 6, point 6.5 apply.

8.5. **Residues in succeeding crops**

Aim of the test

The objective of these studies is to permit an evaluation of possible residues in succeeding crops.

Circumstances in which required

Supplementary studies are only required where it is not possible to extrapolate from data obtained on the active substance in accordance to the requirements of Annex II, Section 6, point 6.6. This might be the case for special formulations, for special application methods or for crops for which data were not submitted in the framework of inclusion of the active substance in Annex I or were not necessary for amending the conditions of its inclusion in Annex I.

Test conditions

The same provisions as provided under the corresponding paragraphs of Annex II, Section 6, point 6.6 apply.

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8.6. **Proposed maximum residue levels (MRLs) and residue definition**

A full justification for the proposed MRLs must be provided, including, where relevant, full details of the statistical analysis used.

If the metabolism studies submitted in accordance with the provisions of point 8.1 indicate that the residue definition should be changed taking into account the actual residue definition and the necessary judgement as outlined under the corresponding paragraph of Annex II, Section 6, point 6.7, a re-evaluation of the active substance may be necessary.

8.7. **Proposed pre-harvest intervals for envisaged uses, or withholding periods or storage periods, in the case of post-harvest uses.**

A full justification for the proposals must be provided.

8.8. **Estimation of the potential and actual exposure through diet and other means**

Consideration will be given to the calculation of a realistic prediction of dietary intake. This may be done in a step-wise fashion leading to an increasingly realistic prediction of intake. Where relevant, other sources of exposure such as residues arising from the use of medicines or veterinary drugs have to be taken into account.

8.9. **Summary and evaluation of residue behaviour**

A summary and evaluation of all data presented in this Section should be carried out according to the guidance given by the competent authorities of the Member States concerning the format of such summaries and evaluations. It should include a detailed and critical assessment of those data in the context of relevant evaluative and decision-making criteria and guidelines, with particular reference to the risks for man and animals that may or do arise, and the extent, quality and reliability of the data base.

Where metabolism data have been submitted the toxicological significance of any non-mammalian metabolites must be addressed.

A schematic diagram should be prepared of the metabolic pathway in plants and animals with a brief explanation of the distribution and chemical changes involved if metabolism data have been submitted.

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9. **Fate and behaviour in the environment**

Introduction

(i) The information provided, taken together with that for the active substance as provided for in Annex II, must be sufficient to permit an assessment of the fate and behaviour of the plant protection product in the environment, and of the non-target species likely to be at risk from exposure to it.

(ii) In particular, the information provided for the plant protection product, together with other relevant information, and that provided for the active substance, should be sufficient to:

— specify the hazard symbols, the indications of danger, and relevant risk and safety phrases for the protection of the environment, which are to be included on packaging (containers),

— predict the distribution, fate, and behaviour in the environment as well as the time courses involved,

— identify non-target species and populations for which hazards arise because of potential exposure, and

— identify measures necessary to minimize contamination of the environment and impact on non-target species.

(iii) Where radio-labelled test material is used, the provisions of Annex II, Chapter 7, introduction, point (iv) apply.

(iv) Where relevant tests should be designed and data analysed using appropriate statistical methods.

Full details of the statistical analysis should be reported (e.g. all point estimates should be given with confidence intervals, exact

▼M6

p-values should be given rather than stating significant/non significant).

(v) Predicted environmental concentrations in soil (PEC_S), water (PEC_{SW} and PEC_{GW}) and air (PEC_A).

Justified estimates must be made of the expected concentrations of the active substance and relevant metabolites, degradation and reaction products, in soil, groundwater, surface water and air, following use as proposed or already occurring. In addition a realistic worst-case estimation must be made.

For the purposes of the estimation of such concentrations the following definitions apply:

— *Predicted environmental concentration in soil (PEC_S)*

The level of residues in the top layer of the soil and to which non-target soil organisms may be exposed (acute and chronic exposure).

— *Predicted environmental concentration in surface water (PEC_{SW})*

The level of residues, in surface water to which non-target aquatic organisms may be exposed (acute and chronic exposure).

— *Predicted environmental concentration in groundwater (PEC_{GW})*

The level of residues in groundwater.

— *Predicted environmental concentration in air (PEC_A)*

The level of residues in air, to which man, animals and other non-target organisms may be exposed (acute and chronic exposure).

For the estimation of these concentrations all relevant information on the plant protection product and on the active substance must be taken into account. A useful approach for these estimations is provided in the EPPO schemes for environmental risk assessment ([1]). Where relevant the parameters provided for in this section should be used.

When models are used for estimation of predicted environmental concentrations they must:

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

— where possible 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.

The information provided must, where relevant, include that referred to in Annex II, Part A, point 7: and

9.1 **Fate and behaviour in soil**

Where appropriate, the same provisions relating to the information to be provided on the soil used and on its selection apply as provided for under Annex II, point 7.1.

9.1.1. *Rate of degradation in soil*

9.1.1.1. Laboratory studies

Aim of the test

The soil degradation studies should provide best possible estimates of the time taken for degradation of 50 and 90 % (DT_{50lab} and DT_{90lab}) of the active substance under laboratory conditions.

([1]) OEPP/EPPO (1993). Decision-making schemes for the environmental risk assessment of plant protection products. Bulletin OEPP/EPPO Bulletin 23, 1-154 and Bulletin 24, 1-87.

▼M6

Circumstances in which required

The persistence and behaviour of plant protection products in soil must be investigated unless it is possible to extrapolate from data obtained on the active substance and relevant metabolites, degradation and reaction products in accordance to the requirements of Annex II, point 7.1.1.2. This extrapolation is, for example, not possible for slow release formulations.

Test conditions

The rate of aerobic and/or anaerobic degradation in soil must be reported.

The duration of the study is normally 120 days except if more than 90 % of the active substance is degraded before that period expires.

Test guideline

SETAC — Procedures for assessing the environmental fate and ecotoxicity of pesticides.

9.1.1.2. Field studies

— Soil dissipation studies

Aim of the test

The soil dissipation studies should provide best-possible estimates of the time taken for dissipation of 50 and 90 % (DT_{50f} and DT_{90f}), of the active substance under field conditions. Where relevant, information on relevant metabolites, degradation and reaction products must be collected.

Circumstances in which required

The dissipation and behaviour of plant protection products in soil must be investigated unless it is possible to extrapolate from data obtained on the active substance and relevant metabolites, degradation and reaction products in accordance to the requirements of Annex II, point 7.1.1.2. This extrapolation is, for example, not possible for slow-release formulations.

Test conditions and test guideline

The same provisions as provided under the corresponding paragraph of Annex II, point 7.1.1.2.2. apply.

— Soil residue studies

Aim of the test

Soil residue studies should provide estimates of the soil residue levels at harvest or at time of sowing or planting succeeding crops.

Circumstances in which required

Soil residue studies must be reported unless it is possible to extrapolate from data obtained on the active substance and relevant metabolites, degradation and reaction products in accordance with the requirements of Annex II, point 7.1.1.2.2. This extrapolation is, for example, not possible for slow-release formulations.

Test conditions

The same provisions as provided under the corresponding paragraph of Annex II, point 7.1.1.2.2. apply.

Test guideline

SETAC — Procedures for assessing the environmental fate and ecotoxicity of pesticides.

— Soil accumulation studies

Aim of the tests

The tests should provide sufficient data to evaluate the possibility of accumulation of residues of the active substance and of relevant metabolites, degradation and reaction products.

Circumstances in which required

Soil accumulation studies must be reported unless it is possible to extrapolate from data obtained on the active substance and relevant metabolites, degradation and reaction products in accordance with

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the requirements of Annex II, point 7.1.1.2.2. This extrapolation is, for example, not possible for slow-release formulations.

Test conditions

The same provisions as provided under the corresponding paragraph of Annex II, point 7.1.1.2.2. apply.

Test guideline

SETAC — Procedures for assessing the environmental fate and ecotoxicity of pesticides.

9.1.2. *Mobility in the soil*

Aim of the test

The test should provide sufficient data to evaluate the mobility and leaching potential of the active substance and relevant metabolites, degradation and reaction products.

9.1.2.1. Laboratory studies

Circumstances in which required

The mobility of plant protection products in soil must be investigated unless it is possible to extrapolate from data obtained in accordance with the requirements of Annex II, points 7.1.2 and 7.1.3.1. This extrapolation is, for example, not possible for slow-release formulations.

Test guideline

SETAC — Procedures for assessing the environmental fate and ecotoxicity of pesticides.

9.1.2.2. Lysimeter studies or field leaching studies

Aim of the tests

The test should provide data on:

— the mobility of the plant protection product in soil,

— the potential for leaching to ground water,

— the potential distribution in soils.

Circumstances in which required

Expert judgement will be necessary to decide whether field leaching studies or lysimeter studies should be carried out, taking into account the results of degradation and mobility studies and the calculated PEC_s. The type of study to be conducted should be discussed with the competent authorities.

These studies must be performed unless it is possible to extrapolate from data obtained on the active substance and relevant metabolites, degradation and reaction products in accordance with the requirements of Annex II, point 7.1.3. This extrapolation is, for example, not possible for slow release formulations.

Test conditions

The same provisions as provided for under the corresponding paragraph of Annex II, point 7.1.3.3 apply.

9.1.3. *Estimation of expected concentrations in soil*

PEC_s estimations must relate both to a single application at the highest rate of application for which authorization is sought, and to the maximum number and highest rates of application for which authorization is sought, for each relevant soil tested, and are expressed in terms of mg of active substance and of relevant metabolites, degradation and reaction products per kg of soil.

The factors to be considered in making PEC_s estimations relate to direct and indirect application to soil, drift, run off, and leaching and include processes such as volatilization, adsorption, hydrolysis, photolysis, aerobic and anaerobic degradation. For the purposes of PEC_s calculations, the bulk density of soils can be assumed to be 1,5 g/cm^3 dry weight, while the depth of the soil layer is assumed to be 5 cm for applications at the soil surface and 20 cm when incorporation in the soil is involved. Where ground cover is present at time of application, it is to be assumed that 50 % (minimum) of the applied dose reaches

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the soil surface unless actual experimental data give more specific information.

Initial, short-term and long-term PEC_s calculations (time weighted averages) must be provided:

— initial: immediately after application,

— short-term: 24 hours, 2 days and 4 days after last application,

— long-term: 7, 28, 50 and 100 days after last application, where relevant.

9.2. **Fate and behaviour in water**

9.2.1. *Estimation of concentrations in groundwater*

The groundwater contamination routes have to be defined taking into account relevant agricultural, plant health, and environmental (including climatic) conditions.

Suitable estimations (calculations) of predicted environmental concentration in groundwater PEC_{GW}, of active substance and relevant metabolites, degradation and reaction products, must be submitted.

PEC estimations must relate to the maximum number and highest rates of application, for which authorization is sought.

Expert judgment is required to decide if additional field tests could provide useful information. Before performing these studies the applicant shall seek the agreement of the competent authorities on the type of study to be performed.

9.2.2. *Impact on water treatment procedures*

In cases where this information is necessary in the framework of a conditional authorization as meant in Annex VI, Part C, point 2.5.1.2 (b), the information provided should permit to establish or to estimate effectiveness of water treatment procedures (drinking water and sewage treatment), and impact on such procedures. Before performing any studies the applicant shall seek the agreement of the competent authorities on the type of information to be provided.

9.2.3. *Estimation of concentrations in surface water*

The surface water contamination routes have to be defined taking into account relevant agricultural, plant health, and environmental (including climatic) conditions.

Suitable estimations (calculations) of predicted environmental concentration in surface water PEC_{sw}, of active substance and relevant metabolites, degradation and reaction products, must be submitted.

PEC estimations must relate to the maximum number and highest rates of application, for which authorization is sought, and be relevant to lakes, ponds, rivers, canals, streams, irrigation/drainage canals and drains.

The factors to be considered in making PEC_{sw} estimations relate to direct application to water, drift, run-off, discharge via drains and atmospheric deposition, and include processes such as volatilization, adsorption, advection, hydrolysis, photolysis, biodegradation, sedimentation and re-suspension.

Initial, short-term and long-term PEC_{sw} calculations relevant to static and slow moving water bodies (time weighted averages) must be provided:

— initial: immediately after application,

— short-term: 24 hours, 2 days and 4 days after last application,

— long-term: 7, 14, 21, 28, and 42 days after last application, where relevant.

Expert judgment is required to decide if additional field tests could provide useful information. Before performing these studies the applicant shall seek the agreement of the competent authorities on the type of study to be performed.

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9.3. **Fate and behaviour in air**

Guidance under development.

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10. **Ecotoxicological studies**

Introduction

(i) The information provided, taken together with that for the active substance(s), must be sufficient to permit an assessment of the impact on non-target species (flora and fauna), of the plant protection product, when used as proposed. Impact can result from single, prolonged or repeated exposure, and can be reversible, or irreversible.

(ii) In particular, the information provided for the plant protection product, together with other relevant information, and that provided for the active substance, should be sufficient to:

— specify the hazard symbols, the indications of danger, and relevant risk and safety phrases for the protection of the environment, to be mentioned on packaging (containers),

— permit an evaluation of the short- and long-term risks for non-target species — populations, communities, and processes as appropriate,

— permit an evaluation of whether special precautions are necessary for the protection of non-target species.

(iii) There is a need to report all potentially adverse effects found during routine ecotoxicological investigations and to undertake and report such additional studies which may be necessary to investigate the mechanisms involved and assess the significance of these effects.

(iv) In general, much of the data relating to impact on non-target species, required for authorization of plant protection products, will have been submitted and evaluated for the inclusion of the active substance(s) in Annex I. The information on fate and behaviour in the environment, generated and submitted in accordance with points 9.1 to 9.3, and on residue levels in plants generated and submitted in accordance with point 8 is central to the assessment of impact on non-target species, in that it provides information on the nature and extent of potential or actual exposure. The final PEC estimations are to be adapted according to the different groups of organisms taking in particular into consideration the biology of the most sensitive species.

The toxicological studies and information submitted in accordance with point 7.1 provide essential information as to toxicity to vertebrate species.

(v) Where relevant, tests should be designed and data analysed using appropriate statistical methods. Full details of the statistical analysis should be reported (e.g. all point estimates should be given with confidence intervals, exact p-values should be given rather than stating significant/non significant).

(vi) Whenever a study implies the use of different doses, the relationship between dose and adverse effect must be reported.

(vii) Where exposure data are necessary to decide whether a study has to be performed, the data obtained in accordance with the provisions of Annex III, point 9 should be used.

For the estimation of exposure of organisms all relevant information on the plant protection product and on the active substance must be taken into account. A useful approach for these estimations is provided in the EPPO/Council of Europe schemes for environmental risk assessment ([1]). Where relevant the parameters provided for in this section should be used. Where it appears from available data that the plant protection product is more toxic as the active substance, the toxicity data

([1]) OEPP/EPPO (1993). Decision-making schemes for the environmental risk assessment of plant protection products. *Bulletin OEPP/EPPO Bulletin 23,* 1-154 and *Bulletin 24,* 1-87.

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of the plant protection product have to be used for the calculation of relevant toxicity/exposure ratios.

(viii) In the context of the influence that impurities can have on ecotoxicological behaviour, it is essential that for each study submitted, a detailed description (specification) of the material used as provided for under point 1.4, be provided.

(ix) In order to facilitate the assessment of the significance of test results obtained the same strain of each relevant species should where possible be used in the various toxicity tests specified.

10.1. **Effects on birds**

Possible effects on birds must be investigated except where the possibility that birds will be exposed, directly or indirectly, can be ruled out such as for use in enclosed spaces or wound healing treatments.

The acute toxicity/exposure ratio (TER_a), the short term dietary toxicity/exposure ratio (TER_{st}) and the long term dietary toxicity/exposure ratio (TER_{lt}) must be reported, where:

TER_a = LD_{50} (mg a.s./kg body weight) / ETE (mg a.s./kg body weight)

TER_{st} = LC_{50} (mg a.s./kg food) / ETE (mg a.s./kg food)

TER_{lt} = NOEC (mg a.s./kg food) / ETE (mg a.s./kg food)

where ETE = estimated theoretical exposure.

In the case of pellets, granules or treated seeds the amount of a.s. in each pellet, granule or seed must be reported as well as the proportion of the LD_{50} for the a.s. in 100 particles and per gram of particles. The size and shape of pellets or granules must be reported.

In the case of baits the concentration of a.s. in the bait (mg/kg) must be reported.

10.1.1. Acute oral toxicity

Aim of the test

The test should provide, where possible, LD_{50} values, the lethal threshold dose, time courses of response and recovery, the NOEL, and must include relevant gross pathological findings.

Circumstances in which required

The acute oral toxicity of preparations must be reported, where TER_a or TER_{st} for the active substance(s) in birds are between 10 and 100 or where results from mammal testing give evidence of a significantly higher toxicity of the prepration compared to the active substance unless it can be justified that it is not likely that birds are exposed to the plant protection product itself.

Test conditions

The study must be conducted on the most sensitive species identified in the studies provided for in Annex II, point 8.1.1 or 8.1.2.

10.1.2. Supervised cage or field trials

Aim of the test

The test will provide sufficient data to evaluate the nature and the extent of the risk in practical conditions of use.

Circumstances in which required

Where the TER_a and TER_{st} are > 100 and when there is no evidence of risk from any further study on the active substance (e.g. reproduction study) no further testing is required. In the other cases, expert judgement is necessary to decide whether there is a need to carry out further studies. This expert judgement will take into account, where relevant, foraging behaviour, repellency, alternative food, actual residue content in the food, persistence of the compound in the vegetation, degradation of the formulated product or treated produce, the amount of predation of the food, acceptance of bait, granules or treated seed and the possibility for bioconcentration.

Where TER_a and $TER_{st} \leq 10$ or $TER_{lt} \leq 5$, cage or field trials must be conducted and reported unless a final assessment is possible on the basis of studies according to point 10.1.3.

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Test conditions

Before performing these studies the applicant should seek the agreement of the competent authorities on the type and conditions of the study to be performed.

10.1.3. Acceptance of bait, granules or treated seeds by birds

Aim of the test

The test will provide sufficient data to evaluate the possibility of consumption of the protection product or plant products treated with it.

Circumstances in which required

In the case of seed dressings, pellets, baits and preparations which are granules and where $TER_a \leq 10$, acceptability (palatability) tests must be conducted.

10.1.4. Effects of secondary poisoning

Expert judgment is required to decide whether the effects of secondary poisoning should be investigated.

10.2. **Effects on aquatic organisms**

Possible effects on aquatic species must be investigated except where the possibility that aquatic species will be exposed can be ruled out.

TER_a and TER_{lt} must be reported, where:

TER_a = acute LC_{50} (mg a.s./l)/realistic worst case PEC_{sw} (initial or short-term, in mg a.s./l)

TER_{lt} = chronic NOEC (mg a.s./l)/long term PEC_{sw} (mg a.s./l)

10.2.1. Acute toxicity to fish, aquatic invertebrates or effects on algal growth

Circumstances in which required

In principle tests should be carried out on one species from each of the three groups of aquatic organisms as referred to in Annex II, point 8.2 (fish, aquatic invertebrates and algae) in case the plant protection product itself can contaminate water. However where the available information permits to conclude that one of these groups is clearly more sensitive, tests on only the most sensitive species of the relevant group have to be performed.

The test must be performed where:

— the acute toxicity of the plant protection product can not be predicted on the basis of the data for the active substance which is especially the case if the formulation contains two or more active substances or formulants such as solvents, emulgators, surfactants, dispersants, fertilizers which are able to increase the toxicity in comparison with the active substance, or

— the intended use includes direct application on water

unless suitable studies referred to under point 10.2.4 are available.

Test conditions and test guidelines

The relevant provisions as under the corresponding paragraphs of Annex II, points 8.2.1, 8.2.4 and 8.2.6 apply.

10.2.2. Microcosm or mesocom study

Aim of the test

The tests must provide sufficient data to evaluate the essential impact on aquatic organisms under field conditions.

Circumstances in which required

Where $TER_a \leq 100$ or where $TER_{lt} \leq 10$, expert judgment must be used to decide whether a microcosm or mesocom study is appropriate. This judgment will take into account the results of any additional data over and above those required by the provisions of Annex II, point 8.2 and of point 10.2.1.

Test conditions

Before performing these studies the applicant shall seek the agreement of the competent authorities on the specific aims of the study to be

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performed and consequently on the type and conditions of the study to be performed.

The study should include at least the highest likely exposure rate, whether from direct applicaiton, drift, drainage or run-off. The duration of the study must be sufficient to permit evaluation of all effects.

Test guideline

Appropriate guidelines are included in:

Setac — Guidance document on testing procedures for pesticides in freshwater mesocosms/Workshop Huntingdon, 3 and 4 July 1991

or

Freshwater field tests for hazard assessment of chemicals — European Workshop on Freshwater Field Tests (EWOFFT).

10.2.3. Residue data in fish

Aim of the test

The test will provide sufficient data to evaluate the potential for occurrence of residues in fish.

Circumstances in which required

In general data are available from bioconcentration studies in fish.

Where bioconcentration has been observed in the study performed in accordance with Annex II, point 8.2.3 expert judgement is required to decide whether a long-term microcosm or mesocosm study has to be carried out in order to establish the maximum residues likely to be encountered.

Test guideline

Setac — Guidance document on testing procedures for pesticides in freshwater mesocosms/Workshop Huntingdon, 3 and 4 July 1991.

10.2.4. Additional studies

The studies referred to in Annex II, points 8.2.2 and 8.2.5 may be required for particular plant protection products where it is not possible to extrapolate from data obtained in the corresponding studies on the active substance.

10.3. **Effects on terrestrial vertebrates other than birds**

Possible effects on wild vertebrate species must be investigated except where it can be justified that it is not likely that terrestrial vertebrates other than birds are exposed, directly or indirectly. TER_a, TER_{st} and TER_{lt} must be reported, where:

TER_a = LD_{50} (mg a.s./kg body weight) / ETE (mg a.s./kg body weight)

TER_{st} = subchronic NOEL (mg a.s./kg food) / ETE (mg a.s./kg food)

TER_{lt} = chronic NOEL (mg a.s./kg food) / ETE (mg a.s./kg food)

where ETE = estimated theoretical exposure.

In principle the evaluation sequence for the assessment of risks to such species is similar to that for birds. In practice it is not often necessary to perform further testing as the studies conducted in accordance with the requirements of Annex II, point 5 and Annex III, point 7 would provide the required information.

Aim of the test

The test will provide sufficient information to evaluate the nature and the extent of risks for terrestrial vertebrates other than birds in practical conditions of use.

Circumstances in which required

Where TER_a and $TER_{st} > 100$ and where there is no evidence of risk from any further study no further testing is required. In the other cases, expert judgment is necessary to decide whether there is a need to carry out further studies. This expert judgment will take into account, where relevant, foraging behaviour, repellency, alternative

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food, actual residue content in the food, persistence of the compound in the vegetation, degradation of the formulated product or treated produce, the amount of predation of the food, acceptance of bait, granules or treated seed and the possibility for bioconcentration.

Where TER_a and $TER_{st} \leq 10$ or $TER_{lt} \leq 5$ cage or field trials or other appropriate studies must be reported.

Test conditions

Before performing these studies the applicant shall seek the agreement of the competent authorities on the type and conditions of the study to be performed and whether the effects of secondary poisoning should be investigated.

10.4. **Effects on bees**

The possible effects on bees must be investigated except where the product is for exclusive use in situations where bees are not likely to be exposed such as:

— food storage in enclosed spaces,

— non-systemic seed dressings,

— non-systemic preparations for application to soil,

— non-systemic dipping treatments for transplanted crops and bulbs,

— wound sealing and healing treatments,

— rodenticidal baits,

— use in glasshouses without pollinators.

The hazard quotients for oral and contact exposure (Q_{HO} and Q_{HC}), must be reported:

Q_{HO} = dose/oral LD_{50} (µg a.s. per bee)

Q_{HC} = dose/contact LD_{50} (µg a.s. per bee)

where

dose = the maximum application rate, for which authorization is sought, in g of active substance per hectare.

10.4.1. Acute oral and contact toxicity

Aim of the test

The test should provide the LD_{50} values (by oral and contact exposure).

Circumstances in which required

Testing is required if:

— the product contains more than one active substance;

— the toxicity of a new formulation cannot be reliably predicted to be either the same or lower than a formulation tested according to the provisions of Annex II, point 8.3.1.1 or of this point.

Test guideline

The test must be carried out according to EPPO Guideline 170.

10.4.2. Residue test

Aim of the test

The test should provide sufficient information to evaluate possible risks to foraging bees from residual traces of plant protection products remaining on crops.

Circumstances in which required

Where $Q_{HC} \geq 50$, expert judgment is required to decide whether the effect of residues must be determined unless there is evidence that there are no significant residual traces remaining on crops which could affect foraging bees or unless sufficient information is available from cage, tunnel or field tests.

Test conditions

The median lethal time (LT_{50}) (in hours) following 24-hour exposure to residues on leaves aged during eight hours must be determined, and

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reported. Where LT_{50} is more than eight hours, no further testing is required.

10.4.3. Cage tests

Aim of the test

The test should provide sufficient information to evaluate possible risks from the plant protection product for bee survival and behaviour.

Circumstances in which required

Where Q_{HO} and Q_{HC} are < 50, further testing is not required except if significant effects are observed in the bee brood feeding test or if there are indications for indirect effects such as delayed action or modification of bee behaviour, in those cases cage and/or field tests shall be carried out.

Where Q_{HO} and Q_{HC} are > 50, cage and/or field testing is required.

Where field testing is conducted and reported in accordance with point 10.4.4, it is not necessary to conduct cage tests. However, cage tests where conducted, must be reported.

Test conditions

The test should be carried out using healthy bees. If bees have been treated, e.g. with a varroacide, it is necessary to wait for four weeks before using the colony.

Test guideline

The tests must be conducted in accordance with EPPO Guideline 170.

10.4.4. Field tests

Aim of the test

The test should provide sufficient information to evaluate possible risks from the plant protection product on bee behaviour, colony survival and development.

Circumstances in which required

Field tests must be conducted where on the basis of expert judgement, taking into account the proposed manner of use and the fate and behaviour of the active substance, significant effects are observed in cage testing.

Test conditions

The test should be carried out using healthy honeybee colonies of similar natural strength. If bees have been treated, e.g. with a varroacide, it is necessary to wait for four weeks before using the colony. The tests shall be conducted under conditions reasonably representative of the proposed use.

Special effects (larval toxicity, long residual effect, disorienting effects on bees) identified by the field tests may require further investigation using specific methods.

Test guideline

The tests must be conducted in accordance with EPPO Guideline 170.

10.4.5. Tunnel tests

Aim of the test

The test should provide sufficient information to evaluate the impact on bees resulting from feeding on contaminated honey dew or flowers.

Circumstances in which required

Where it is not possible to investigate certain effects in cage or field trials, a tunnel test should be carried out, e.g. in the case of plant protection products intended for control of aphids and other sucking insects.

Test conditions

The test should be carried out using healthy bees. If bees have been treated, e.g. with a varroacide, it is necessary to wait for four weeks before using the colony.

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Test guideline

The test must be carried out in accordance with EPPO Guideline 170.

10.5. **Effects on arthropods other than bees**

The effects of plant protection products on non-target terrestrial arthropods (e.g. predators or parasitoids of harmful organisms) must be investigated. The information obtained for these species can also be used to indicate the potential for toxicity to non-target species inhabiting the same environment.

10.5.1. Laboratory, extended laboratory and semi-field tests

Aim of the test

The test should provide sufficient information to evaluate the toxicity of the plant protection product for selected arthropod species that are relevant to the intended use of the product.

Circumstances in which required

Testing is not required where severe toxicity (> 99 % effect on the organisms compared to control) can be predicted from relevant available data or where the plant protection product is for exclusive use in situations where non-target arthropods are not exposed such as:

— food storage in enclosed spaces,

— wound sealing and healing treatments,

— rodenticidal baits.

Testing is required when significant effects on the organisms in comparison with the control are reported in the laboratory tests at the maximum recommended dose, conducted in accordance with the requirements of Annex II, point 8.3.2. Effects on a particular test species are considered to be significant when they exceed the threshold values as defined in the EPPO schemes for the environmental risk assessment unless species-specific threshold values are defined in the respective test guidelines.

Testing is also required if:

— the product contains more than one active substance,

— the toxicity of a new formulation cannot be reliably predicted to be either the same or lower than a formulation tested according to the provisions of Annex II, point 8.3.2 or of this point,

— on the basis of the proposed manner of use or on the basis of the fate and behaviour continued or repeated exposure can be anticipated,

— there is a significant change in the proposed use, e.g. from arable crops to orchards, and species relevant to the new use have not previously been tested,

— there is an increase in the recommended application rate, above that previously tested under Annex II.

Test conditions

Where significant effects were observed in the studies performed in accordance with the requirements of Annex II, point 8.3.2, or in the case of change of use such as arable crops to orchards, the toxicity of two additional relevant species must be investigated and reported. These must be different to the relevant species already tested under Annex II, point 8.3.2.

For a new mixture or formulation, the toxicity should initially be assessed using the two most sensitive species as identified in studies already performed for which the threshold values were exceeded but effects still remain below 99 %. This will enable a comparison to be made; if it significantly more toxic two species relevant to its proposed use must be tested.

Testing must be conducted at a rate equivalent to the maximum rate of application for which authorization is sought. A sequential testing approach should be adopted, i.e. laboratory, and if necessary extended laboratory and/or semi-field.

Where there will be more than one application per season, the product should be applied at twice the recommended application rate unless this

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information is already available from studies performed in accordance with Annex II, point 8.3.2.

Where on the basis of the proposed manner of use or on the basis of the fate and behaviour continued or repeated exposure can be anticipated (such as the product is to be applied more than three times per season with a re-application of 14 days or less), expert judgment is required to examine whether further testing is required, beyond initial laboratory testing, which will reflect the proposed use pattern. These tests may be performed in the laboratory or under semi-field conditions. When the test is done in the laboratory a realistic substrate such as plant material or a natural soil should be used. However it may be more appropriate to carry out field tests.

Test guideline

Where relevant testing should be done according to appropriate guidelines which satisfy as least the requirements for testing as included in Setac - Guidance document on regulatory testing procedures for pesticides with non-target arthropods.

10.5.2. Field tests

Aim of the test

The tests should provide sufficient information to evaluate the risk of the plant protection product for arthropods under field conditions.

Circumstances in which required

Where significant effects are seen following laboratory and semi-field exposure, or where on the basis of the proposed manner of use or on the basis of the fate and behaviour continued or repeated exposure can be anticipated expert judgment is required to examine whether more extensive testing is necessary to permit an accurate risk assessment.

Test conditions

The tests must be conducted under representative agricultural conditions and in accordance with the proposed recommendations for use, resulting in a realistic worst case study.

A toxic standard should be included in all tests.

Test guideline

Where relevant testing should be done according to appropriate guidelines which satisfy at least the requirements for testing as included in Setac — Guidance document on regulatory testing procedures for pesticides with non-target arthropods.

10.6. **Effects on earthworms and other soil non-target macro-organisms, believed to be at risk**

10.6.1. Effects on earthworms

The possible impact on earthworms must be reported except where it can be justified that it is not likely that earthworms are exposed, directly or indirectly.

TER_a and TER_{lt} must be reported where:

TER_a = LC_{50} (mg a.s./kg)/realistic worst case PEC_s (initial or short-term, in mg a.s./kg)

TER_{lt} = NOEC (mg a.s./kg)/long term PECs (mg a.s./kg).

10.6.1.1. Acute toxicity tests

Aim of the test

The test should provide the LC_{50}, where possible the highest concentration causing no mortality and the lowest concentration causing 100 % mortality and must include observed morphological and behavioural effects.

Circumstances in which required

These studies are only required where

— the product contains more than one active substance,

— the toxicity of a new formulation cannot be reliably predicted from the formulation tested according to the provisions of Annex II, point 8.4 or of this point.

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Test guideline

The tests must be conducted in accordance to OECD Method 207.

10.6.1.2. Tests for sublethal effects

Aim of the test

The test should provide the NOEC and the effects on growth, reproduction and behaviour.

Circumstances in which required

These studies are only required where

— the product contains more than one active substance,

— the toxicity of a new formulation cannot be reliably predicted from the formulation tested according to the provisions of Annex II, point 8.4 or of this point,

— there is an increase in the recommended application rate, above that previously tested.

Test conditions

The same provisions as under the corresponding paragraphs of Annex II, point 8.4.2 apply.

10.6.1.3. Field studies

Aim of the test

The test should provide sufficient data to evaluate the effects on earthworms in field conditions.

Circumstances in which required

Where $TER_{lt} < 5$ a field study to determine effects under practical field conditions must be conducted and reported.

Expert judgment is required to decide whether residue contents of earthworms should be investigated.

Test conditions

Fields selected shall have a reasonable earthworm population.

The test must be carried out at the maximum proposed application rate. A toxic reference product must be included in the test.

10.6.2. Effects on other soil non-target macro-organisms

Aim of the test

The test should provide sufficient data to evaluate the impact of the plant protection product on macro-organisms that contribute to the breakdown of dead plant and animal organic matter.

Circumstances in which required

Testing is not required where in accordance with Annex III, point 9.1, it is evident that DT_{90} values are less than 100 days, or the nature and manner of use of the plant protection product are such that exposure does not occur or when data from studies on the active substance performed in accordance with the provisions of Annex II, points 8.3.2, 8.4 and 8.5 indicate that there is no risk for soil macrofauna, earthworms or soil microflora.

Impact on organic matter breakdown must be investigated and reported, where the DT_{90f} values determined in field dissipation studies (point 9.1) are > 365 days.

10.7. **Effects on soil non-target micro-organisms**

10.7.1. Laboratory testing

Aim of the test

The test should provide sufficient data to evaluate the impact of the plant protection product on soil microbial activity in terms of nitrogen transformation and carbon mineralization.

Circumstances in which required

Where the DT_{90f} values determined in field dissipation studies (point 9.1) are > 100 days, impact on soil non-target micro-organisms must

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be investigated through laboratory testing. Testing is, however, not required if in the studies performed in accordance with the provisions of Annex II, point 8.5 deviations from control values in terms of metabolic activity of the microbial biomass after 100 days is < 25 %, and such data are relevant to the uses, nature, and properties of the particular preparation to be authorized.

Test guideline

Setac — Procedures for assessing the environmental fate and ecotoxicity of pesticides.

10.7.2. Additional testing

Aim of the test

The test should provide sufficient data to evaluate the impact of the plant protection product under field conditions on microbial activitiy.

Circumstances in which required

Where at the end of 100 days, measured activity deviates by more than 25 % from the control, in the laboratory testing further testing in the laboratory, under glass and/or in the field may be necessary.

10.8. **Available data from biological primary screening in summary form**

A summary of available data from preliminary tests used to assess the biological activity and dose range finding whether positive or negative, which provides information with respect to possible impact on non/target species, both flora and fauna, must be provided, together with a critical assessment as to its relevance to potential impact on non-target species.

11. *Summary and evaluation of points 9 and 10*

A summary and evaluation of all data presented in points 9 and 10 should be carried out according to the guidance given by the competent authorities of the Member States concerning the format of such summaries and evaluations. It should include a detailed and critical assessment of those data in the context of relevant evaluative and decision making criteria and guidelines, with particular reference to the risks for the environment and non-target species that may or do arise, and the extent, quality and reliability of the data base. In particular the following issues should be addressed:

— predicting distribution and fate in the environment, and the time courses involved,

— identifying non-target species and populations at risk, and predicting the extent of potential exposure,

— evaluation as to the short- and long-term risks for non-target species — populations, communities, and processes — as appropriate,

— evaluation as to the risk of fish kills, and fatalities in large vertebrates, or terrestrial predators, regardless of effects at population or community level, and

— identification of precautions necessary to avoid or minimize contamination of the environment, and for the protection of non-target species.

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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

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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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PART B

Introduction

(i) This Part provides data requirements for the authorisation of a plant protection product based on preparations of micro-organisms including viruses.

The term 'micro-organism' as defined in the introduction of Annex II, Part B, also applies to Annex III, Part B.

(ii) Where relevant, data should be analysed using appropriate statistical methods. Full details of the statistical analysis should be reported (e.g. all point estimates should be given with confidence intervals, exact p-values should be given rather than stating significant/non significant).

(iii) Pending the acceptance of specific guidelines at international level, the information required shall be generated using test guidelines accepted by the competent authority (e.g. USEPA guideline [1]); where appropriate test guidelines as described in Annex II, Part A, should be adapted in such a way that they are appropriate for micro-organisms. Testing should include viable and, if appropriate, non-viable micro-organisms, and a blank control.

(iv) Whenever a study implies the use of different doses, the relationship between dose and adverse effect must be reported.

(v) Where testing is done, a detailed description (specification) of the material used and its impurities, according to the provisions of section 1, point 1.4, must be provided.

(vi) In cases where a new preparation is to be dealt with, extrapolation from Annex II, Part B, could be acceptable, provided that all the possible effects of the formulants and other components, especially on pathogenicity and infectiveness, are also evaluated.

1. IDENTITY OF THE PLANT PROTECTION PRODUCT

The information provided, taken together with that provided for the micro-organism(s), must be sufficient to precisely identify and define preparations. The information and data referred to, unless otherwise specified, are required for all plant protection products. This is with the view to identify if any factor could alter the properties of the micro-organism as a plant protection product in comparison to the micro-organism as such, which is treated in Annex II, Part B, to Directive 91/414/EEC.

1.1. **Applicant**

The name and address of the applicant (permanent community address) must be provided as must the name, position, telephone and fax 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 authorisation is being sought, the name and address of the local office, agent or representative should be provided, as should the name, position, telephone and fax number of the appropriate person to contact.

1.2. **Manufacturer of the preparation and the micro-organism(s)**

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

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

If the micro-organism originates from a producer from which data according to Annex II, Part B, had not been submitted previously, detailed information on the name and species description, as required in

[1] *USEPA Microbial Pesticide Test Guidelines, OPPTS Series 885, February 1996*(http://www.epa.gov/oppbppd1/biopesticides/guidelines/series885.htm).

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Annex II, Part B, section 1.3, and on impurities, as required in Annex II, Part B, section 1.4, 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 referred to in the dossier as well as the current names and numbers must be provided. Full detail of any differences must be provided. (The proposed trade name must not give rise to confusion with the trade name of already authorised plant protection products.)

1.4. **Detailed quantitative and qualitative information on the composition of the preparation**

(i) Each micro-organism that is subject to the application should be identified and named at the species level. The micro-organism should be deposited at a recognised culture collection and given an accession number. The scientific name must be stated, as well as the group assignment (bacteria, virus, etc.) and any other denomination relevant to the micro-organism (e.g. strain, serotype). In addition, the development phase of the micro-organism (e.g. spores, mycelium) in the marketed product shall be stated.

(ii) For preparations the following information must be reported:

— the content of the micro-organism(s) in the plant protection product and the content of the micro-organism in the material used for manufacturing of plant protection products. These must include the maximum, minimum and nominal content of the viable and non-viable material,

— the content of formulants,

— the content of other components (such as by-products, condensates, culture medium, etc.) and contaminating micro-organisms, derived from production process.

The contents should be expressed in terms as provided for in Article 6(2) of Directive 78/631/EEC for chemicals and appropriate terms for micro-organisms (number of active units per volume or weight or any other manner that is relevant to the micro-organism).

(iii) Formulants must where possible, be identified either 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 EC (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.

(iv) For formulants the function must be given:

— adhesive (sticker)

— antifoaming agent

— antifreeze

— binder

— buffer

— carrier

— deodorant

— dispersing agent

— dye

— emetic

— emulsifier

— fertiliser

— odorant

— parfume

— preservative

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— propellant

— repellent

— safener

— solvent

— stabiliser

— synergist

— thickener

— wetting agent

— miscellaneous (specify).

(v) Identification of contaminating micro-organisms and other components derived from production process.

Contaminating micro-organisms must be identified as outlined in Annex II, Part B, section 1, point 1.3.

Chemicals (inert components, by-products, etc.) must be identified as outlined in Annex II, Part A, section 1, point 1.10.

Where the information provided does not fully identify a component, such as condensate, culture medium, etc., detailed information on the composition must be provided for each such component.

1.5. **Physical state and nature of the preparation**

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**

The biological function must be specified from among the following:

— control of bacteria,

— control of fungi,

— control of insects,

— control of mites,

— control of molluscs,

— control of nematodes,

— control of weeds,

— other (must be specified).

2. PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF THE PLANT PROTECTION PRODUCT

The extent to which plant protection products for which authorisation is sought comply with relevant FAO specifications, as agreed by the Group of Experts on Pesticide Specification 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. **Storage stability and shelf-life**

2.2.1. *Effects of light, temperature and humidity on technical characteristics of the plant protection product*

(i) The physical and biological stability of the preparation at the recommended storage temperature including information on the

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growth of contaminating micro-organisms must be determined and reported. The conditions under which the test has been performed must be justified.

(ii) Additionally in the case of liquid preparations, the effect of low temperatures on physical stability, must be determined and reported according to CIPAC ([1]) Methods MT 39, MT 48, MT 51 or MT 54 as appropriate.

(iii) The shelf life of the preparation at the recommended storage 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 ([2]) Monograph No 17.

2.2.2. *Other factors affecting stability*

Effect of exposure to air, packaging, etc., on the product stability must be explored.

2.3. **Explosivity and oxidising properties**

Explosivity and oxidising properties will be determined as defined in Annex III, Part A, section 2, point 2.2, unless it can be justified that it is technically or scientifically not necessary to perform such studies.

2.4. **Flash point and other indications of flammability or spontaneous ignition**

Flash point and flammability must be determined, as defined in Annex III, Part A, section 2, point 2.3, unless it can be justified that it is technically or scientifically not necessary to perform such studies.

2.5. **Acidity, alkalinity and if necessary pH value**

Acidity, alkalinity and pH will be determined as defined in Annex III, Part A, section 2, point 2.4, unless it can be justified that it is technically or scientifically not necessary to perform such studies.

2.6. **Viscosity and surface tension**

Viscosity and surface tension will be determined as defined in Annex III, Part A, section 2, point 2.5, unless it can be justified that it is technically or scientifically not necessary to perform such studies.

2.7. **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. If tests have to be performed, they must be done at temperatures compatible with survival of the micro-organism.

2.7.1. *Wettability*

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

2.7.2. *Persistent foaming*

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

2.7.3. *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.

([1]) Collaborative International Pesticides Analytical Council.
([2]) International Group of National Pesticide Manufacturers' Associations.

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2.7.4. *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.

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

(i) 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.

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

(iii) 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.

2.7.6. *Emulsifiability, re-emulsifiability, emulsion stability*

(i) The emulsifiability, emulsion stability and re-emulsifiability of preparations which form emulsions, must be determined and reported according to CIPAC Method MT 36 or MT 173 as appropriate.

(ii) 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.

2.7.7. *Flowability, pourability (rinsability) and dustability*

(i) The flowability of granular preparations must be determined and reported according to CIPAC Method MT 172.

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

(iii) The dustability of dustable powders must be determined and reported according to CIPAC Method MT 34 or another suitable method.

2.8. **Physical, chemical and biological compatibility with other products including plant protection products with which its use is to be authorised**

2.8.1. *Physical compatibility*

The physical compatibility of recommended tank mixes must be determined and reported.

2.8.2. *Chemical compatibility*

The chemical compatibility of recommended 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.

2.8.3. *Biological compatibility*

The biological compatibility of tank mixes must be determined and reported. Effects (e.g. antagonism, fungicidal effects) on the activity of the micro-organism after mixing with other micro-organisms or chemicals must be described. The possible interaction of the plant protection product with other chemical products to be applied on the crops under the expected condition of use of the preparation should be investigated, based on the efficacy data. Intervals between application of the biological

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pesticide and chemical pesticides should be specified, if appropriate, in order to avoid loss of efficacy.

2.9. **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.

2.10. **Summary and evaluation of data presented under points 2.1 to 2.9**

3. DATA ON APPLICATION

3.1. **Field of use envisaged**

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

— field use, such as agriculture, horticulture, forestry and viticulture,

— protected crops (e.g. in glasshouses),

— amenity,

— weed control on non-cultivated areas,

— home gardening,

— house plants,

— stored products,

— other (specify).

3.2. **Mode of action**

The way by which uptake of the product may occur (e.g. contact, stomach, inhalation) or the pest controlling action (fungitoxic, fungistatic action, nutrient competition, etc.) must be stated.

It must also be stated whether or not the product is translocated in plants and, where relevant, if such translocation is apoplastic, symplastic or both.

3.3. **Details of intended use**

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

Intervals between the application of the plant protection product containing micro-organisms and chemical pesticides, or a list with active substances of chemical plant protection products not to be used together with the plant protection product containing micro-organisms on the same crop, should also be provided.

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 or l for the preparation and in terms of appropriate units for the micro-organism, 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. **Content of micro-organism in material used (e.g. in the diluted spray, baits or treated seed)**

The content of micro-organism shall be reported, as appropriate, in number of active unit/ml or g or any other relevant unit.

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

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protected and the development stages of the harmful organisms, must be indicated. Where possible and necessary 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 phytopathogenic effects on succeeding crops**

Where relevant, minimum waiting periods between last application and sowing or planting of succeeding crops, which are necessary to avoid phytopathogenic effects on succeeding crops, must be stated, and follow from the data provided under section 6, point 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 and compatibility of the preparation with proposed packaging materials**

(i) 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'.

(ii) 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 standard 8317.

(iii) 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 determined, using e.g. biotests, 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 micro-organism(s) and that provided under sections 7 and 8.

(i) Where relevant pre-harvest intervals, re-entry periods or withholding periods necessary to minimise 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.

(ii) 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.

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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 relevant, information on combustion products must be provided. The risks likely to arise and the methods and procedures to minimise the hazards arising, must be specified. Procedures to preclude or minimise the generation of waste or leftovers must be provided.

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

The nature and characteristics of protective clothing and equipment proposed must be provided. The data provided must be sufficient to evaluate the suitability and effectiveness under realistic conditions of use (e.g. field or glasshouse circumstances).

4.5. **Measures in the case of an accident**

Whether arising during transport, storage or use, detailed procedures to be followed in the event of an accident, 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. *Controlled incineration*

In many cases the preferred or sole means to safely dispose of plant protection products and in particular the formulants contained in it, contaminated materials, or contaminated packaging, is through controlled incineration in a licensed incinerator.

The applicant must provide detailed instructions for safe disposal.

4.6.2. *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.

5. ANALYTICAL METHODS

Introduction

The provisions of this section only cover analytical methods required for post-registration control and monitoring purposes.

It is desirable to have a plant protection product without contaminants, if possible. The level of acceptable contaminants should be judged from a risk assessment point of view, by the competent authority.

Both production and product must be subject to a continuous quality control by the applicant. The quality criteria for the product should be submitted.

For analytical methods used for generation of data as required in this Directive or for other purposes the applicant has to provide a justification for the method used; where necessary separate guidance will be developed for such methods on the basis of the same requirements as defined for methods for post-registration control and monitoring purposes.

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Descriptions of methods must be provided and include details of equipment, materials and conditions used. The applicability of existing CIPAC methods must be reported.

As far as practicable these methods must employ the simplest approach, involve the minimum cost, and require commonly available equipment.

For this section the following applies:

Impurities	Any component (including contaminating micro-organisms and/or chemical substances) other than the specified micro-organism, originating from the manufacturing process or from degradation during storage
Relevant impurities	Impurities, as defined above, that are of concern for human or animal health and/or the environment
Metabolites	Metabolites include products resulting from degradative and biosynthetic reactions taking place within the micro-organism or other organisms used to produce the micro-organism of interest
Relevant metabolites	Metabolites that are of concern for human or animal health and/or the environment
Residues	Viable micro-organisms and substances produced in significant quantities by these micro-organisms which persist after the disappearance of the micro-organisms and are of concern for human or animal health and/or the environment.

On request the following samples must be provided:

(i) samples of the preparation;

(ii) samples of the micro-organism as manufactured;

(iii) analytical standards of the pure micro-organism;

(iv) analytical standards of relevant metabolites and all other components included in the residue definition;

(v) if available, samples of reference substances for the relevant impurities.

5.1. **Methods for the analysis of the preparation**

— Methods, which must be described in full, must be provided for the identification and the determination of the content of the micro-organism in the preparation. In the case of a preparation containing more than one micro-organism, methods capable of identifying and determining the content of each one should be provided.

— Methods to establish regular control of the final product (preparation) in order to show that it does not contain other organisms than the indicated ones and to establish its uniformity.

— Methods to identify any contaminating micro-organisms of the preparation.

— Methods used to determine the storage stability and shelf life of the preparation must be provided.

5.2. **Methods to determine and quantify residues**

Analytical methods for the determination of residues, as defined in Annex II, Part B, section 4, point 4.2, must be submitted unless it is justified that the information already submitted according to the requirements of Annex II, Part B, section 4, point 4.2, is sufficient.

6. EFFICACY DATA

The provisions for efficacy data have already been adopted under Commission Directive 93/71/EEC ([1]).

7. EFFECTS ON HUMAN HEALTH

For proper evaluation of the toxicity including potential for pathogenicity and infectiveness of preparations sufficient information should be available

([1]) OJ L 221, 31.8.1993, p. 27.

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on acute toxicity, irritation and sensitisation of the micro-organism. If possible, additional information on mode of toxic action, toxicological profile and all other known toxicological aspects of the micro-organism should be submitted. Special attention should be given to co-formulants.

While performing toxicology studies, all signs of infection or pathogenicity should be noted. Toxicology studies should include clearance studies.

In the context of the influence that impurities and other components can have on toxicological behaviour, it is essential that for each study submitted, a detailed description (specification) of the material used, be provided. Tests must be conducted using the plant protection product to be authorised. In particular, it must be clear that the micro-organism used in the preparation, and the conditions of culturing it, are the same for which information and data are submitted in the context of Annex II, Part B.

A tiered testing system will be applied to the study of the plant protection product.

7.1. **Basic acute toxicity studies**

The studies, data and information to be provided and evaluated, must be sufficient to permit the identification of effects following a single exposure to the plant protection product, and in particular to establish, or indicate:

— the toxicity of the plant protection product,

— toxicity of the plant protection product relative to the micro-organism,

— the time course and characteristics of the effect with full details of behavioural changes and possible gross pathological findings at post-mortem,

— where possible the mode of toxic action, and

— the relative hazard associated with the different routes of exposure.

While the emphasis must be on estimating the toxicity ranges involved, the information generated must also permit the plant protection product to be classified in accordance with Directive 78/631/EEC. The information generated through acute toxicity testing is of particular value in assessing hazards likely to arise in accident situations.

7.1.1. *Acute oral toxicity*

Circumstances in which required

An acute oral test should always be carried out unless the applicant can justify to the satisfaction of the competent authority that Article 3(2) of Directive 78/631/EEC can be invoked.

Test guideline

The test must be carried out in accordance with Method B.1 or B.1 *bis* of Commission Directive 92/69/EEC [1].

7.1.2. *Acute inhalation toxicity*

Aim of the test

The test will provide the inhalation toxicity to rats of the plant protection product.

Circumstances in which required

The test must be carried out where the plant protection product:

— is used with fogging equipment,

— is an aerosol,

— is a powder containing a significant proportion of particles of diameter < 50 micrometre (> 1 % on a weight basis),

— is to be applied from aircraft in cases where inhalation exposure is relevant,

[1] OJ L 383, 29.12.1992, p. 113.

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— is to be applied in a manner which generates a significant proportion of particles or droplets of diameter < 50 micrometre (> 1 % on a weight basis),

— contains a volatile component at greater than 10 %.

Test guideline

The test must be carried out in accordance with Method B.2 of Directive 92/69/EEC.

7.1.3. *Acute percutaneous toxicity*

Circumstances in which required

An acute percutaneous test should always be carried out unless the applicant can justify to the satisfaction of the competent authority that Article 3(2) of Directive 78/631/EEC can be invoked.

Test guideline

The test must be carried out in accordance with Method B.3 of Directive 92/69/EEC.

7.2. **Additional acute toxicity studies**

7.2.1. *Skin irritation*

Aim of the test

The test will provide the potential of skin irritancy of the plant protection product including the potential reversibility of the effects observed.

Circumstances in which required

The skin irritancy of the plant protection product must always be determined, except where the formulants are not expected to be skin irritant or the micro-organism is shown not to be skin irritant or where it is likely, as indicated in the test guideline, that severe skin effects can be excluded.

Test guideline

The test must be carried out in accordance with Method B.4 of Directive 92/69/EEC.

7.2.2. *Eye irritation*

Aim of the test

The test will provide the potential for eye irritation of the plant protection product, including the potential reversibility of the effects observed.

Circumstances in which required

The eye irritancy of the plant protection product must be determined, where the formulants are suspected to be eye irritant, except where the micro-organism is eye irritant or where it is likely, as indicated in the test guideline, that severe effects on the eyes may be produced.

Test guideline

The eye irritation must be determined in accordance with Method B.5 of Directive 92/69/EEC.

7.2.3. *Skin sensitisation*

Aim of the test

The test will provide sufficient information to assess the potential of the plant protection product to provoke skin sensitisation reactions.

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Circumstances in which required

The test must be carried out where the formulants are suspected to have skin sensitising properties, except where the micro-organism(s) or the formulants are known to have skin sensitising properties.

Test guideline

The tests have to be carried out in accordance with Method B.6 of Directive 92/69/EEC.

7.3. **Data on exposure**

The risks for those in contact with plant protection products (operators, bystanders, workers), depend on the physical, chemical and toxicological properties of the plant protection product as well as the type of the product (undiluted/diluted), formulation type, and on the route, the degree and duration of exposure. Sufficient information and data must be generated and reported to permit an assessment of the extent of exposure to the plant protection product likely to occur under the proposed conditions of use.

In the cases where there is particular concern on the possibility of dermal absorption based on the information for the micro-organism available in Annex II, Part B, section 5, or from the information provided for the preparation in the present section of Annex III, Part B, further dermal absorption data can be necessary.

Results from exposure monitoring during production or use of the product must be submitted.

The abovementioned information and data must provide the basis for the selection of appropriate protective measures including personal protective equipment to be used by operators and workers and to be specified on the label.

7.4. **Available toxicological data relating to non-active substances**

A copy of the notification and the safety data sheet submitted in the context of European Parliament and Council Directive 1999/45/EC [1] and Commission Directive 91/155/EEC of 5 March 1991 defining and laying down the detailed arrangements for the system of specific information relating to dangerous preparations in implementation of Article 10 of Directive 88/379/EEC [2] must be submitted for each formulant. All other available information should be submitted.

7.5. **Supplementary studies for combinations of plant protection products**

Aim of the test

In certain cases it may be necessary to carry out the studies as referred to under points 7.1 to 7.2.3 for a combination of plant protection products 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. Decisions as to the need for supplementary studies must be made on a case-by-case basis, taking into account the results of the acute toxicity studies of the individual plant protection products, the possibility for exposure to the combination of the products concerned and available information or practical experience with the products concerned or similar products.

7.6. **Summary and evaluation of health effects**

A summary of all data and information provided under paragraphs 7.1 through 7.5, must be submitted, and include a detailed and critical assessment of those data in the context of relevant evaluative and decision-making criteria and guidelines, with particular reference to the risks for man and animals that may or do arise, and the extent, quality and reliability of the database.

8. RESIDUES IN OR ON TREATED PRODUCTS, FOOD AND FEED

The same provisions as detailed in Annex II, Part B, section 6, apply; the information required according to this section has to be provided unless it

[1] OJ L 200, 30.7.1999, p. 1.
[2] OJ L 76, 22.3.1991, p. 35.

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is possible to extrapolate the residue behaviour of the plant protection product on the basis of the data available for the micro-organism. Special attention should be paid towards the influence of formulation substances on the residue behaviour of the micro-organism and its metabolites.

9. FATE AND BEHAVIOUR IN THE ENVIRONMENT

The same provisions as detailed in Annex II, Part B, section 7, apply; the information required according to this section has to be provided unless it is possible to extrapolate the fate and behaviour of the plant protection product in the environment on the basis of the data available in Annex II, Part B, section 7.

10. EFFECTS ON NON-TARGET ORGANISMS

Introduction

(i) The information provided, taken together with that for the micro-organism(s), must be sufficient to permit an assessment of the impact on non-target species (flora and fauna), of the plant protection product, when used as proposed. Impact can result from single, prolonged or repeated exposure, and can be reversible, or irreversible.

(ii) The choice of the appropriate non-target organisms for testing of environmental effects should be based on the information on the micro-organism, as required in Annex II, Part B, and on the information on the formulants and other components, as required by sections 1 to 9 of the present Annex. From such knowledge it would be possible to choose the appropriate test organisms, such as organisms closely related to the target organism.

(iii) In particular, the information provided for the plant protection product, together with other relevant information, and that provided for the micro-organism, should be sufficient to:

— specify the hazard symbols, the indications of danger, and relevant risk and safety phrases for the protection of the environment, to be mentioned on packaging (containers),

— permit an evaluation of the short- and long-term risks for non-target species — populations, communities, and processes as appropriate,

— permit an evaluation whether special precautions are necessary for the protection of non-target species.

(iv) There is a need to report all potentially adverse effects found during routine investigations of environmental effects and to undertake and report such additional studies which may be necessary to investigate the mechanisms involved and assess the significance of these effects.

(v) In general, much of the data relating to impact on non-target species, required for authorisation of plant protection products, will have been submitted and evaluated for the inclusion of the micro-organism(s) in Annex I.

(vi) Where exposure data are necessary to decide whether a study has to be performed, the data obtained in accordance with the provisions of Annex III, Part B, section 9, should be used.

For the estimation of exposure of organisms all relevant information on the plant protection product and on the micro-organism must be taken into account. Where relevant the parameters provided for in this section should be used. Where it appears from available data that the plant protection product has a stronger effect than the micro-organism, the data on effects on non target organisms of the plant protection product have to be used for the calculation of relevant effect/exposure ratios.

(vii) In order to facilitate the assessment of the significance of test results obtained, the same strain of each relevant species should where possible be used in the various specified tests for effects on non target organisms.

10.1. **Effects on birds**

The same information as provided in Annex II, Part B, section 8, point 8.1, has to be reported where it is not possible to predict the effects of the plant protection product on the basis of the data available for the

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micro-organism, unless it can be justified that exposure of birds is unlikely to occur.

10.2. **Effects on aquatic organisms**

The same information as provided in Annex II, Part B, section 8, point 8.2, has to be reported where it is not possible to predict the effects of the plant protection product on the basis of the data available for the micro-organism, unless it can be justified that exposure of aquatic organisms is unlikely to occur.

10.3. **Effects on bees**

The same information as provided in Annex II, Part B, section 8, point 8.3, has to be reported where it is not possible to predict the effects of the plant protection product on the basis of the data available for the micro-organism, unless it can be justified that exposure of bees is unlikely to occur.

10.4. **Effects on arthropods other than bees**

The same information as provided in Annex II, Part B, section 8, point 8.4, has to be reported where it is not possible to predict the effects of the plant protection product on the basis of the data available for the micro-organism, unless it can be justified that exposure of arthropods other than bees is unlikely to occur.

10.5. **Effects on earthworms**

The same information as provided in Annex II, Part B, section 8, point 8.5, has to be reported where it is not possible to predict the effects of the plant protection product on the basis of the data available for the micro-organism, unless it can be justified that exposure of earthworms is unlikely to occur.

10.6. **Effects on soil micro-organisms**

The same information as provided in Annex II, Part B, section 8, point 8.6, has to be reported where it is not possible to predict the effects of the plant protection product on the basis of the data available for the micro-organism, unless it can be justified that exposure of non target soil micro-organisms is unlikely to occur.

10.7. **Additional studies**

Expert judgement is required to decide whether additional studies are necessary. Such decision will take into consideration the available information in this and other sections, in particular data on the specificity of the micro-organism, and the expected exposure. Useful information may also be available from the observations carried out in efficacy testing.

Special attention should be given to possible effects on naturally occurring and deliberately released organisms of importance in IPM. In particular the compatibility of the product with IPM should be taken into consideration.

Additional studies might include further studies on additional species or higher tier studies such as studies on selected non-target organisms.

Before performing such studies, the applicant shall seek agreement of the competent authorities on the type of study to be performed.

11. SUMMARY AND EVALUATION OF ENVIRONMENTAL IMPACT

A summary and evaluation of all data relevant to the environmental impact should be carried out according to the guidance given by the competent authorities of the Member States concerning the format of such summaries and evaluations. It should include a detailed and critical assessment of those data in the context of relevant evaluative and decision making criteria and guidelines, with particular reference to the risks for the environment and non-target species that may or do arise, and the extent, quality and reliability of the database. In particular the following issues should be addressed:

— prediction of distribution and fate in the environment, and the time courses involved,

— identification of non-target species and populations at risk, and prediction of the extent of potential exposure,

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— identification of precautions necessary to avoid or minimise contamination of the environment, and for the protection of non-target species.

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ANNEX IV

STANDARD PHRASES FOR SPECIAL RISKS FOR HUMANS OR THE ENVIRONMENT AS REFERRED TO IN ARTICLE 16

INTRODUCTION

The following additional standard phrases are defined to supplement the phrases provided for by Directive 1999/45/EC, which applies to plant-protection products. The provisions of that Directive shall also be used for plant-protection products containing micro-organisms or viruses as active substances. The labelling of products containing these active substances shall also reflect the provisions concerning dermal and respiratory sensitisation testing, which are laid down in Annex IIb and Annex IIIb to Directive 91/414/EEC.

The harmonised phrases provide the basis for complementary and specific instructions for use and are, therefore, without prejudice to other elements of Article 16, in particular Article 16(1)(k) to (n) and 16(4).

1. **Standard phrases for special risks**

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1.1. *Special risks related to humans (RSh)*

RSh 1

ES: **Tóxico en contacto con los ojos.**

CS: **Toxický při styku s očima.**

DA: **Giftig ved kontakt med øjnene.**

DE: **Giftig bei Kontakt mit den Augen.**

ET: **Mürgine silma sattumisel.**

EL: **Τοξικό όταν έρθει σε επαφή με τα μάτια.**

EN: **Toxic by eye contact.**

FR: **Toxique par contact oculaire.**

IT: **Tossico per contatto oculare.**

LV: **Toksisks nonākot saskarē ar acīm.**

LT: **Toksiška patekus į akis.**

HU: **Szemmel érintkezve mérgező.**

MT: **Tossiku meta jmiss ma' l-għajnejn.**

NL: **Giftig bij oogcontact.**

PL: **Działa toksycznie w kontakcie z oczami.**

PT: **Tóxico por contacto com os olhos.**

SK: **Jedovatý pri kontakte s očami.**

SL: **Strupeno v stiku z očmi.**

FI: **Myrkyllistä joutuessaan silmään.**

SV: **Giftigt vid kontakt medögonen.**

RSh 2

ES: **Puede causar fotosensibilización.**

CS: **Může vyvolat fotosenzibilizaci.**

DA: **Kan give overfølsomhed over for sollys/UV-stråling.**

DE: **Sensibilisierung durch Licht möglich.**

ET: **Võib põhjustada valgussensibiliseerimist.**

EL: **Μπορεί να προκαλέσει φωτοευαισθητοποίηση.**

EN: **May cause photosensitisation.**

FR: **Peut entraîner une photosensibilisation.**

IT: **Può causare fotosensibilizzazione.**

LV: **Var izraisīt fotosensibilizāciju.**

LT: **Gali sukelti fotosensibilizaciją.**

HU: **Fényérzékenységet okozhat.**

MT: **Jista' jikkawża fotosensitiżżazzjoni.**

NL: **Kan fotosensibilisatie veroorzaken.**

▼M55

PL: **Może powodować nadwrażliwość na światło.**

PT: **Pode causar fotossensibilização.**

SK: **Môže spôsobiť fotosenzibilizáciu.**

SL: **Lahko povzroči preobčutljivost na svetlobo.**

FI: **Voi aiheuttaa herkistymistä valolle.**

SV: **Kan orsaka överkänslighet för solljus/UV-strålning.**

RSh 3

ES: **El contacto con los vapores provoca quemaduras de la piel y de los ojos; el contacto con el producto líquido provoca congelación.**

CS: **Při styku s parami způsobuje poleptání kůže a očí a při styku s kapalinou způsobuje omrzliny.**

DA: **Kontakt med dampe giver ætsninger på hud og øjne, og kontakt med væske giver forfrysninger.**

DE: **Kontakt mit Dämpfen verursacht Verätzungen an Haut und Augen und Kontakt mit der Flüssigkeit verursacht Erfrierungen.**

ET: **Kokkupuude auruga põhjustab põletushaavu nahale ja silmadele ning kokkupuude vedelikuga põhjustab külmumist.**

EL: **Οι ατμοί μπορεί να προκαλέσουν εγκαύματα στο δέρμα και στα μάτια·η επαφή με το υγρό μπορεί να προκαλέσει κρυοπαγήματα.**

EN: **Contact with vapour causes burns to skin and eyes and contact with liquid causes freezing.**

FR: **Le contact avec les vapeurs peut provoquer des brûlures de la peau et des yeux; le contact avec le gaz liquide peut causer des engelures.**

IT: **Il contatto con il vapore può causare ustioni della pelle e bruciori agli occhi; il contatto con il liquido può causare congelamento.**

LV: **Saskare ar tvaikiem izraisa ādas un acu apdegumus un saskare ar šķidrumu izraisa apsaldējumus.**

LT: **Garai sukelia odos ir akių nudegimą, skystis- nušalimą.**

HU: **Az anyag gőzével való érintkezés a bőr és a szem égési sérülését okozhatja, illetve a folyadékkal való érintkezés fagyást okozhat.**

MT: **Kuntatt mal-fwar jikkawża ħruq fil-ġilda u fl-għajnejn filwaqt li kuntatt mal-likwidu jikkawża iffriżar.**

NL: **Contact met de damp veroorzaakt brandwonden aan huid en ogen; contact met de vloeistof veroorzaakt bevriezing.**

PL: **Kontakt z oparami powoduje poparzenia skóry i oczu, kontakt z cieczą powoduje zamarzanie.**

PT: **O contacto com vapores do produto provoca queimaduras na pele e nos olhos; o contacto com o produto líquido provoca congelação.**

SK: **Pri kontakte s parou spôsobuje popáleniny pokožky a očí a kontakt s kvapalinou spôsobuje omrzliny.**

SL: **Stik s hlapi povzroča opekline kože in oči, stik s tekočino povzroča ozebline.**

FI: **Kosketus höyryyn voi aiheuttaa palovammoja iholle ja silmiin ja kosketus nesteeseen paleltumavammoja.**

SV: **Kontakt med ångor orsakar frätskador på hud och ögon, kontakt med vätska orsakar förfrysningsskador.**

▼M45

1.2. *Special risks related to the environment (RSe)*

None.

2. **Attribution criteria for standard phrases for special risks**

2.1. *Attribution criteria for standard phrases related to humans*

RSh 1

Toxic by eye contact.

The phrase shall be assigned where an eye irritation test according to Annex IIIA point 7.1.5 has resulted in overt signs of systemic toxicity (e.g. related to cholinesterase inhibition) or mortality among the animals tested, which is likely to be attributable to absorption of the active substance through the mucous membranes of the eye. The risk phrase shall also be applied if there is evidence in humans for systemic toxicity after eye contact.

▼**M45**

Eye protection should be specified in these cases, as outlined in the general provisions of Annex V.

RSh 2

May cause photosensitisation.

The phrase shall be assigned where there is clear evidence from experimental systems or documented human exposure that products show photosensitising effects. The phrase shall also be applied to products containing a given active substance or formulation ingredient, which shows photosensitising effects in humans if the product contains this photosensitising component at a concentration of 1 % (w/w) or higher.

Personal protective measures should be specified in these cases, as outlined in the general provisions of Annex V.

RSh 3

Contact with vapour causes burns to skin and eyes and contact with liquid causes freezing.

The phrase shall be assigned to plant-protection products being formulated as liquefied gas, where appropriate (e.g. preparations of methyl bromide).

Personal protective measures should be specified in these cases, as outlined in the general provisions of Annex V.

In cases where R34 or 35 are applied according to Directive 1999/45/EC, the phrase shall not be used.

2.2. *Attribution criteria for standard phrases related to the environment*

None.

▼M45

ANNEX V

STANDARD PHRASES FOR SAFETY PRECAUTIONS FOR THE PROTECTION OF HUMANS OR THE ENVIRONMENT AS REFERRED TO IN ARTICLE 16

INTRODUCTION

The following additional standard phrases are defined to supplement the phrases provided for by Directive 1999/45/EC, which applies to plant-protection products. The provisions of that Directive shall also be used for plant-protection products containing micro-organisms or viruses as active substances. The labelling of products containing these active substances shall also reflect the provisions concerning dermal and respiratory sensitisation testing, which are laid down in Annex IIb and Annex IIIb to Directive 91/414/EEC.

The harmonised phrases provide the basis for complementary and specific instructions for use and are, therefore, without prejudice to other elements of Article 16, in particular Article 16(1)(k) to (n) and 16(4).

▼M55

1. **General provisions**

All plant-protection products should be labelled with the following phrase, which should be supplemented by the text in parentheses, as appropriate:

SP 1

ES: **No contaminar el agua con el producto ni con su envase. [No limpiar el equipo de aplicación del producto cerca de aguas superficiales/Evítese la contaminación a través de los sistemas de evacuación de aguas de las explotaciones o de los caminos.]**

CS: **Neznečišťujte vody přípravkem nebo jeho obalem. (Nečistěte aplikační zařízení v blízkosti povrchových vod/Zabraňte kontaminaci vod splachem z farem a z cest).**

DA: **Undgå forurening af vandmiljøet med produktet eller med beholdere, der har indeholdt produktet. [Rens ikke sprøjteudstyr nær overfladevand/Undgå forurening via dræn fra gårdspladser og veje].**

DE: **Mittel und/oder dessen Behälter nicht in Gewässer gelangen lassen. (Ausbringungsgeräte nicht in unmittelbarer Nähe von Oberflächengewässern reinigen/Indirekte Einträge über Hof- und Straßenabläufe verhindern.)**

ET: **Vältida vahendi või selle pakendi vette sattumist (Seadmeid pinnavee lähedal mitte puhastada/Vältida saastamist läbi lauda ja teede drenaazhide).**

EL: **Μην μολύνετε το νερό με το προϊόν ή τη συσκευασία του. [Να μην πλένετε τον εξοπλισμό εφαρμογής κοντά σε επιφανειακά ύδατα/Να αποφευχθεί η μόλυνση μέσω των συστημάτων αποχέτευσης από τις λιθόστρωτες επιφάνειες και τους δρόμους.]**

EN: **Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).**

FR: **Ne pas polluer l'eau avec le produit ou son emballage. [Ne pas nettoyer le matériel d'application près des eaux de surface./Éviter la contamination via les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.]**

IT: **Non contaminare l'acqua con il prodotto o il suo contenitore. [Non pulire il materiale d'applicazione in prossimità delle acque di superficie./Evitare la contaminazione attraverso i sistemi di scolo delle acque dalle aziende agricole e dalle strade.]**

LV: **Nepiesārņot ūdeni ar augu aizsardzības līdzekli un tā iepakojumu/netīrīt smidzināšanas tehniku ūdenstilpju un ūdensteču tuvumā/izsargāties no piesārņošanas caur drenāžu no pagalmiem un ceļiem.**

LT: **Neužteršti vandens augalų apsaugos produktu ar jo pakuote (Neplauti purškimo įrenginių šalia paviršinio vandens telkinių/vengti taršos per drenažą iš sodybų ar nuo kelių).**

HU: **A termékkel vagy annak tartályával ne szennyezze a vizeket. (A berendezést vagy annak részeit ne tisztítsa felszíni vizek közelében/kerülje a gazdaságban vagy az utakon lévő vízelvezetőkön keresztül való szennyeződést).**

▼M55

MT: **Tikkontaminax ilma bil-prodott jew il-kontenitur tiegħu (Tnaddafx apparat li jintuża għall-applikazzjoni qrib ilma taxxita/Ara li ma jkunx hemm kontaminazzjoni minn btieħi u toroq).**

NL: **Zorg ervoor dat u met het product of zijn verpakking geen water verontreinigt. [Reinig de apparatuur niet in de buurt van oppervlaktewater/Zorg ervoor dat het water niet via de afvoer van erven of wegen kan worden verontreinigd.]**

PL: **Nie zanieczyszczać wód produktem lub jego opakowaniem (Nie myć aparatury w pobliżu wód powierzchniowych/Unikaćzanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg).**

PT: **Não poluir a água com este produto ou com a sua embalagem. [Não limpar o equipamento de aplicação perto de águas de superfície./Evitar contaminações pelos sistemas de evacuação de águas das explorações agrícolas e estradas.]**

SK: **Neznečisťujte vodu prípravkom alebo jeho obalom (Nečistite aplikačné zariadenie v blízkosti povrchových vôd/Zabráňte kontaminácii prostredníctvom odtokových kanálov z poľnohospodárskych dvorov a vozoviek).**

SL: **S sredstvom ali njegovo embalažo ne onesnaževati vode. (Naprav za nanašanje ne čistiti ali izplakovati v bližini površinskih voda./ Preprečiti onesnaženje preko drenažnih in odtočnih jarkov na kmetijskih zemljiščih in cestah.)**

FI: **Älä saastuta vettä tuotteella tai sen pakkauksella. (Älä puhdista levityslaitteita pintaveden lähettyvillä./Vältä saastumista piha- ja maantieojien kautta.)**

SV: **Förorena inte vatten med produkten eller dess behållare. (Rengör inte sprututrustning i närheten av vattendrag/Undvik förorening via avrinning från gårdsplaner och vägar.)**

▼M45

2. **Specific safety precautions**

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2.1. *Safety precautions for operators (SPo)*

General provisions

1. Member States may identify suitable personal protective equipment for operators and prescribe specific elements of this equipment (e.g. coveralls, apron, gloves, sturdy shoes, rubber boots, face protection, face shield, tightly fitting glasses, hat, hood or respirator of a specified type). Such supplementary safety precautions are without prejudice to the standard phrases applicable according to Directive 1999/45/EC.

2. Member States may further identify the specific tasks which require particular protective equipment, such as mixing, loading or handling the undiluted product, applying or spraying the diluted product, handling recently treated materials like plants or soil or entering recently treated areas.

3. Member States may add specifications of engineering controls, such as:

   — a closed transfer system must be used when transferring the pesticide from the product container to the spray tank,

   — the operator must work within a closed cabin (with an air conditioning/air filtration system) during spraying,

   — engineering controls may replace personal protective equipment if they provide an equal or higher standard of protection.

Specific provisions

SPo 1

ES: **En caso de contacto con la piel, elimínese primero el producto con un paño seco y después lávese la piel con agua abundante.**

CS: **Po zasažení kůže přípravek nejdříve odstraňte pomocí suché látky a poté kůži opláchněte velkým množstvím vody.**

DA: **Efter kontakt med huden, fjern først produktet med en tør klud og vask derefter med rigeligt vand.**

DE: **Nach Kontakt mit der Haut zuerst das Mittel mit einem trockenen Tuch entfernen und dann die Haut mit reichlich Wasser abspülen.**

ET: **Nahaga kokkupuutel kõigepealt eemaldada vahend kuiva lapiga ning seejärel pesta nahka rohke veega.**

▼**M55**

EL: **Ύστερα από επαφή με το δέρμα, αφαιρέστε πρώτα το προϊόν με ένα στεγνό πανί και στη συνέχεια ξεπλύνετε το δέρμα με άφθονο νερό.**

EN: **After contact with skin, first remove product with a dry cloth and then wash the skin with plenty of water.**

FR: **Après contact avec la peau, éliminer d'abord le produit avec un chiffon sec, puis laver la peau abondamment à l'eau.**

IT: **Dopo il contatto con la pelle, rimuovere il prodotto con un panno asciutto e quindi lavare abbondantemente con acqua.**

LV: **Pēc saskares ar ādu, vispirms notīrīt augu aizsardzības līdzekli no ādas ar sausu drānu un pēc tam mazgāt ādu ar lielu ūdens daudzumu.**

LT: **Patekus ant odos, pirmiausia nuvalyti sausu audiniu, po to gerai nuplauti vandeniu.**

HU: **Bőrrel való érintkezés esetén először száraz ruhával távolítsa el a terméket, majd a szennyeződött bőrt bő vízzel mossa le.**

MT: **Wara kuntatt mal-ġilda, l-ewwel neħħi l-prodott b'xoqqa niexfa u mbgħad aħsel il-ġilda b'ħafna ilma.**

NL: **Na contact met de huid moet u eerst het gewasbeschermingsmiddel met een droge doek verwijderen en daarna de huid met veel water wassen.**

PL: **Po kontakcie ze skórą najpierw usunąć produkt suchą szmatką, a następnie przemyć skórę dużą ilością wody.**

PT: **Em caso de contacto com a pele, remover primeiro o produto com um pano seco e, em seguida, lavar a pele com muita água.**

SK: **Po kontakte s pokožkou najskôr odstráňte prípravok suchou tkaninou a potom opláchnite veľkým množstvom vody.**

SL: **Ob stiku s kožo odstraniti sredstvo s suho krpo in sprati kožo z obilo vode.**

FI: **Ihokosketuksen jälkeen tuote pyyhitään aluksi pois kuivalla kankaalla ja sitten iho pestään runsaalla vedellä.**

SV: **Efter kontakt med huden, avlägsna först produkten med en torr trasa och tvätta sedan med mycket vatten.**

SPo 2

ES: **Lávese toda la ropa de protección después de usarla.**

CS: **Veškerý ochranný oděv po použití vyperte.**

DA: **Vask alle personlige værnemidler efter brug.**

DE: **Die gesamte Schutzkleidung muss nach Gebrauch gewaschen werden.**

ET: **Peale kasutamist kogu kaitseriietus pesta.**

EL: **Ξεπλύνετε όλες τις προστατευτικές ενδυμασίες μετά τη χρήση.**

EN: **Wash all protective clothing after use.**

FR: **Laver tous les équipements de protection après utilisation.**

IT: **Lavare tutto l'equipaggiamento di protezione dopo l'impiego.**

LV: **Pēc lietošanas izmazgāt visu aizsargtērpu.**

LT: **Po darbo išskalbti visus apsauginius drabužius.**

HU: **Használat után minden védőruházatot ki kell mosni.**

MT: **Aħsel l-ilbies protettiv wara li-tuża.**

NL: **Was alle beschermende kleding na gebruik.**

PL: **Uprać odzież ochronną po użyciu.**

PT: **Depois da utilização do produto, lavar todo o vestuário de protecção.**

SK: **Ochranný odev po aplikácii očistite.**

SL: **Po uporabi oprati vso zaščitno obleko.**

FI: **Kaikki suojavaatteet pestävä käytön jälkeen.**

SV: **Tvätta alla skyddskläder efter användning.**

SPo 3

ES: **Tras el inicio de la combustión del producto, abandónese inmediatamente la zona tratada sin inhalar el humo.**

▼M55

CS: **Po vznícení přípravku nevdechujte kouř a ihned opusťte ošetřovaný prostor.**

DA: **Efter antænding af produktet, undgå at indånde røgen og forlad det behandlede område øjeblikkeligt.**

DE: **Nach Anzünden des Mittels Rauch nicht einatmen und die behandelte Fläche sofort verlassen.**

ET: **Peale vahendi süttimist suitsu mitte sisse hingata ning käideldud alalt otsekohe lahkuda.**

EL: **Μετά την ανάφλεξη τουπροϊόντος μην εισπνεύσετε τον καπνό και απομακρυνθείτε αμέσως από την περιοχή χρήσης.**

EN: **After igniting the product, do not inhale smoke and leave the treated area immediately.**

FR: **Après déclenchement de la fumigation, ne pas inhaler la fumée et quitter la zone traitée immédiatement.**

IT: **Una volta iniziata la combustione, non inalare il fumo e abbandonare immediatamente la zona trattata.**

LV: **Pēc augu aizsardzības līdzekļa aizdedzināšanas, neieelpot dūmus un nekavējoties atstāt apstrādāto platību.**

LT: **Užsidegus neįkvėpti dūmų ir nedelsiant palikti apdorotą plotą.**

HU: **A termék meggyújtása után óvakodjon a keletkező füst belélegzésétől, és azonnal hagyja el a kezelt területet.**

MT: **Wara li tqabbad il-prodott, tiblax id-duħħan u warrab minnufih mill-post li jkun ġie ittrattat.**

NL: **Nadat u het product hebt aangestoken, mag u de rook niet inademen en moet u de behandelde ruimte onmiddellijk verlaten.**

PL: **Po zapaleniu produktu nie wdychać dymu i niezwłocznie opuścić obszar poddany zabiegowi.**

PT: **Depois de iniciada a fumigação do produto, não inalar os fumos e sair imediatamente da zona em tratamento.**

SK: **Po zapálení prípravku, nevdychujte dym a okamžite opustite ošetrovaný priestor.**

SL: **Po zažigu sredstva ne vdihavati dima in takoj zapustiti tretirano območje.**

FI: **Tuotteen syttyessä vältettävä savun hengittämistä ja poistuttava käsitellyltä alueelta viipymättä.**

SV: **När produkten antänts, andas inte in röken och lämna det behandlade området genast.**

SPo 4

ES: **El recipiente debe abrirse al aire libre y en tiempo seco.**

CS: **Obal s přípravkem musí být otevřen ve venkovním prostředí a za sucha.**

DA: **Beholderen skal åbnes udendørs og under tørre forhold.**

DE: **Der Behälters muss im Freien und Trockenen geöffnet werden.**

ET: **Pakend tuleb avada õues ning kuivades tingimustes.**

EL: **Το δοχείο πρέπει να ανοιχθεί στο ύπαιθρο και σε συνθήκες ξηρασίας.**

EN: **The container must be opened outdoors and in dry conditions.**

FR: **L'emballage doit être ouvert à l'extérieur par temps sec.**

IT: **L'imballaggio deve essere aperto all'esterno e in condizioni di tempo secco.**

LV: **Iepakojumu atvērt ārpus telpām un sausos apstākļos.**

LT: **Pakuotę atidaryti lauke, esant sausoms oro sąlygoms.**

HU: **A tartályt csak a szabad levegőn, száraz időben lehet kinyitni.**

MT: **Il-kontenitur għandu jinfetaħ f'ambjent miftuħ u xott.**

NL: **De verpakking moet buiten, in droge omstandigheden, worden geopend.**

PL: **Opakowanie otwierać na zewnątrz i w suchych warunkach.**

PT: **Abrir a embalagem ao ar livre e com tempo seco.**

SK: **Nádobu otvárajte vonku a za suchého počasia.**

SL: **Embalažo odpreti na prostem in v suhih razmerah.**

▼**M55**

FI: **Pakkaus avattava ulkona kuivissa olosuhteissa.**

SV: **Behållaren måste öppnas utomhus och under torra förhållanden.**

SPo 5

ES: **Ventilar las zonas/los invernaderos tratados [bien/**durante un tiempo especificado/**hasta que se haya secado la pulverización] antes de volver a entrar.**

CS: **Před opětovným vstupem ošetřené prostory/skleníky [důkladně/** uveďte dobu/**do zaschnutí postřikového nánosu] vyvětrejte.**

DA: **De behandlede områder/drivhuse ventileres [grundigt/**eller angivelse af tid/**indtil sprøjtemidlet er tørret], før man igen går ind i dem.**

DE: **Vor dem Wiederbetreten ist die behandelte Fläche/das Gewächshaus (gründlich/**oder Zeit angeben/**bis zur Abtrocknung des Spritzbelages) zu lüften.**

ET: **Õhutada käideldud alad/põhjalikult kasvuhooned/**määratletud aja jooksul/**enne uuesti sisenemist kuni pihustatud vahendi kuivamiseni.**

EL: **Να αερίσετε τους χώρους/τα θερμοκήπια όπου χρησιμοποιήθηκαν φυτοφάρμακα [πλήρως/**ή να προσδιοριστεί η χρονική περίοδος/**μέχρι να στεγνώσει το προϊόν] πριν ξαναμπείτε.**

EN: **Ventilate treated areas/greenhouses thoroughly/**time to be specified/ **until spray has dried before re-entry.**

FR: **Ventiler [à fond/**ou durée à préciser**/jusqu'au séchage de la pulvérisation] les zones/serres traitées avant d'y accéder.**

IT: **Ventilare [a fondo/**per una durata da specificare/**fino all'essiccazione dello spray] le zone serre trattate prima di accedervi.**

LV: **Pirms atgriešanās rūpīgi vēdināt apstrādātās platības/siltumnīcas (**norāda laiku**) kamēr izsmidzinātais šķidrums nožuvis.**

LT: **Gerai išvėdinti apdorotus plotus/šiltnamius (**vėdinimo laikas turi būti nurodytas**). Įeiti į apdorotus plotus leidžiama tik visiškai jiems išdžiūvus.**

HU: **A kezelt területet/üvegházakat [alaposan/**az előírt időn át/**a permet felszáradásáig] szellőztesse az oda való visszatérés előtt.**

MT: **Ħalli l-arja tgħaddi minn dawk il-postijiet/serer li ġew ittrattati sew/**speċifika t-tul ta' ħin/**sakemm jinxef il-bexx qabel ma terġa' tidħol.**

NL: **Voordat u opnieuw in behandelde ruimten/kassen binnengaat, moet u die [grondig ventileren/gedurende (**geef de periode aan**) ventileren/ventileren tot de sproeistof is opgedroogd].**

PL: **Dokładnie wietrzyć obszar poddany zabiegowi/szklarnie/**przez określony czas/**Przed ponownym wejściem poczekać do wyschnięcia cieczy.**

PT: **Arejar [bem] os locais/estufas tratados [durante (**neste caso, precisar o período**)/até à secagem do pulverizado] antes de neles voltar a entrar.**

SK: **Pred ďalším vstupom dôkladne vyvetrajte ošetrovaný priestor/** skleník tak**, aby rozprášený roztok prípravku zaschol/uveďte potrebný čas/.**

SL: **Pred ponovnim vstopom temeljito zračiti tretirane površine/ rastlinjake/**določi se čas/**dokler se nanešeno sredstvo ne posuši.**

FI: **Käsitellyt alueet/kasvihuoneet/käsiteltyjä alueita/kasvihuoneita tuuletettava (perusteellisesti/**tai täsmennetään tuuletusaika/**kunnes tuote on kuivunut) ennen sinne palaamista.**

SV: **Vädra (omsorgsfullt/**eller ange tidsperiod/**tills produkten torkat) före vistelse i behandlade utrymmen/växthus.**

2.2. *Safety precautions related to the environment (SPe)*

SPe 1

ES: **Para proteger [las aguas subterráneas/los organismos del suelo], no aplicar este producto ni ningún otro que contenga** (precísese la sustancia o la familia de sustancias, según corresponda) **más de** (indíquese el tiempo o la frecuencia)**.**

CS: **Za účelem ochrany podzemních vod/půdních organismů neaplikujte tento ani žádný jiný přípravek obsahující** (uveďte účinnou látku nebo popřípadě skupinu účinných látek) **déle/více než** (uveďte určitou lhůtu nebo četnost aplikací)**.**

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DA: **For at beskytte [grundvandet/jordorganismer] må dette produkt eller andre produkter, der indeholder** (angiv navnet på aktivstoffet eller gruppe af aktivstoffer)**, kun anvendes/ikke anvendes mere end** (angiv tidsperiode eller antal behandlinger)**.**

DE: **Zum Schutz von (Grundwasser/Bodenorganismen) das Mittel '…' oder andere … haltige Mittel** (Identifizierung des Wirkstoffes oder einer Wirkstoffgruppe) **nicht mehr als …** (Angabe der Anwendungshäufigkeit in einem bestimmten Zeitraum) **anwenden.**

ET: **Põhjavee/mullaorganismide kaitsmiseks mitte kasutada seda või ükskõik millist muud vahendit, mis sisaldab** (määratleda vastavalt toimeaine või aine klass) **rohkem kui** (periood või määratletav sagedus)**.**

EL: **Για να προστατέψετε [τα υπόγεια νερά/τους οργανισμούς στο έδαφος] μην χρησιμοποιείτε αυτό ή οποιοδήποτε άλλο προϊόν που περιέχει** (προσδιορίστε τη δραστική ουσία ή την κατηγορία των ουσιών αναλόγως) **περισσότερο από** (να προσδιοριστεί η χρονική περίοδος ή η συχνότητα)**.**

EN: **To protect groundwater/soil organisms do not apply this or any other product containing** (identify active substance or class of substances, as appropriate) **more than** (time period or frequency to be specified)**.**

FR: **Pour protéger [les eaux souterraines/les organismes du sol], ne pas appliquer ce produit ou tout autre produit contenant** (préciser la substance ou la famille de substances selon le cas) **plus de** (fréquence à préciser)**.**

IT: **Per proteggere [le acque sotterranee/gli organismi del suolo] non applicare questo o altri prodotti contenenti** (specificare la sostanza attiva o la classe di sostanze, secondo il caso) **più di** (indicare la durata o la frequenza)**.**

LV: **Lai aizsargātu gruntsūdeni/augsnes organismus, nelietot augu aizsardzības līdzekli '…' vai citu augu aizsardzības līdzekli, kurš satur '…'**(norāda darbīgo vielu vai darbīgo vielu grupu) **vairāk nekā …** (norāda apstrāžu skaitu noteiktā laika periodā)**.**

LT: **Siekiant apsaugoti požeminį vandenį/dirvos organizmus nenaudoti šio ar bet kurio kito produkto, kurio sudėtyje yra** (nurodyti veikliąją medžiagą ar medžiagų grupę, kaip tinka) **dažniau kaip** (laikas ar dažnumas turi būti nurodytas)**.**

HU: **A talajvíz/a talaj élő szervezeteinek védelme érdekében ezt vagy** (a megfelelő hatóanyag vagy anyagcsoport)**-ot tartalmazó bármilyen más készítményt ne használja** (az előírt időtartam/gyakoriság)**-nál hosszabb ideig/többször.**

MT: **Sabiex tipproteġi l-ilma tal-pjan/organiżmi fil-ħamrija tapplikax dan il-prodott jew xi prodott ieħor li jkun fih** (identifika s-sustanza jew klassi ta' sustanzi attivi kif imiss) **iżjed minn** (speċifika ż-żmien jew il-frekwenza)**.**

NL: **Om [het grondwater/de bodemorganismen] te beschermen mag u dit product of andere producten die** (geef naar gelang van het geval de naam van de werkzame stof of van de categorie werkzame stoffen) **bevatten, niet langer dan gedurende** (geef de tijdsduur aan) **gebruiken/ten hoogste** (geef de frequentie) **gebruiken.**

PL: **W celu ochrony wód gruntowych/organizmów glebowych nie stosować tego lub żadnego innego produktu zawierającego** (określić substancję aktywną lub klasę substancji, kiedy dotyczy) **nie dłużej niż** (określony czas)**/nie częściej niż** (określona częstotliwość)**.**

PT: **Para protecção [das águas subterrâneas/dos organismos do solo], não aplicar este produto ou qualquer outro que contenha** (indicar, consoante o caso, a substância activa ou a família de substâncias activas) **durante mais de** (período a precisar) **ou mais do que** (frequência a precisar)**.**

SK: **Z dôvodu ochrany podzemnej vody nepoužívajte tento alebo iný prípravok obsahujúci** (uveďte účinnú látku alebo skupinu účinných látok) **dlhšie ako** (upresnite obdobie alebo frekvenciu)**.**

SL: **Zaradi zaščite podtalnice/talnih organizmov ne uporabljati tega ali drugih sredstev, ki vsebujejo** (navede se aktivno snov ali skupino aktivnih snovi) **več kot** (navede se časovno obdobje ali število tretiranj)**.**

FI: **(Pohjaveden/maaperän eliöiden) suojelemiseksi vältettävä tämän tai minkä tahansa muun tuotteen, joka sisältää** (tapauksen mukaan tehoaine tai aineluokka)**, käyttöä useammin** (ajanjakso tai käyttötiheys)**.**

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SV: **För att skydda (grundvatten/marklevande organismer), använd inte denna produkt eller andra produkter innehållande** (ange verksamt ämne eller grupp av ämnen) **mer än** (ange tidsperiod eller antal behandlingar)**.**

SPe 2

ES: **Para proteger [las aguas subterráneas/los organismos acuáticos], no aplicar en suelos** (precísese la situación o el tipo de suelos)**.**

CS: **Za účelem ochrany podzemních vod/vodních organismů neaplikujte přípravek na půdách** (uveďte druh půdy nebo situaci)**.**

DA: **For at beskytte [grundvandet/organismer, der lever i vand] må dette produkt ikke anvendes** (på beskrevet jordtype eller under beskrevne forhold)**.**

DE: **Zum Schutz von (Grundwasser/Gewässerorganismen) nicht auf** (genaue Angabe der Bodenart oder Situation) **Böden ausbringen.**

ET: **Põhjavee/veeorganismide kaitsmiseks mitte kasutada** (määratleda pinnasetüüp või olukord)**.**

EL: **Για να προστατέψετε [τα υπόγεια νερά/τους υδρόβιους οργανισμούς] μην χρησιμοποιείτε το προϊόν αυτό σε εδάφη** (προσδιορίστε τον τύπο του εδάφους ή τις ιδιαίτερες συνθήκες)**.**

EN: **To protect groundwater/aquatic organisms do not apply to** (soil type or situation to be specified)**soils.**

FR: **Pour protéger [les eaux souterraines/les organismes aquatiques], ne pas appliquer ce produit sur** (type de sol ou situation à préciser)**.**

IT: **Per proteggere [le acque sotterranee/gli organismi acquatici] non applicare sul suolo** (indicare il tipo di suolo o la situazione)**.**

LV: **Lai aizsargātu gruntsūdeņus/ūdens organismus, nelietot** (norāda augsnes tipu vai apstākļus) **augsnēs.**

LT: **Siekiant apsaugoti požeminį vandenį/vandens organizmus nenaudoti** (nurodyti dirvožemio tipą ar situaciją) **dirvožemiuose.**

HU: **A talajvíz/a vízi szervezetek védelme érdekében** (az előírt talajtípus vagy helyzet) **talajokra ne használja.**

MT: **Biex tipproteġi l-ilma tal-pjan/organiżmi ta' l-ilma tapplikax f'ħamrija** (speċifika t-tip ta' ħamrija jew is-sitwazzjoni)**.**

NL: **Om [het grondwater/in het water levende organismen] te beschermen mag dit product niet worden gebruikt op** (benoem het soort bodem of geef een beschrijving ervan) **bodems.**

PL: **W celu ochrony wód gruntowych/organizmów wodnych nie stosować na glebach** (określić typ gleby lub warunki glebowe)**.**

PT: **Para protecção [das águas subterrâneas/dos organismos aquáticos], não aplicar este produto em solos** (precisar a situação ou o tipo de solo)**.**

SK: **Z dôvodu ochrany podzemnej vody/vodných organizmov neaplikujte na** (upresnite typ pôdy alebo situáciu) **pôdu.**

SL: **Zaradi zaščite podtalnice/vodnih organizmov ne uporabljati na** (navede se tip tal ali druge posebne razmere) **tleh.**

FI: **(Pohjaveden/vesieliöiden) suojelemiseksi ei saa käyttää** (täsmennetään maaperätyyppi tai tilanne) **maaperään.**

SV: **För att skydda (grundvatten/vattenlevande organismer), använd inte denna produkt på** (ange jordtyp eller markförhållande)**.**

SPe 3

ES: **Para proteger [los organismos acuáticos/las plantas no objetivo/los artrópodos no objetivo/los insectos], respétese sin tratar una banda de seguridad de** (indíquese la distancia) **hasta [la zona no cultivada/las masas de agua superficial].**

CS: **Za účelem ochrany vodních organismů/necílových rostlin/necílových členovců/hmyzu dodržujte neošetřené ochranné pásmo** (uveďte vzdálenost) **vzhledem k nezemědělské půdě/povrchové vodě.**

DA: **Må ikke anvendes nærmere end** (angiv afstand) **fra [vandmiljøet, vandløb, søer m.v./ikke dyrket område] for at beskytte [organismer, der lever i vand/landlevende ikke-målorganismer, vilde planter, insekter og leddyr].**

DE: **Zum Schutz von (Gewässerorganismen/Nichtzielpflanzen/Nichtzielarthropoden/Insekten) eine unbehandelte Pufferzone von** (genaue

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Angabe des Abstandes) **zu (Nichtkulturland/Oberflächengewässer) einhalten.**

ET: **Veeorganismide/mittetaimsete sihtliikide/mittesihtlülijalgsete/putukate kaitsmiseks pidada kinni mittepritsitavast puhvervöön-dist** (määratleda kaugus) **põllumajanduses mittekasutatavast maast/pinnaseveekogudest.**

EL: **Για να προστατέψετε [τους υδρόβιους οργανισμούς/μη στοχευόμενα φυτά/μη στοχευόμενα αρθρόποδα/έντομα] να αφήσετε μιαν αψέκαστη ζώνη προστασίας** (προσδιορίστε την απόσταση) **μέχρι [μη γεωργική γη/σώματα επιφανειακών υδάτων].**

EN: **To protect aquatic organisms/non-target plants/non-target arthropods/insects respect an unsprayed buffer zone of** (distance to be specified) **to non-agricultural land/surface water bodies.**

FR: **Pour protéger [les organismes aquatiques/les plantes non cibles/les arthropodes non cibles/les insectes], respecter une zone non traitée de** (distance à préciser) **par rapport à [la zone non cultivée adjacente/aux points d'eau].**

IT: **Per proteggere [gli organismi acquatici/gli insetti/le piante non bersaglio/gli artropodi non bersaglio] rispettare una fascia di sicurezza non trattata di** (precisare la distanza) **da [zona non coltivata/corpi idrici superficiali].**

LV: **Lai aizsargātu ūdens organismus/ar lietojumu nesaistītos augus/ar lietojumu nesaistītos posmkājus/kukaiņus, ievērot aizsargjoslu** (norāda attālumu) **līdz lauksaimniecībā neizmantojamai zemei/ūdenstilpēm un ūdenstecēm.**

LT: **Siekiant apsaugoti vandens organizmus/netikslinius augalus/netikslinius nariuotakojus/vabzdžius būtina išlaikyti apsaugos zoną** (nurodyti atstumą) **iki ne žemės ūkio paskirties žemės/paviršinio vandens telkinių.**

HU: **A vízi szervezetek/nem célzott növények/nem célzott ízeltlábúak/rovarok védelme érdekében a nem mezőgazdasági földterülettől/felszíni vizektől** (az előírt távolság) **távolságban tartson meg egy nem permetezett biztonsági övezetet.**

MT: **Sabiex tipproteġi organiżmi ta' l-ilma/pjanti mhux immirati/artropodi/insetti mhux immirati, irrispetta żona konfini ħielsa mill-bexx ta'**(speċifika d-distanza) **minn art mhix agrikola/għadajjar ta' l-ilma fil-wiċċ.**

NL: **Om [in het water levende organismen/niet tot de doelsoorten behorende planten/niet tot de doelsoorten behorende geleedpotigen/de insecten] te beschermen mag u in een bufferzone van** (geef de afstand aan) **rond [niet-landbouwgrond/oppervlaktewater] niet sproeien.**

PL: **W celu ochrony organizmów wodnych/roślin nie będących obiektem zwalczania/stawonogów/owadów nie będących obiektem zwalczania konieczne jest określenie strefy buforowej w odległości** (określona odległość) **od terenów nieużytkowanych rolniczo/zbiorników i cieków wodnych.**

PT: **Para protecção [dos organismos aquáticos/das plantas não visadas/dos insectos/artrópodes não visados], respeitar uma zona não pulverizada de** (distância a precisar) **em relação [às zonas não cultivadas/às águas de superfície].**

SK: **Z dôvodu ochrany vodných organizmov/necielených rastlín/necielených článkonožcov/hmyzu udržiavajte medzi ošetrovanou plochou a neobhospodarovanou zónou/povrchovými vodnými plochami ochranný pás zeme v dĺžke** (upresnite dĺžku)**.**

SL: **Zaradi zaščite vodnih organizmov/neciljnih rastlin/neciljnih členonožcev/žuželk upoštevati netretiran varnostni pas** (navede se razdaljo) **do nekmetijske površine/vodne površine.**

FI: **(Vesieliöiden/muiden kuin torjuttavien kasvien/muiden kuin torjuttavien niveljalkaisten/hyönteisten) suojelemiseksi (muun kuin maatalousmaan/pintavesialueiden) väliin on jätettävä** (täsmennetään etäisyys) **ruiskuttamaton suojavyöhyke.**

SV: **För att skydda (vattenlevande organismer/andra växter än de man avser att bekämpa/andra leddjur än de man avser att bekämpa/insekter), lämna en sprutfri zon på** (ange avstånd) **till (icke-jordbruksmark/vattendrag).**

SPe 4

ES: **Para proteger [los organismos acuáticos/las plantas no objetivo], no aplicar sobre superficies impermeables como el asfalto, el**

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cemento, los adoquines, [las vías del ferrocarril] ni en otras situaciones con elevado riesgo deescorrentía.

CS: **Za účelem ochrany vodních organismů/necílových rostlin neaplikujte přípravek na nepropustný povrch, jako je asfalt, beton, dlážděný povrch, železniční trať nebo v jiných případech, kdy hrozí vysoké riziko odplavení.**

DA: **Må ikke anvendes på befæstede arealer såsom asfalterede, beton-, sten- eller grusbelagte områder og veje [jernbanespor] eller på andre områder, hvorfra der er en stor risiko for run-off til omgivelserne. [For at beskytte organismer, der lever i vand/planter, man ikke ønsker at bekæmpe].**

DE: **Zum Schutz von (Gewässerorganismen/Nichtzielpflanzen) nicht auf versiegelten Oberflächen wie Asphalt, Beton, Kopfsteinpflaster (Gleisanlagen) bzw. in anderen Fällen, die ein hohes Abschwemmungsrisiko bergen, ausbringen.**

ET: **Veeorganismide/mittesihtliikide kaitsmiseks mitte kasutada läbilaskmatutel pindadel nagu näiteks asfalt, betoon, munakivi, raudteeröödad ning muudes oludes, kus on kõrge lekkimisoht.**

EL: **Για να προστατέψετε [υδρόβιους οργανισμούς/μη στοχευόμενα φυτά] να μην χρησιμοποιείται σε αδιαπέραστες επιφάνειες όπως άσφαλτο, σκυρόδεμα, λιθόστρωτα [σιδηροτροχιές] και άλλες επιφάνειες με υψηλό κίνδυνο απορροής.**

EN: **To protect aquatic organisms/non-target plants do not apply on impermeable surfaces such as asphalt, concrete, cobblestones, railway tracks and other situations with a high risk of run-off.**

FR: **Pour protéger [les organismes aquatiques/les plantes non cibles], ne pas appliquer sur des surfaces imperméables telles que le bitume, le béton, les pavés, [les voies ferrées] et dans toute autre situation où le risque de ruissellement est important.**

IT: **Per proteggere [gli organismi acquatici/le piante non bersaglio] non applicare su superfici impermeabili quali bitume, cemento, acciottolato, [binari ferroviari] e negli altri casi ad alto rischio di deflusso superficiale.**

LV: **Lai aizsargātu ūdens organismus/ar lietojumu nesaistītos augus, nelietot augu aizsardzības līdzekli uz necaurlaidīgas virsmas, piemēram, asfalta, betona, bruģa, sliežu ceļiem, un citās vietās ar augstu noteces risku.**

LT: **Siekiant apsaugoti vandens organizmus/netikslinius augalus nenaudoti ant nepralaidžių paviršių tokių kaip asfaltas, betonas, grindinio akmenys, geležinkelio bėgių ar kitose situacijose, kuriuose didelė nuotėkio tikimybė.**

HU: **A vízi szervezetek/nem célzott növények védelme érdekében a vizet nem áteresztő felületeken (pl. aszfalt, beton, utcakövezet, vasúti pályák és az elfolyás egyéb veszélye esetén) ne alkalmazza.**

MT: **Biex tipproteġi organiżmi ta' l-ilma/pjanti mhux immirati tapplikax fuq uċuh impermeabbli bħal l-asfalt, konkrit, ċangaturi, linji tal-ferrovija u sitwazzjonijiet oħra b'riskju kbir ta' skul.**

NL: **Om [in het water levende organismen/niet tot de doelsoorten behorende planten] te beschermen mag u dit product niet gebruiken op ondoordringbare oppervlakken, zoals asfalt, beton [,/en] kasseien [en spoorlijnen,] of op andere plaatsen waar het product gemakkelijk kan wegstromen.**

PL: **W celu ochrony organizmów wodnych/roślin nie będących obiektem zwalczania nie stosować na nieprzepuszczalnych powierzchniach, takich jak: asfalt, beton, bruk, torowiska i innych przypadkach, gdy istnieje wysokie ryzyko spływania cieczy.**

PT: **Para protecção [dos organismos aquáticos/das plantas não visadas], não aplicar este produto em superfícies impermeáveis, como asfalto, betão, empedrados [ou linhas de caminho-de-ferro], nem em qualquer outra situação em que o risco de escorrimentos seja elevado.**

SK: **Z dôvodu ochrany vodných organizmov/necielených rastlín neaplikujte na nepriepustné povrchy, ako je asfalt, betón, dlažobné kocky, koľajnice a iné povrchy, pri ktorých je zvýšené riziko stekania vody.**

SL: **Zaradi zaščite vodnih organizmov/neciljnih rastlin ne uporabljati na neprepustnih površinah kot so asfalt, beton, tlak, železniški tiri in drugih površinah, kjer je velika nevarnost odtekanja.**

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FI: **(Vesieliöiden/muiden kuin torjuttavien kasvien) suojelemiseksi ei saa käyttää läpäisemättömillä pinnoilla, kuten asvaltilla, betonilla, katukivillä, (rautatiekiskoilla) ja muissa tilanteissa, joissa on suuri huuhtoutumisen vaara.**

SV: **För att skydda (vattenlevande organismer/andra växter än de man avser att bekämpa), använd inte denna produkt på hårdgjorda ytor såsom asfalt, betong, kullersten, (järnvägsspår) och andra ytor med hög risk för avrinning.**

SPe 5

ES: **Para proteger [las aves/los mamíferos silvestres], el producto debe incorporarse completamente al suelo; asegurarse de que se incorpora al suelo totalmente al final de los surcos.**

CS: **Za účelem ochrany ptáků/volně žijících savců musí být přípravek zcela zapraven do půdy; zajistěte, aby byl přípravek zcela zapraven do půdy také na konci výsevních nebo výsadbových řádků.**

DA: **For at beskytte [fugle/vilde pattedyr] skal produktet omhyggeligt graves ned i jorden. Sørg for, at produktet også er helt tildækket for enden af rækkerne.**

DE: **Zum Schutz von (Vögeln/wild lebenden Säugetieren) muss das Mittel vollständig in den Boden eingearbeitet werden; es ist sicherzustellen, dass das Mittel auch am Ende der Pflanz- bzw. Saatreihen vollständig in den Boden eingearbeitet wird.**

ET: **Lindude/metsloomade kaitsmiseks peab vahend täielikult mullaga ühinema; tagada vahendi täielik ühinemine ka ridade lõpus.**

EL: **Για να προστατέψετε [πουλιά/άγρια θηλαστικά] το προϊόν πρέπει να καλυφθεί πλήρως από το έδαφος. Βεβαιωθείτε πως το προϊόν έχει καλυφθεί πλήρως στις άκρες των αυλακιών.**

EN: **To protect birds/wild mammals the product must be entirely incorporated in the soil; ensure that the product is also fully incorporated at the end of rows.**

FR: **Pour protéger [les oiseaux/mammifères sauvages], le produit doit être entièrement incorporé dans le sol; s'assurer que le produit est également incorporé en bout de sillons.**

IT: **Per proteggere [gli uccelli/i mammiferi selvatici] il prodotto deve essere interamente incorporato nel terreno; assicurarsi che il prodotto sia completamente incorporato in fondo al solco.**

LV: **Lai aizsargātu putnus/savvaļas zīdītājus, augu aizsardzības līdzekli pilnībā iestrādāt augsnē; nodrošināt līdzekļa pilnīgu iestrādi augsnē arī kultūraugu rindu galos.**

LT: **Siekiant apsaugoti paukščius/laukinius gyvūnus būtina produktą visiškai įterpti į dirvą, užtikrinti, kad produktas būtų visiškai įterptas vagų gale.**

HU: **A madarak/vadon élő emlősök védelme érdekében a terméket teljes egészében be kell dolgozni a talajba; ügyeljen arra, hogy az anyag a sorok végén is teljes egészében be legyen dolgozva.**

MT: **Sabiex tipproteġi għasafar/mammiferi selvaġġi l-prodott għandu jkun inkorporat għal kollox fil-ħamrija; żgura li l-prodott ikun ukoll inkorporat għal kollox f'tarf ir-raddi.**

NL: **Om [de vogels/de wilde zoogdieren] te beschermen moet het product volledig in de bodem worden ondergewerkt; zorg ervoor dat het product ook aan het voorend is ondergewerkt.**

PL: **W celu ochrony ptaków/dzikich ssaków produkt musi być całkowicie przykryty glebą; zapewnić że produkt jest również całkowicie przykryty na końcach rzędów.**

PT: **Para protecção [das aves/dos mamíferos selvagens], incorporar totalmente o produto no solo, incluindo no final dos sulcos.**

SK: **Z dôvodu ochrany vtákov/divo žijúcich cicavcov sa musí všetok prípravok zakryť pôdou. Presvedčte sa, či je prípravok dobre zakrytý pôdou aj na konci brázdy.**

SL: **Zaradi zaščite ptic/divjih vrst sesalcev je treba sredstvo popolnoma vdelati v tla; zagotoviti, da je sredstvo v celoti vdelano v tla tudi na koncih vrst.**

FI: **(Lintujen/luonnonvaraisten nisäkkäiden) suojelemiseksi tuote on sekoitettava maaperään; varmistettava, että tuote sekoittuu maaperään täysin myös vakojen päässä.**

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SV: **För att skydda (fåglar/vilda däggdjur) måste produkten nedmyllas helt och hållet i jorden; se till att produkten även nedmyllas helt i slutet avraderna.**

SPe 6

ES: **Para proteger [las aves/los mamíferos silvestres], recójase todo derrame accidental.**

CS: **Za účelem ochrany ptáků/volně žijících savců odstraňte rozsypaný nebo rozlitý přípravek.**

DA: **For at beskytte [fugle/vilde pattedyr] skal alt spildt produkt fjernes.**

DE: **Zum Schutz von (Vögeln/wild lebenden Säugetieren) muss das verschüttete Mittel beseitigt werden.**

ET: **Lindude/metsloomade kaitsmiseks kõrvaldada mahavalgunud vahend.**

EL: **Για να προστατέψετε [πουλιά/άγρια ζώα] μαζέψτε όσο προϊόν έχει χυθεί κατά λάθος.**

EN: **To protect birds/wild mammals remove spillages.**

FR: **Pour protéger [les oiseaux/les mammifères sauvages], récupérer tout produit accidentellement répandu.**

IT: **Per proteggere [gli uccelli/i mammiferi selvatici] recuperare il prodotto fuoriuscito accidentalmente.**

LV: **Lai aizsargātu putnus/savvaļas zīdītājus, novērst izšļakstīšanos.**

LT: **Siekiant apsaugoti paukščius/laukinius gyvūnus pašalinti pabiras ar išsiliejusį produktą.**

HU: **A madarak/vadon élő emlősök védelme érdekében távolítsa el a véletlenül kiömlött anyagot.**

MT: **Neħħi kull tixrid biex tipproteġi l-għasafar/mammiferi selvaġġi.**

NL: **Om [de vogels/de wilde zoogdieren] te beschermen moet u gemorst product verwijderen.**

PL: **W celu ochrony ptaków/dzikich ssaków usuwać rozlany/rozsypany produkt.**

PT: **Para protecção [das aves/dos mamíferos selvagens], recolher todo o produto derramado.**

SK: **Z dôvodu ochrany vtákov/divo žijúcich cicavcov odstráňte náhodne rozsypaný prípravok.**

SL: **Zaradi zaščite ptic/divjih vrst sesalcev odstraniti razsuto sredstvo.**

FI: **Lintujen/luonnonvaraisten nisäkkäiden) suojelemiseksi ympäristöön vahingossa levinnyt tuote poistettava.**

SV: **För att skydda (fåglar/vilda däggdjur), avlägsna spill.**

SPe 7

ES: **No aplicar durante el período de reproducción de las aves.**

CS: **Neaplikujte v době hnízdění ptáků.**

DA: **Må ikke anvendes i fuglenes yngletid.**

DE: **Nicht während der Vogelbrutzeit anwenden.**

ET: **Mitte kasutada lindude pesitsusperioodil.**

EL: **Να μην χρησιμοποιείται κατά την περίοδο αναπαραγωγής των πουλιών.**

EN: **Do not apply during the bird breeding period.**

FR: **Ne pas appliquer durant la période de reproduction des oiseaux.**

IT: **Non applicare durante il periodo di riproduzione degli uccelli.**

LV: **Nelietot putnu vairošanās periodā.**

LT: **Nenaudoti paukščių veisimosi laikotarpiu.**

HU: **A madarak költési időszaka alatt nem alkalmazható.**

MT: **Tapplikax matul it-tberrik ta' l-għasafar.**

NL: **Niet gebruiken tijdens de vogelbroedperiode.**

PL: **Nie stosować w okresie rozrodczym ptaków.**

PT: **Não aplicar este produto durante o período de reprodução das aves.**

SK: **Neaplikujte v čase rozmnožovania vtákov.**

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SL: **Ne tretirati v času valjenja ptic.**

FI: **Ei saa käyttää lintujen lisääntymisaikaan.**

SV: **Använd inte denna produkt under fåglarnas häckningsperiod.**

SPe 8

ES: **Peligroso para las abejas./Para proteger las abejas y otros insectos polinizadores, no aplicar durante la floración de los cultivos./No utilizar donde haya abejas en pecoreo activo./Retírense o cúbranse las colmenas durante el tratamiento y durante** (indíquese el tiempo) **después del mismo./No aplicar cuando las malas hierbas estén en floración./Elimínense las malas hierbas antes de su floración./No aplicar antes de** (indíquese el tiempo)**.**

CS: **Nebezpečný pro včely./Za účelem ochrany včel a jiných hmyzích opylovačů neaplikujte na kvetoucí plodiny./Neaplikujte na místech, na nichž jsou včely aktivní při vyhledávání potravy./Úly musí být během aplikace a po aplikaci** (uveďte dobu) **přemístěny nebo zakryty./Neaplikujte, jestliže se na pozemku vyskytují kvetoucí plevele./Plevele odstraňte před jejich kvetením./ Neaplikujte před** (uveďte dobu)**.**

DA: **Farligt for bier./For at beskytte bier og andre bestøvende insekter må dette produkt ikke anvendes i blomstrende afgrøder./Må ikke anvendes i biernes flyvetid./Tildæk eller flyt bikuber i behandlingsperioden og i** (nævn antal timer/dage) **efter behandlingen./Må ikke anvendes i nærheden af blomstrende ukrudt./Fjern ukrudt inden blomstring./Må ikke anvendes inden** (tidspunkt)**.**

DE: **Bienengefährlich./Zum Schutz von Bienen und anderen bestäubenden Insekten nicht auf blühende Kulturen aufbringen./Nicht an Stellen anwenden, an denen Bienen aktiv auf Futtersuche sind./Bienenstöcke müssen während der Anwendung und für** (Angabe der Zeit) **nach der Behandlung entfernt oder abgedeckt werden./Nicht in Anwesenheit von blühenden Unkräutern anwenden./Unkräuter müssen vor dem Blühen entfernt werden./ Nicht vor** (Angabe der Zeit) **anwenden.**

ET: **Mesilastele ohtlik/Mesilaste ning muude tolmlevate putukate kaitsmiseks mitte kasutada põllumajanduskultuuride õitsemise ajal/Mitte kasutada aktiivsel korjealal/Kasutamise ajaks ning** (määratleda aeg) **peale töötlemist tarud eemaldada või katta kinn/ Õitseva umbrohu olemasolu korral mitre kasutada/Umbrohi enne õitsemist eemaldada/Mitte kasutada enne** (määratleda aeg)**.**

EL: **Επικίνδυνο για τις μέλισσες. Για να προστατέψετε τις μέλισσες και άλλα έντομα επικονίασης μην χρησιμοποιείτε το προϊόν σε καλλιέργειες κατά την ανθοφορία./Μην χρησιμοποιείτε το προϊόν κατά την περίοδο που οι μέλισσες συλλέγουν γύρη./Απομακρύνετε ή καλύψτε τις κυψέλες κατά τη χρήση του προϊόντος και επί** (αναφέρατε το χρόνο) **μετά τη χρήση./Μην χρησιμοποιείτε το προϊόν κατά την περίοδο ανθοφορίας ζιζανίων./Απομακρύνετε τα ζιζάνια πριν από την ανθοφορία./Μην το χρησιμοποιείτε πριν** (αναφέρατε το χρόνο)**.**

EN: **Dangerous to bees./To protect bees and other pollinating insects do not apply to crop plants when in flower./Do not use where bees are actively foraging./Remove or cover beehives during application and for** (state time) **after treatment./Do not apply when flowering weeds are present./Remove weeds before flowering./Do not apply before** (state time)**.**

FR: **Dangereux pour les abeilles./Pour protéger les abeilles et autres insectes pollinisateurs, ne pas appliquer durant la floraison./Ne pas utiliser en présence d'abeilles./Retirer ou couvrir les ruches pendant l'application et** (indiquer la période) **après traitement./Ne pas appliquer lorsque des adventices en fleur sont présentes./ Enlever les adventices avant leur floraison./Ne pas appliquer avant** (indiquer la date)**.**

IT: **Pericoloso per le api./Per proteggere le api e altri insetti impollinatori non applicare alle colture al momento dellafioritura./Non utilizzare quando le api sono in attività./Rimuovere o coprire gli alveari durante l'applicazione e per** (indicare il periodo) **dopo il trattamento./Non applicare in presenza di piante infestanti in fiore./Eliminare le piante infestanti prima della fioritura./Non applicare prima di** (indicare il periodo)**.**

LV: **Bīstams bitēm. Lai aizsargātu bites un citus apputeksnētājus, nelietot kultūraugu ziedēšanas laikā. Nelietot vietās, kur bites aktīvi meklē barību. Bišu stropus pārvietot vai pārsegt augu aizsardzības līdzekļa smidzināšanas laikā un …** (norāda uz cik

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ilgu laiku) **pēc smidzināšanas darba beigām. Nelietot platībās, kurās ir ziedošas nezāles. Apkarot nezāles pirms ziedēšanas. Nelietot pirms …** (norāda laiku)**.**

LT: **Pavojingas bitėms/Siekiant apsaugoti bites ir kitus apdulkinančius vabzdžius nenaudoti augalų žydėjimo metu/Nenaudoti bičių aktyvaus maitinimosi metu/Pašalinti ar uždengti bičių avilius purškimo metu ar** (nurodyti laiką) **po purškimo./Nenaudoti kai yra žydinčių piktžolių/Sunaikinti piktžoles iki jų žydėjimo/ Nenaudoti iki** (nurodyti laiką)**.**

HU: **Méhekre veszélyes/A méhek és egyéb beporzást végző rovarok védelme érdekében virágzási időszakban nem alkalmazható/ Méhek aktív táplálékszerzési időszaka idején nem alkalmazható/ Az alkalmazás idejére és a kezelés után** (megadott időszak) **ideig távolítsa el vagy fedje be a méhkaptárakat/Virágzó gyomnövények jelenléte esetén nem alkalmazható/Virágzás előtt távolítsa el a gyomnövényeket/**(megadott időpont) **előtt nem alkalmazható.**

MT: **Perikoluż għan-naħal/Sabiex tħares in-naħal u insetti oħra taddakra tapplikax fuq uċuħ tar-raba' meta jkunu bil-fjur/Tużax fejn in-naħal ikun qed jirgħa sew/Neħħi jew agħtti l-ġarar tan-naħal waqt l-applikazzjoni u għal** (speċifika l-ħin) **wara t-trattament/Tapplikax meta jkun hemm ħaxix ħażin bil-fjur/Neħħi l-ħaxix ħażin qabel ma jwarrad/Tapplikax qabel** (speċifika l-ħin)**.**

NL: **Gevaarlijk voor bijen./Om de bijen en andere bestuivende insecten te beschermen mag u dit product niet gebruiken op in bloei staande gewassen./Gebruik dit product niet op plaatsen waar bijen actief naar voedsel zoeken./Verwijder of bedek bijenkorven tijdens het gebruik van het product en gedurende** (geef de tijdsduur aan) **na de behandeling./Gebruik dit product niet in de buurt van in bloei staand onkruid./Verwijder onkruid voordat het bloeit./Gebruik dit product niet vóór** (geef de datum of de periode aan)**.**

PL: **[Niebezpieczne dla pszczół/W celu ochrony pszczół i innych owadów zapylających nie stosować na rośliny uprawne w czasie kwitnienia/Nie używać w miejscach gdzie pszczoły mają pożytek/ Usuwać lub przykrywać ule podczas zabiegu i przez** (określić czas) **po zabiegu/Nie stosować kiedy występują kwitnące chwasty/ Usuwać chwasty przed kwitnieniem/Nie stosować przed** (określić czas)**.**

PT: **Perigoso para as abelhas./Para protecção das abelhas e de outros insectos polinizadores, não aplicar este produto durante a floração das culturas./Não utilizar este produto durante o período de presença das abelhas nos campos./Remover ou cobrir as colmeias durante a aplicação do produto e durante** (indicar o período) **após o tratamento./Não aplicar este produto na presença de infestantes em floração./Remover as infestantes antes da floração./Não aplicar antes de** (critério temporal a precisar)**.**

SK: **Nebezpečný pre včely/Z dôvodu ochrany včiel a iného opeľujúceho hmyzu neaplikujte na plodiny v čase kvetu/Nepoužívajte, keď sa v okolí nachádzajú včely/Počas aplikácie a** (uveďte čas) **po aplikácii úle prikryte alebo presuňte na iné miesto/ Neaplikujte, keď sa v okolí nachádzajú kvitnúce buriny/ Odstráňte buriny pred kvitnutím/Neaplikujte pred** (uveďte čas)**.**

SL: **Nevarno za čebele./Zaradi zaščite čebel in drugih žuželk opraševalcev ne tretirati rastlin med cvetenjem./Ne tretirati v času paše čebel./Med tretiranjem in** (navede se časovno obdobje) **po tretiranju odstraniti ali pokriti čebelje panje./Ne tretirati v prisotnosti cvetočega plevela./Odstraniti plevel pred cvetenjem./ Ne tretirati pred** (navede se časovno obdobje)**.**

FI: **Vaarallista mehiläisille./Mehiläisten ja muiden pölyttävien hyönteisten suojelemiseksi ei saa käyttää viljelykasvien kukinta-aikaan./Ei saa käyttää aikana, jolloin mehiläiset lentävät aktiivisesti./Mehiläispesät poistettava tai suojattava levittämisen ajaksi ja** (aika) **ajaksi käsittelyn jälkeen./Ei saa käyttää, jos alueella on kukkivia rikkakasveja./Poista rikkakasvit ennen kukinnan alkua./ Ei saa käyttää ennen** (aika)**.**

SV: **Farligt för bin./För att skydda bin och andra pollinerande insekter, använd inte denna produkt på blommande gröda./Får inte användas där bin aktivt söker efter föda./Avlägsna eller täck över bikupor under behandling och under** (ange tidsperiod) **efter behandling./Använd inte denna produkt då det finns blommande ogräs./Avlägsna ogräs före blomning./Använd inte denna produkt före** (ange tidsperiod)**.**

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2.3. *Safety precautions related to good agricultural practice*

SPa 1

ES: **Para evitar la aparición de resistencias, no aplicar este producto ni ningún otro que contenga** (indíquese la sustancia activa o la clase de sustancias, según corresponda) **más de** (indíquese el número de aplicaciones o el plazo)**.**

CS: **K zabránění vzniku rezistence neaplikujte tento ani žádný jiný přípravek, který obsahuje** (uveďte účinnou látku nebo popřípadě skupinu účinných látek) **více/déle než** (uveďte četnost aplikací nebo lhůtu)**.**

DA: **For at undgå udviklingen af resistens må dette produkt eller andre produkter, der indeholder** (angiv aktivstof eller gruppe af aktivstoffer)**, kun anvendes/ikke anvendes mere end** (i tidsperioden eller antal gange)**.**

DE: **Zur Vermeidung einer Resistenzbildung darf dieses oder irgendein anderes Mittel, welches** (entsprechende Benennung des Wirkstoffes oder der Wirkstoffgruppe) **enthält, nicht mehr als** (Angabe der Häufigkeit oder der Zeitspanne) **ausgebracht werden.**

ET: **Resistentsuse tekkimise vältimiseks seda või ükskõik millist muud vahendit mitte kasutada rohkem kui** (kasutamiskordade arv või määratletav periood)**, mis sisaldab** (määratleda vastavalt toimeaine või ainete liik)**.**

EL: **Προκειμένου να μην αναπτυχθεί αντίσταση μην χρησιμοποιείτε αυτό ή οποιοδήποτε άλλο προϊόν που περιέχει** (προσδιορίστε τη δραστική ουσία ή την κατηγορία των ουσιών αναλόγως) **περισσότερο από** (να προσδιοριστεί η συχνότητα) **φορές.**

EN: **To avoid the build-up of resistance do not apply this or any other product containing** (identify active substance or class of substances, as appropriate) **more than** (number of applications or time period to be specified)**.**

FR: **Pour éviter le développement de résistances, ne pas appliquer ce produit ou tout autre contenant** (préciser la substance ou la famille de substances selon le cas) **plus de** (nombre d'applications ou durée à préciser)**.**

IT: **Per evitare l'insorgenza diresistenza non applicare questo o altri prodotti contenenti** (indicare la sostanza attiva o la classe di sostanze, a seconda del caso) **più di** (numero di applicazioni o durata da precisare)**.**

LV: **Lai izvairītos no rezistences veidošanās, nelietot šo vai jebkuru citu augu aizsardzības līdzekli, kurš satur …** (norāda darbīgās vielas vai darbīgo vielu grupas nosaukumu) **vairāk nekā …** (norāda apstrāžu skaitu vai laiku)**.**

LT: **Siekiant išvengti atsparumo išsivystymo, nenaudoti šio produkto ar kito produkto, kurio sudėtyje yra** (nurodyti veikliąją medžiagą ar medžiagų grupę) **dažniau kaip** (nurodyti apdorojimų skaičių arba laikotarpį)**.**

HU: **Rezisztancia kialakulásának elkerülése érdekében ezt vagy** (a megfelelő hatóanyag vagy anyagcsoport)**-ot tartalmazó bármilyen más készítményt ne használja** (az előírt kezelésszám vagy időszakok)**-nál többször/hosszabb ideig.**

MT: **Sabiex tevita li tinbena reżistenza tapplikax dan jew xi prodott ieħor li jkun fih** (identifika s-sustanza jew klassi ta' sustanzi attivi kif imiss) **aktar minn** (l-għadd ta' applikazzjonijiet jew il-ħin li għandu jkun speċifikat)

NL: **Om resistentieopbouw te voorkomen mag u dit product of andere producten die** (geef naar gelang van het geval de naam van de werkzame stof of van de categorie werkzame stoffen) **bevatten, niet vaker gebruiken dan** (geef het aantal toepassingen aan)**/niet langer gebruiken dan** (geef de tijdsduur aan)**.**

PL: **W celu uniknięcia powstawania odporności nie stosować tego lub żadnego innego produktu zawierającego** (określić substancję aktywną lub klasę substancji, kiedy dotyczy) **nie dłużej niż** (określony czas)**/nie częściej niż** (określona częstotliwość)**.**

PT: **Para evitar o desenvolvimento de resistências, não aplicar este produto ou qualquer outro que contenha** (indicar, consoante o caso, a substância activa ou a família de substâncias activas) **mais de** (número ou período de aplicações a precisar)**.**

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SK: **Na zabránenie vzniku rezistencie neaplikujte tento alebo iný prípravok obsahujúci** (uveďte účinnú látku alebo skupinu látok) **dlhšie ako** (upresnite počet aplikácií alebo časový úsek)**.**

SL: **Zaradi preprečevanja nastanka odpornosti ne uporabljati tega ali drugih sredstev, ki vsebujejo** (navede se aktivno snov ali skupino aktivnih snovi) **več kot** (navede se časovno obdobje ali število tretiranj)**.**

FI: **Resistenssin kehittymisen estämiseksi ei saa käyttää tätä tai mitä tahansa muuta tuotetta, joka sisältää** (tapauksen mukaan tehoaine tai aineluokka)**, käyttöä useammin** (käyttötiheys)**.**

SV: **För att undvika utveckling av resistens använd inte denna produkt eller andra produkter innehållande** (ange verksamt ämne eller grupp av ämnen) **mer än** (ange antal behandlingar eller tidsperiod)**.**

2.4. *Specific safety precautions for rodenticides (SPr)*

SPr 1

ES: **Los cebos deben colocarse de forma que se evite el riesgo de ingestión por otros animales. Asegurar los cebos de manera que los roedores no puedan llevárselos.**

CS: **Nástrahy musí být kladeny tak, aby se minimalizovalo riziko požití jinými zvířaty. Zabezpečte nástrahy, aby nemohly být hlodavci rozvlékány.**

DA: **Produktet skal anbringes på en sådan måde, at risikoen for, at andre dyr kan indtage produktet, formindskes mest muligt. F. eks. ved at produktet anbringes inde i en kasse med små indgangshuller til gnaverne eller inde i gnavernes eget gangsystem. Pas på, at produkt i blokform ikke kan flyttes væk af de gnavere, der skal bekæmpes.**

DE: **Die Köder verdeckt und unzugänglich für andere Tiere ausbringen. Köder sichern, so dass ein Verschleppen durch Nagetiere nicht möglich ist.**

ET: **Peibutussööt tuleb ohutult ladustada selliselt, et minimeerida teiste loomade poolt tarbimise ohtu. Peibutussöödabriketid kindlustada selliselt, et närilised neid ära vedada ei saaks.**

EL: **Τα δολώματα θα πρέπει να τοποθετηθούν με τρόπο τέτοιο που να ελαχιστοποιηθεί η πιθανότητα να καταναλωθούν από άλλα ζώα. Ασφαλίστε τα δολώματα έτσι ώστε να μην μπορούν να τα παρασύρουν τα τρωκτικά.**

EN: **The baits must be securely deposited in a way so as to minimise the risk of consumption by other animals. Secure bait blocks so that they cannot be dragged away by rodents.**

FR: **Les appâts doivent être disposés de manière à minimiser le risque d'ingestion par d'autres animaux. Sécuriser les appâts afin qu'ils ne puissent pas être emmenés par les rongeurs.**

IT: **Le esche devono essere disposte in modo da minimizzare il rischio di ingerimento da parte di altri animali. Fissare le esche in modo che non possano essere trascinate via dai roditori.**

LV: **Ēsmu ejā ievietot tā, lai, tā nebūtu pieejama citiem dzīvniekiem. Ēsmu nostiprināt, lai grauzēji to nevarētu aizvilkt.**

LT: **Jaukas turi būti saugiai išdėstytas taip, kad sumažėtų rizika kitiems gyvūnams jį vartoti. Jauko blokai turi būti taip saugomi, kad graužikai negalėtų jų ištampyti.**

HU: **A csalétket úgy kell biztonságosan kihelyezni, hogy a lehető legkisebb legyen annak a veszélye, hogy abból más állatok is fogyasztanak. A csalétket úgy kell rögzíteni, hogy azt a rágcsálók ne hurcolhassák el.**

MT: **Il-lixki għandhom jitqegħdu hekk li jitnaqqas ir-riskju li jkunu mittiekla minn annimali oħrajn. Orbot il-blokki tal-lixka sew fejn ikunu biex ma' jiġux mkaxkra minn fuq il-post minn rodenti.**

NL: **De lokmiddelen moeten zo worden geplaatst dat het risico dat andere dieren ervan eten zoveel mogelijk wordt beperkt. Maak de blokjes stevig vast, zodat ze niet door de knaagdieren kunnen worden weggesleept.**

PL: **Przynęty muszą być rozłożone w taki sposób, aby zminimalizować ryzyko zjedzenia przez inne zwierzęta. Zabezpieczyć przynętę w ten sposób, aby nie mogła zostać wywleczona przez gryzonie.**

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PT: **Colocar os iscos de modo a minimizar o risco de ingestão por outros animais. Fixar os iscos, para que não possam ser arrastados pelos roedores.**

SK: **Návnady sa musia umiestniť tak, aby sa k nim nedostali iné zvieratá. Zabezpečte návnady tak, aby ich hlodavce nemohli odtiahnuť.**

SL: **Vabe je treba nastaviti varno, tako da je tveganje zaužitja za druge živali minimalno. Zavarovati vabe tako, da jih glodalci ne morejo raznesti.**

FI: **Syötit on sijoitettava siten, että ne eivät eiheuta riskiä muille eläimille. Syötit on kiinnitettävä siten, että jyrsijät eivät saa vietyä niitä mukanaan.**

SV: **Betena måste placeras så att andra djur inte kan förtära dem. Förankra betena så att de inte kan släpas iväg av gnagare.**

SPr 2

ES: **La zona tratada debe señalizarse durante el tratamiento. Debe advertirse del riesgo de intoxicación (primaria o secundaria) por el anticoagulante así como del antídoto correspondiente.**

CS: **Plocha určená košetření musí být během ošetřování označena. Je třeba upozornit na nebezpečí otravy (primární nebo sekundární) antikoagulantem a uvést protijed.**

DA: **Det behandlede område skal afmærkes i behandlingsperioden. Faren for forgiftning (primær eller sekundær) ved indtagelse af antikoaguleringsmidler, samt modgiften herfor, skal nævnes på opslag.**

DE: **Die zu behandelnde Fläche muss während der Behandlungszeit markiert sein. Die Gefahr der (primären oder sekundären) Vergiftung durch das Antikoagulans und dessen Gegenmittel sollte erwähnt werden.**

ET: **Käideldud ala tuleb käitlemisperioodiks märgistada. Antikoagulandi mürgituse (esmane või teisene) oht ning selle vastane antidoot peab olema ära mainitud.**

EL: **Η περιοχή στην οποία έχει χρησιμοποιηθεί το προϊόν πρέπει να έχει σημαδευτεί κατά την περίοδο χρήσης. Θα πρέπει να αναφέρεται ο κίνδυνος (πρωτογενούς ή δευτερογενούς) δηλητηρίασης από το αντιπηκτικό καθώς και το αντίδοτο σε περίπτωση δηλητηρίασης.**

EN: **Treatment area must be marked during the treatment period. The danger from being poisoned (primary or secondary) by the anticoagulant and the antidote against it should be mentioned.**

FR: **La zone de traitement doit faire l'objet d'un marquage pendant la période de traitement. Le risque d'empoisonnement (primaire ou secondaire) par l'anticoagulant, ainsi que son antidote doivent être mentionnés.**

IT: **Durante il trattamento la zona interessata deve essere chiaramente segnalata. Il pericolo di avvelenamento (primario o secondario) dovuto all'anticoagulante deve essere evidenziato assieme al relativo antidoto.**

LV: **Apstrādes laikā apstrādājamo platību marķēt. Norādīt saindēšanās (primārās vai sekundārās) apdraudējumu ar antikoagulantu un tā antidotu.**

LT: **Apdorojami plotai turi būti pažymėti visą apdorojimo laikotarpį. Turi būti paminėtas apsinuodijimo antikoaguliantu pavojus (tiesioginis ar netiesioginis) ir nurodytas priešnuodis.**

HU: **A kezelt területet a kezelés ideje alatt külön jelöléssel kell megjelölni. A jelölésben fel kell hívni a figyelmet a véralvadásgátló szertől való mérgeződés veszélyére és annak ellenszerére.**

MT: **Il-post ittrattat għandu jkun immarkat filwaqt li jkun qiegħed jiġi ittrattat. Għandu jissemma l-periklu ta' avvelenament (primarju jew sekondarju) bl-antikoagulant u l-antitodu tiegħu.**

NL: **De behandelde zone moet tijdens de verdelgingsperiode worden gemarkeerd. Het risico van een (primaire of secundaire) vergiftiging door het antistollingsmiddel moet worden vermeld, alsmede het tegengif.**

PL: **Obszar poddany zabiegowi musi być oznakowany podczas zabiegu. Niebezpieczeństwo zatrucia (pierwotnego lub wtórnego) antykoagulantem i antidotum powinno być wyszczególnione.**

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PT: **Durante o período de tratamento, marcar a zona, com menção ao perigo de envenenamento (primário ou secundário) pelo anticoagulante e indicação do antídoto deste último.**

SK: **Ošetrovaná plocha sa počas ošetrenia musí označiť. Musí sa uviesť nebezpečenstvo možnej otravy (primárnej alebo sekundárnej) antikoagulantami a protilátky.**

SL: **Tretirano območje je treba v času tretiranja označiti. Navesti je treba nevarnost zastrupitve (neposredne ali posredne) z antikoagulanti in ustrezne antidote.**

FI: **Käsiteltävä alue on merkittävä käsittelyaikana. Antikoagulantin aiheuttama myrkytysvaara (primaarinen tai sekundaarinen) ja vasta-aine mainittava.**

SV: **Det behandlade området skall markeras under behandlingsperioden. Faran för förgiftning (primär eller sekundär) av antikoagulanten samt motgift skall anges.**

SPr 3

ES: **Durante el tratamiento, los roedores muertos deben retirarse diariamente de la zona tratada. No tirarlos en cubos de basura ni en vertederos.**

CS: **Mrtvé hlodavce během doby použití přípravku denně odstraňujte. Neodkládejte je do nádob na odpadky ani na smetiště.**

DA: **Døde gnavere skal fjernes fra behandlingsområdet hver dag. Anbring ikke de døde gnavere i åbne affaldsbeholdere.**

DE: **Tote Nager während der Einsatzperiode täglich entfernen. Nicht in Müllbehältern oder auf Müllkippen entsorgen.**

ET: **Surnud närilised tuleb eemaldada käitlemisalalt käitlemise ajal iga päev. Mitte panna prügikastidesse või prügi mahapaneku kohtadesse.**

EL: **Τα νεκρά τρωκτικά πρέπει να απομακρύνονται καθημερινά από την περιοχή χρήσης σε όλη τη διάρκεια χρησιμοποίησης του προϊόντος. Να μην τοποθετούνται σε κάδους απορριμμάτων ούτε σε σακούλες σκουπιδιών.**

EN: **Dead rodents must be removed from the treatment area each day during treatment. Do not place in refuse bins or on rubbish tips.**

FR: **Les rongeurs morts doivent être retirés quotidiennement de la zone de traitement pendant toute la période du traitement. Ne pas les jeter dans les poubelles ni les décharges.**

IT: **I roditori morti devono essere rimossi quotidianamente dalla zona del trattamento per tutta la durata dello stesso e non devono essere gettati nei rifiuti o nelle discariche.**

LV: **Apstrādes laikā beigtos grauzējus no apstrādātās platības aizvākt katru dienu. Neizmest tos atkritumu tvertnēs vai kaudzēs.**

LT: **Žuvę graužikai turi būti surenkami iš apdoroto ploto kiekvieną dieną viso naikinimo metu. Nemesti i šiukšlių dėžes arba sąvartynus.**

HU: **Az elhullott rágcsálókat a kezelés alatt naponta el kell távolítani a kezelt területről. A tetemeket tilos hulladéktartályban vagy hulladéklerakóban elhelyezni.**

MT: **Għandhom jitneħħew kuljum ir-rodenti mejta mill-post ittrattat. Tarmihomx f'kontenituri taż-żibel jew fuq il-miżbliet.**

NL: **Tijdens de verdelgingsperiode moeten de knaagdieren elke dag uit de behandelde zone worden verwijderd. Gooi ze niet in vuilnisbakken of op storten.**

PL: **Martwe gryzonie usuwać z obszaru poddanego zabiegowi każdego dnia. Nie wyrzucać do pojemników na śmieci i nie wywozić na wysypiska śmieci.**

PT: **Durante o período de tratamento, remover diariamente os roedores mortos da zona de tratamento, mas sem os deitar ao lixo ou depositar em lixeiras.**

SK: **Mŕtve hlodavce treba z ošetrovanej plochy každý deň odstrániť. Nehádžte ich do odpadových nádob alebo na smetisko.**

SL: **Poginule glodalce je treba odstraniti s tretiranega območja sproti, vsak dan v času tretiranja, vendar ne v zabojnike za odpadke ali odlagališča smeti.**

FI: **Kuolleet jyrsijät on kerättävä käsittelyaikana alueelta päivittäin. Niitä ei saa heittää jätesäiliöihin tai kaatopaikoille.**

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SV: **Döda gnagare skall tas bort från behandlingsområdet varje dag under behandlingen. Får inte läggas i soptunnor eller på soptipp..**

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3. **Attribution criteria for standard phrases for specific safety precautions**

3.1. *INTRODUCTION*

In general, plant-protection products are only authorised for those specified uses, which are acceptable on the basis of an assessment according to the uniform principles laid down in Annex VI of this Directive.

As far as applicable, the specific safety precautions should reflect the results of such assessments according to the uniform principles and should be applied in particular in those cases where risk-mitigation measures are necessary to prevent unacceptable effects.

3.2. *Attribution criteria for standard phrases for safety precautions for operators*

SPo 1

After contact with skin, first remove product with a dry cloth and then wash the skin with plenty of water.

The phrase shall be assigned for plant-protection products containing ingredients which may react violently with water, such as cyanide salts or aluminium phosphide.

SPo 2

Wash all protective clothing after use.

The phrase is recommended when protective clothing is required to protect operators. It is obligatory for all plant-protection products classified as T or T+.

SPo 3

After igniting the product, do not inhale smoke and leave the treated area immediately.

The phrase may be assigned to plant-protection products used for fumigation in cases where the use of a respiratory mask is not warranted.

SPo 4

The container must be opened outdoors and in dry conditions.

The phrase should be assigned to plant-protection products containing active substances which may react violently with water or damp air, such as aluminium phosphide, or which may cause spontaneous combustion, such as (alkylenebis-) dithiocarbamates. This phrase may also be assigned to volatile products classified with R20, 23 or 26. Expert judgement must be applied in individual cases, to assess whether the properties of the preparation and the packaging are such as to cause harm to the operator.

SPo 5

Ventilate treated areas/greenhouses thoroughly/*time to be specified*/until spray has dried before re-entry.

The phrase may be assigned to plant-protection products used in greenhouses or other confined spaces, such as stores.

3.3. *Attribution criteria for standard phrases for safety precautions for the environment*

SPe 1

To protect groundwater/soil organisms do not apply this or any other product containing *(identify active substance or class of substances, as appropriate)* **more than** *(time period or frequency to be specified)***.**

The phrase shall be assigned to plant-protection products for which an evaluation according to the uniform principles shows for one or more of the labelled uses that risk-mitigation measures are necessary to avoid accumulation in soil, effects on earthworms or other soil-dwelling organisms or soil microflora and/or contamination of groundwater.

SPe 2

To protect groundwater/effects on aquatic organisms do not apply to *(soil type or situation to be specified)* **soils.**

The phrase may be assigned as a risk-mitigation measure to avoid any potential contamination of groundwater or surface water under vulnerable

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conditions (e.g. associated to soil type, topography or for drained soils), if an evaluation according to the uniform principles shows for one or more of the labelled uses that risk-mitigation measures are necessary to avoid unacceptable effects.

SPe 3

To protect aquatic organisms/non-target plants/non-target arthropods/insects respect an unsprayed buffer zone of *(distance to be specified)* **to non-agricultural land/surface water bodies.**

The phrase shall be assigned to protect non-target plants, non-target arthropods and/or aquatic organisms, if an evaluation according to the uniform principles shows for one or more of the labelled uses that risk-mitigation measures are necessary to avoid unacceptable effects.

SPe 4

To protect aquatic organisms/non-target plants do not apply on impermeable surfaces such as asphalt, concrete, cobblestones, railway tracks and other situations with a high risk of run-off.

Depending on the use pattern of the plant-protection product, Member States may assign the phrase to mitigate the risk of run-off in order to protect aquatic organisms or non-target plants.

SPe 5

To protect birds/wild mammals the product must be entirely incorporated in the soil; ensure that the product is also fully incorporated at the end of rows.

The phrase shall be assigned to plant-protection products, such as granules or pellets, which must be incorporated to protect birds or wild mammals.

SPe 6

To protect birds/wild mammals remove spillages.

The phrase shall be assigned to plant-protection products, such as granules or pellets, to avoid uptake by birds or wild mammals. It is recommended for all solid formulations, which are used undiluted.

SPe 7

Do not apply during bird breeding period.

The phrase shall be assigned when an evaluation according to the uniform principles shows that for one or more of the labelled uses such a mitigation measure is necessary.

SPe 8

Dangerous to bees/To protect bees and pollinating insects do not apply to crop plants when in flower/Do not use where bees are actively foraging/Remove or cover beehives during application and for *(state time)* **after treatment/Do not apply when flowering weeds are present/Remove weeds before flowering/Do not apply before** *(state time)*

The phrase shall be assigned to plant-protection products for which an evaluation according to the uniform principles shows for one or more of the labelled uses that risk-mitigation measures must be applied to protect bees or other pollinating insects. Depending on the use pattern of the plant-protection product, and other relevant national regulatory provisions, Member States may select the appropriate phrasing to mitigate the risk to bees and other pollinating insects and their brood.

3.4. *Attribution criteria for standard phrases for safety precautions for good agricultural practice*

SPa 1

To avoid the build-up of resistance do not apply this or any other product containing *(identify active substance or class of substances, as appropriate)* **more than** *(number of applications or time period to be specified)***.**

The phrase shall be assigned when such a restriction appears necessary to limit the risk of development of resistance.

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3.5. *Attribution criteria for standard phrases for specific safety precautions for rodenticides*

SPr 1

The baits must be securely deposited in a way so as to minimise the risk of consumption by other animals. Secure bait blocks so that they cannot be dragged away by rodents.

To ensure compliance of operators the phrase should appear prominently on the label, so that misuse is excluded as far as possible.

SPr 2

Treatment area must be marked during the treatment period. The danger from being poisoned (primary or secondary) by the anticoagulant and the antidote against it should be mentioned.

The phrase should appear prominently on the label, so that accidental poisoning is excluded as far as possible.

SPr 3

Dead rodents must be removed from the treatment area each day during treatment. Do not place in refuse bins or on rubbish tips.

To avoid secondary poisoning of animals the phrase shall be assigned to all rodenticides containing anticoagulants as active substances.

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ANNEX VI

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PART I

UNIFORM PRINCIPLES FOR EVALUATION AND AUTHORISATION OF CHEMICAL PLANT PROTECTION PRODUCTS

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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, results 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.

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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 ITALICly 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 judgements 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 harzards 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 conditions under which the plant protection product may

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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 Member 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 underestimating 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 priciples**

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,

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— 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,

— 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 a 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 them;

(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.

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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 2.1.1 will be carried out in relation to the information supplied for the tank mix.

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 the 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, a 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,

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— 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,

— 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,

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— 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 the case of post-harvest uses,

— nature of the 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.

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 a 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 the 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.

(*) 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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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 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.

As long as there is no validated Community calculation model, Member States shall base their evaluation especially on the results of mobility and persistance 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;

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(vii) where relevant, monitoring data on the presence or absence of the active substance and relevant metabolites, degradation or reaction products 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; such monitoring data shall be interpreted in a consistent scientific way.

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;

(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;

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(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 to the same residues;

(b) This evaluation will include:

(i) the fate and distribution, including persistence and bioconcentration, 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;

(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 non-observable effects of concentration (NOEC) expressed on an active substance basis and the estimated exposure expressed in mg/kg body weight.

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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 they 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 exptected 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;

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(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, 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 on 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.

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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,

— 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 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 lethal and sublethal effects,

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

(iii) a calculation of the actue 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 of 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.

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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.

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.

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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.

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 above.

   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 neutralization of the adverse effects of the product if it is accidentally dispersed, and

([1]) OJ L 206, 29. 7. 1978, p. 13. Directive as last amended by Directive 92/32/EEC (OJ L 154, 5. 6. 1992, p. 1).

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— 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 where the advantages of the use of the plant protection product under the proposed conditions of use outweight 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.

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 co-operation with the applicant, measures to improve the performance of the plant protection product, and/or

(b) define, where possible, in close co-operation 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 applicants of any measures identified under (a) or (b) and shall invite applicants to provide any supplementary data and information necessary to demonstrate peformance 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

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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 to 2.1.4.

Where proposed label claims include recommendations for use of the preparation with specified plant protection products or adjuvants as a tank mix, 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.

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 products 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.

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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 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 (sixth special directive within the meaning of Article 16 (2) of Directive 89/39/EEC) [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. 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.

[1] OJ L 327, 3. 12. 1980, p. 8. Directive as last amended by Directive 88/642/EEC (OJ L 356, 24. 12. 1988, p. 74).

[2] OJ L 196, 26. 7. 1990, p. 1. Directive as amended by Directive 97/42/EC (OJ L 179, 8. 7. 1997, p. 4).

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2.4.2.2. Where no Community maximum residue limit (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 procedure 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.

Taking into account all registered uses, the proposed use cannot be authorized if the best possible estimate of dietary exposure exceeds the 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.

(*) 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 orgin ([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 feeding-stuffs ([6]).

([1]) OJ L 340, 9. 12. 1976, p. 26. Directive as last amended by Directive 97/41/EC (OJ L 184, 12. 7. 1997, p. 33).

([2]) OJ L 221, 7. 8. 1986, p. 37. Directive as last amended by Directive 97/41/EC (OJ L 184, 12. 7. 1997, p. 33).

([3]) OJ L 221, 7. 8. 1986, p. 43. Directive as last amended by Directive 97/41/EC (OJ L 184, 12. 7. 1997, p. 33).

([4]) OJ L 224, 18. 8. 1990, p. 1. Regulation as last amended by Commission Regulation (EC) No 749/97 (OJ L 110, 26. 4. 1997, p. 24).

([5]) OJ L 350, 14. 12. 1990, p. 71. Directive as amended by Directive 97/41/EC (OJ L 184, 12. 7. 1997, p. 33).

([6]) OJ L 66, 13. 3. 1991, p. 16.

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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 non-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. No authorization shall be granted if the concentration of the active substance or of relevant metabolites, degradation or reaction products in groundwater, may be expected to exceed, as a result of use of the plant protection product under the proposed conditions of use, the lower of the following limit values:

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

(ii) the maximum concentration 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

unless it is scientifically demonstrated that under relevant field conditions the lower concentration is not exceeded.

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 the 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 ([2]), 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.

([1]) OJ L 229, 30. 8. 1980, p. 11. Directive as last amended by Directive 91/692/EEC (OJ L 377, 31. 12. 1991, p. 48).
([2]) 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).

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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 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.

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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 level mg/kg	Difference mg/kg	Difference in %
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 level mg/kg	Difference mg/kg	Difference in %
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;

(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	LMR × 0,5

2.7. *Physical and chemical properties*

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

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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 °C	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.

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PART II

UNIFORM PRINCIPLES FOR EVALUATION AND AUTHORISATION OF PLANT PROTECTION PRODUCTS CONTAINING MICRO-ORGANISMS

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A. **INTRODUCTION**

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

2. In evaluating applications for granting authorisations Member States shall:

   (a) — ensure that dossiers on microbial plant protection products supplied are in accordance with the requirements of Annex IIIB, at the latest at the time of finalisation 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 IIB data concerning the active substance consisting of micro-organisms (including viruses) in the plant protection product, submitted for the purpose of inclusion of the micro-organism 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 metabolites/toxins.

3. Where, in the specific principles on evaluation, reference is made to Annex IIB 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 granting authorisations for which the data gaps are such that it is not possible to finalise 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, the Member State 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 IIIB.

6. The judgements made by the competent authorities of the Member States during the evaluation and decision-making process must be based on scientific principles, preferably recognised at international level, and be made with the benefit of expert advice.

7. A microbial plant protection product may contain viable and non-viable micro-organisms (including viruses) and formulation substances. It may also contain relevant metabolites/toxins produced during growth, residues from the growth medium, and microbial contaminants. The micro-organism, relevant metabolites/toxins and the plant protection product with residual growth medium and microbial contaminants present must all be evaluated.

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8. Member States must take into account those guidance documents taken note of in the Standing Committee on the Food Chain and Animal Health (SCFCAH).

9. For genetically modified micro-organisms, Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms [1], must be taken into account. The evaluation completed in the framework of that Directive must be provided and taken into account.

10. Definitions and explanations of microbiological terms

Antibiosis: A relationship between two or more species in which one species is actively harmed (as by the production of toxins by the harming species).

Antigenic: Any substance that, as a result of coming in contact with appropriate cells, induces a state of sensitivity and/or immune responsiveness after a latent period (days to weeks) and which reacts in a demonstrable way with antibodies and/or immune cells of the sensitised subject in vivo or in vitro.

Antimicrobial: Antimicrobial agents or antimicrobial(s) refer to naturally occurring, semi-synthetic or synthetic substances that exhibit antimicrobial activity (kill or inhibit the growth of micro-organisms).

The term Antimicrobial(s) includes:

— antibiotics, which refer to substances produced by or derived from micro-organisms, and

— anticoccidials, which refer to substances that are active against coccidia, single cell protozoan parasites.

CFU: Colony-forming unit; one or more cells that grow to form a single visible colony.

Colonisation: Proliferation and persistence of a micro-organism in an environment, such as on external (skin) or internal body surfaces (intestine, lungs). For colonisation, the micro-organism should at least persist for a longer period than expected in a specific organ. The population of micro-organisms may decline but at a slower rate than normal clearance; it may be a steady population or it may be a growing population. Colonisation can be related to harmless and functional micro-organisms as well as to pathogenic micro-organisms. The possible occurrence of effects is not indicated.

Ecological niche: Unique environmental position occupied by a particular species, perceived in terms of actual physical space occupied and function performed within the community or ecosystem.

Host: An animal (including humans) or plant that harbours or nourishes another organism (parasite).

Host specificity: The range of different host-species that can be colonised by a microbial species or strain. A host-specific micro-organism colonises or has adverse effects on one or only a small number of different host-species. A non-host-specific micro-organism might colonise or might have adverse effects on a broad range of different host-species.

Infection: The introduction or entry of a pathogenic micro-organism into a susceptible host, whether or not it causes pathological effects or disease. The organism must enter the body of the host, usually the cells, and be able to reproduce to form new infective units. Simply ingesting a pathogen does not imply infection.

Infective: Capable of transmitting an infection.

Infectivity: The characteristics of a micro-organism that allow it to infect a susceptible host.

Invasion: The entry of a micro-organism into the host body (e.g. actual penetration of the integument, gut epithelial cells, etc.). ‘Primary invasiveness’ is a property of pathogenic micro-organisms.

[1] OJ L 106, 17.4.2001, p. 1. Directive as last amended by Regulation (EC) No 1830/2003 (OJ L 268, 18.10.2003, p. 24).

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Multiplication: Ability of a micro-organism to reproduce and increase in numbers during an infection.

Mycotoxin: A fungal toxin.

Non-viable micro-organism: A micro-organism that is not capable of replication or of transferring genetic material.

Non-viable residue: A residue that is not capable of replication or of transferring genetic material.

Pathogenicity: The ability of a micro-organism to cause disease and/or inflict damage on the host. Many pathogens cause disease by a combination of (i) toxicity and invasiveness or (ii) toxicity and colonising ability. However, some invasive pathogens cause disease that results from an abnormal reaction of the host's defence system.

Symbiosis: A type of interaction between organisms where one organism lives in intimate association with another, which is favourable for both organisms.

Viable micro-organism: A micro-organism that is capable of replication or of transferring genetic material.

Viable residue: A residue that is capable of replication or of transferring genetic material.

Viroid: Any of a class of infectious agents consisting of a small strand of RNA not associated with any protein. The RNA does not code for proteins and is not translated; it is replicated by host cell enzymes. Viroids are known to cause several plant diseases.

Virulence: Measurement of the degree of disease producing ability of a micro-organism as indicated by the severity of the disease produced. Measure of the dosage (inoculum size) required to cause a specific degree of pathogenicity. It is measured experimentally by the median lethal dose (LD_{50}) or median infective dose (ID_{50}).

B. **EVALUATION**

The objective of an evaluation is to identify and assess, on a scientific basis and until further experience is reached on a case-by-case basis, potential adverse effects on human and animal health and the environment of the use of a microbial plant protection product. The evaluation shall also be carried out in order to identify the need for risk management measures and to identify and recommend suitable measures.

Due to the ability of micro-organisms to replicate, there is a clear difference between chemicals and micro-organisms used as plant protection products. Hazards arising are not necessarily of the same nature as those presented by chemicals, especially in relation to the capacity of micro-organisms to persist and multiply in different environments. Moreover, micro-organisms consist of a wide range of different organisms, all with their own unique characteristics. These differences between micro-organisms should be taken into account in the evaluation.

The micro-organism in the plant protection product should ideally function as a cell factory working directly on the spot where the target organism is harmful. Thus understanding the mode of action is a crucial step in the evaluation process.

Micro-organisms may produce a range of different metabolites (e.g. bacterial toxins or mycotoxins) many of which may have toxicological significance, and one or more of which may be involved in the mode of action of the plant protection product. The characterisation and identification of relevant metabolites should be assessed and the toxicity of these metabolites should be addressed. Information on production and/or relevance of metabolites may be deduced from:

(a) toxicity studies,

(b) biological properties of the micro-organism,

(c) relationship to known plant, animal or human pathogens,

(d) mode of action,

(e) analytical methods.

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On the basis of this information, metabolites may be considered as possibly being relevant. Therefore potential exposure to these metabolites should be assessed, in order to decide on their relevance.

1. **General principles**

1.1. Having regard to current scientific and technical knowledge, Member States shall evaluate the information provided in accordance with the requirements of Annex IIB and IIIB and in particular:

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

(b) assess the performance in terms of efficacy and phytotoxicity/pathogenicity of the plant protection product for each use for which authorisation is sought.

1.2. The quality/methodology of tests, where there are no standardised test methods, must be evaluated and the following characteristics, when available, of the methods described must be assessed:

relevance; representativeness; sensitivity; specificity; reproducibility; interlaboratory validations; predictiveness.

1.3. 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 underestimating 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 must 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.

1.4. Member States shall evaluate each microbial plant protection product for which an application for authorisation is made in that Member State — the information evaluated for the micro-organism can be taken into account. Member States must take into account the fact that any co-formulants might have an impact on the characteristics of the plant protection product compared to the micro-organism.

1.5. In evaluating applications and granting authorisations Member States shall consider the proposed practical conditions of use and in particular the purpose of use, the dose, the manner, frequency and timing of applications, and the nature and composition of the plant protection product. Whenever possible Member States shall also take into account the principles of integrated pest control.

1.6. In the evaluation, Member States shall consider the agricultural, plant health or environmental (including climatic) conditions in the areas of use.

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

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

(b) be submitted to an evaluation as referred to in point 1.3.,

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

(d) be relevant to the conditions in the area of use,

(e) be supported with details indicating how the model calculates estimates provided, and explanations of all the

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inputs to the model and details of how they have been derived.

1.8. The data requirements, specified in Annex IIB and IIIB, contain guidance as to when and how certain information must be submitted and as to procedures that must be followed when preparing and evaluating a dossier. That guidance must be respected.

2. **Specific principles**

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

2.1. *Identity*

2.1.1. Identity of the micro-organism in the plant protection product

The identity of the micro-organism should be clearly established. It must be ensured that the appropriate data are provided to allow for checking the identity of the micro-organism at strain level in the plant protection product.

The identity of the micro-organism shall be evaluated on the strain level. Where the micro-organism is either a mutant or a genetically modified organism [1], the specific differences from other strains within the same species must be recorded. Occurrence of resting stages must be recorded.

The deposition of the strain at an internationally recognised culture collection must be checked.

2.1.2. Identity of the plant protection product

Member States shall evaluate the detailed quantitative and qualitative information provided on the composition of the plant protection product, such as that concerning the micro-organism (see above), relevant metabolites/toxins, residual growth medium, co-formulants and microbial contaminants present.

2.2. *Biological, physical, chemical, and technical properties*

2.2.1. Biological properties of the micro-organism in the plant protection product

2.2.1.1. The origin of the strain, where relevant, its natural habitat including indications on the natural background level, life cycle and the possibilities for survival, colonisation, reproduction and dispersal must be evaluated. Proliferation of indigenous micro-organisms should after a short growth period level off and continue as for the background micro-organisms.

2.2.1.2. The ability of micro-organisms to adapt to the environment must be evaluated. In particular, Member States must take account of the following principles:

(a) depending on the conditions (e.g. availability of substrates for growth and metabolism) micro-organisms can switch on or off the expression of given phenotypic traits;

(b) the microbial strains most adapted to the environment can survive and multiply better than the non-adapted strains. Adapted strains have a selective advantage and can form the majority within a population after a number of generations;

(c) the relatively rapid multiplication of micro-organisms leads to a higher frequency of mutations. If a mutation is promoting survival in the environment, the mutant strain can become dominant;

[1] See definition of ‘genetically modified’ in Directive 2001/18/EC.

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(d) the properties of viruses, in particular, can change rapidly, including their virulence.

Therefore, where appropriate, information on the genetic stability of the micro-organism under the environmental conditions of proposed use must be evaluated, as well as information on the micro-organism's capacity to transfer genetic material to other organisms and information on the stability of encoded traits.

2.2.1.3. The mode of action of the micro-organism should be evaluated in as much detail as appropriate. The possible role of metabolites/toxins for the mode of action should be evaluated and when identified, the minimal effective concentration for each active metabolite/toxin should be established. Information on mode of action can be a very valuable tool in identifying potential risks. Aspects to be considered in the evaluation, are:

(a) antibiosis,

(b) induction of plant resistance,

(c) interference with the virulence of a pathogenic target organism,

(d) endophytic growth,

(e) root colonisation,

(f) competition of ecological niche (e.g. nutrients, habitats),

(g) parasitisation,

(h) invertebrate pathogenicity.

2.2.1.4. In order to evaluate possible effects on non-target organisms, information on the micro-organism's host specificity must be evaluated, taking into account the characteristics and properties described in (a) and (b).

(a) The ability of a micro-organism to be pathogenic for non-target organisms (humans, animals, and other non-target organisms) must be assessed. Any relationship to known plant, animal or human pathogens that are species of the genus of the active and/or contaminating micro-organisms must be assessed.

(b) Pathogenicity as well as virulence is strongly related to the host-species (e.g. determined by body temperature, physiological environment) and to the host conditions (e.g. health condition, immune status). For example, multiplication in humans depends upon the ability of the micro-organism to grow at the body temperature of the host. Some micro-organisms can only grow and be metabolically active at temperatures far below or above human body temperature, and therefore can not be pathogenic for humans. However, the route of entry of the micro-organism into the host (oral, inhalation, skin/wound) can also be the critical factor. For example, a microbial species may cause a disease following entry via skin damage, but not via the oral route.

2.2.1.5. Many micro-organisms produce antibiosis substances that cause normal interferences in the microbial community. Resistance to antimicrobial agents of importance for human and veterinary medicine must be assessed. The possibility for transfer of genes that code for resistance to antimicrobial agents must be evaluated.

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

2.2.2.1. Depending on the nature of the micro-organism and the formulation type, the technical properties of the plant protection product must be evaluated.

2.2.2.2. Shelf-life and storage stability of the preparation must be evaluated, taking into account possible changes in composition such as growth of the micro-organism or of contaminating micro-organisms, production of metabolites/toxins, etc.

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2.2.2.3. Member States shall evaluate the physical and chemical properties of the plant protection product and the retention of these characteristics after storage and take into consideration:

(a) where a suitable Food and Agriculture Organisation of the United Nations (FAO) specification exists, the physical and chemical properties addressed in that specification,

(b) where no suitable FAO specification exists, all relevant physical and chemical properties for the formulation referred to in the Manual on the development and use of FAO and World Health Organisation (WHO) specifications for pesticides.

2.2.2.4. 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 concerning the compatibility of the preparation with other plant protection products as a tank mix, those plant protection products or adjuvants must be physically and chemically compatible in the tank mix. Biological compatibility must also be demonstrated for tank-mixtures, i.e. it must be shown that each plant protection product in the mixture performs as expected and that no antagonism occurs.

2.3. *Further information*

2.3.1. Quality control of the production of the micro-organism in the plant protection product

The quality assurance criteria proposed for production of the micro-organism must be evaluated. In the evaluation criteria relating to process control, good manufacturing practice, operational practices, process flows, cleaning practices, microbial monitoring and hygiene conditions should be taken into account to ensure good quality of the micro-organism. The quality, stability, purity etc., of the micro-organism must be addressed in the quality control system.

2.3.2. Quality control of the plant protection product

The quality assurance criteria proposed must be evaluated. If the plant protection product contains metabolites/toxins produced during growth and residues from the growth medium this should be evaluated. The possibility of the occurrence of contaminating micro-organisms must be evaluated.

2.4. *Efficacy*

2.4.1. 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.

2.4.2. 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.

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

(a) the choice of the crop or cultivar,

(b) the agricultural and environmental (including climatic) conditions (if necessary for acceptable efficacy such data/information should also be given for the time before and after application),

(c) the presence and density of the harmful organism,

(d) the development stage of crop and organism,

(e) the amount of the microbial plant protection product used,

(f) if required on the label, the amount of adjuvant added,

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(g) the frequency and timing of the applications,

(h) the type of application equipment,

(i) the need for any special cleaning measures for the application equipment.

2.4.4. Member States shall evaluate the performance of the plant protection product under the range of agricultural, plant health and environmental (including climatic) conditions likely to be encountered in practice in the area of proposed use. The effect on integrated control must be included in the evaluation. In particular, consideration should be paid to:

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

(b) where relevant, the 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, where they exist, 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 likely to be encountered in practice in the area of proposed use.

2.4.5. 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 a suitable reference product or products, where they exist, and/or an untreated control.

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

(i) efficacy data;

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

(iii) all relevant information on the micro-organism, including biological properties e.g. mode of action, survival, host specificity.

(b) This evaluation will include:

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

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

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

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

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

(vi) where micro-organisms are disseminated, the adverse impact on adjacent crops.

2.4.6. Where the plant protection 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 2.4.3 to 2.4.5 in relation to the information supplied for the tank mix.

Where the plant protection product label includes recommendations for use of the plant protection product with other plant

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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.

2.4.7. Where the available data indicate that the micro-organism or significant relevant metabolites/toxins, degradation and reaction products of the formulants 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.

2.4.8. Where the proposed use of a plant protection product is intended 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:

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

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

2.5. *Identification/detection and quantification methods*

Member States shall evaluate the analytical methods proposed for post-registration control and monitoring purposes of the viable and non-viable components both in the formulation and as residues in or on treated crops. Sufficient validation is required for pre-authorisation methods and post-authorisation monitoring methods. Methods that are considered suitable for post-authorisation monitoring must be clearly identified.

2.5.1. Analytical methods for the plant protection product

2.5.1.1. Non-viable components

Member States shall evaluate the analytical methods proposed to identify and quantify the toxicologically, ecotoxicologically or environmentally significant non-viable components resulting from the micro-organism and/or present as impurity or co-formulant (including eventually resulting breakdown and/or reaction products thereof).

This evaluation will take into consideration the information on analytical methods provided for in Annex IIB and IIIB and the results of the evaluation thereof. In particular, the following information must be taken into account:

(a) the specificity and linearity of the proposed methods,

(b) the precision (repeatability) of the proposed methods,

(c) the importance of interferences,

(d) the accuracy of the proposed methods at appropriate concentrations,

(e) the limit of quantification of the proposed methods.

2.5.1.2. Viable components

Member States shall evaluate the methods proposed to quantify and identify the specific strain concerned and especially methods that discriminate that strain from closely related strains.

This evaluation will take into consideration the information on analytical methods provided for in Annex IIB and IIIB and the results of the evaluation thereof. In particular, the following information must be taken into account:

(a) the specificity of the proposed methods,

(b) the precision (repeatability) of the proposed methods,

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(c) the importance of interferences,

(d) the quantifiability of the proposed methods.

2.5.2. Analytical methods for the determination of residues

2.5.2.1. Non-viable residues

Member States shall evaluate the analytical methods proposed to identify and quantify the toxicologically, ecotoxicologically or environmentally significant non-viable residues resulting from the micro-organism (including eventually resulting breakdown and/or reaction products thereof).

This evaluation will take into consideration the information on analytical methods provided for in Annex IIB and IIIB and the results of the evaluation thereof. In particular, the following information must be taken into account:

(a) the specificity and linearity of the proposed methods,

(b) the precision (repeatability) of the proposed methods,

(c) the reproducibility (independent laboratory validation) of the proposed methods,

(d) the importance of interferences,

(e) the accuracy of the proposed methods at appropriate concentrations,

(f) the limit of quantification of the proposed methods.

2.5.2.2. Viable residues

Member States shall evaluate the methods proposed to identify the specific strain concerned and especially methods that discriminate that strain from closely related strains.

This evaluation will take into consideration the information on analytical methods provided for in Annex IIB and IIIB and the results of the evaluation thereof. In particular, the following information must be taken into account:

(a) the specificity of the proposed methods,

(b) the precision (repeatability) of the proposed methods,

(c) the importance of interferences,

(d) the quantifiability of the proposed methods.

2.6. *Impact on human or animal health*

The impact on human or animal health must be evaluated. In particular, Member States must take account of the following principles:

(a) due to the ability of micro-organisms to replicate, there is a clear difference between chemicals and micro-organisms used as plant protection products. Hazards arising are not necessarily of the same nature as those presented by chemicals, especially in relation to the capacity of micro-organisms to persist and multiply in different environments;

(b) the pathogenicity of the micro-organism to humans and non-target animals, the infectiveness of the micro-organism, the ability of the micro-organism to colonise, the toxicity of metabolites/toxins as well as the toxicity of the residual growth medium, contaminants and co-formulants, are important endpoints in assessing adverse effects arising from the plant protection product;

(c) colonisation, infectiveness and toxicity comprise a complex set of interactions between micro-organisms and hosts and these endpoints may not be resolved easily as independent endpoints;

(d) in combining these endpoints, the most important aspects of the micro-organism that must be assessed are:

— ability to persist and multiply in a host (indicative of colonisation or infectivity),

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— ability to produce non-adverse or adverse effects in a host, indicative of infectivity, pathogenicity, and/or toxicity;

(e) moreover, the complexity of the biological issues should be taken into account in evaluating the hazards and risks presented by use of these plant protection products for human and animals. An assessment of pathogenicity and infectiveness is necessary even if the potential of exposure is deemed low;

(f) for risk assessment purposes the acute toxicity studies used should, where available, include at least two doses (e.g. one very high dose and one corresponding to the expected exposure under practical conditions).

2.6.1. Effects on human or animal health arising from the plant protection product

2.6.1.1. Member States shall evaluate operator exposure to the micro-organism, and/or to toxicologically relevant compounds in the plant protection product (e.g. their metabolites/toxins, residual growth medium, contaminants and co-formulants), likely to occur under the proposed conditions of use (including in particular dose, application method and climatic conditions). Realistic data on exposure levels must be used and, if such data are not available, a suitable, validated calculation model. When available, a European harmonised generic exposure database for plant protection products should be used.

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

(i) the medical data and the toxicity, infectivity and pathogenicity studies as provided for in Annex IIB, and the results of the evaluation thereof. Tier 1 tests should permit an evaluation to be made of a micro-organism with respect to its ability to persist or grow in the host and its ability to cause effects/reactions in the host. Parameters that indicate the absence of ability to persist and multiply in the host, and the absence of ability to produce non-adverse or adverse effects in a host, include fast and complete clearance from the body, no activation of the immune system, no histopathological changes, and for replication temperatures far below or far above mammalian body temperatures. These parameters can in some cases be assessed using acute studies and existing human data, and sometimes can only be assessed using repeated dose studies.

Evaluation based on relevant parameters of Tier 1 tests should lead to an assessment of the possible effects of occupational exposure, taking into account the intensity and duration of exposure including exposure due to repeated use during practical use.

The toxicity of certain metabolites/toxins can only be assessed, if it has been demonstrated that the test animals are actually exposed to these metabolites/toxins;

(ii) other relevant information on the micro-organism, the metabolites/toxins, residual growth medium, contaminants and co-formulants in the plant protection product, such as their biological, physical and chemical properties (e.g. survival of the micro-organism at the body temperature of humans and animals, ecological niche, behaviour of the micro-organism and/or metabolites/toxins during application);

(iii) the toxicological studies provided for in Annex IIIB;

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

— composition of the preparation,

— nature of the preparation,

— size, design and type of packaging,

— field of use and nature of the crop or target,

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— method of application including handling, loading and mixing of the plant protection 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) On the basis of the information mentioned in (a) the following overall end-points should be established for single or repeated operator exposure following the intended use:

— persistence or growth of the micro-organism in the host,

— adverse effects observed,

— observed or expected effects of contaminants (including contaminating micro-organisms),

— observed or expected effects of relevant metabolites/ toxins.

If there are indications of colonisation in the host and/or if any adverse effects, indicative of toxicity/infectivity are observed, taking into account the exposure scenario (i.e. acute or repeated exposure), further testing is indicated.

(c) 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 into account mixing, loading operations, application of the plant protection product and cleaning and routine maintenance of application equipment. Where relevant, other authorised uses of the plant protection product in the area of envisaged use containing the same active substance or which give rise to the same residues may also be taken into account. It should be taken into account that if replication of the micro-organism is expected, exposure assessment could be highly speculative.

(d) The absence or presence of the potential for colonisation or the possibility of effects in operators at the tested dose levels as provided for in Annex IIB and IIIB should be assessed with regard to measured or estimated levels of human exposure. This risk assessment, preferably quantitative, should include consideration of e.g. mode of action, biological, physical and chemical properties of the micro-organism and other substances in the formulation.

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

(a) the type of packaging,

(b) its dimensions and capacity,

(c) the size of the opening,

(d) the type of closure,

(e) its strength, leakproofness and resistance to normal transport and handling,

(f) its resistance to and compatibility with the contents.

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

(a) obtainability and suitability,

(b) effectiveness,

(c) ease of wearing taking into account physical stress and climatic conditions,

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(d) resistance to and compatibility with the plant protection product.

2.6.1.4. Member States shall evaluate the possibility of exposure of other humans (workers exposed after the application of the plant protection product, such as re-entering workers, or bystanders) or animals to the micro-organism 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:

(a) the medical data and the toxicity, infectivity and pathogenicity studies provided for in Annex IIB, and the results of the evaluation thereof. Tier 1 tests should permit an evaluation to be made of a micro-organism with respect to its ability to persist or grow in the host and its ability to cause effects/reactions in the host. Parameters that indicate the absence of ability to persist and multiply in the host, and the absence of ability to produce non-adverse or adverse effects in a host, include rapid and complete clearance from the body, no activation of the immune system, no histopathological changes, and inability to replicate at mammalian body temperatures. These parameters can in some cases be assessed using acute studies and existing human data, and sometimes can only be assessed using repeated dose studies.

Evaluation based on relevant parameters of Tier 1 tests should lead to an assessment of the possible effects of occupational exposure, taking into account the intensity and duration of exposure, including exposure due to repeated use during practical use.

The toxicity of certain metabolites/toxins can only be assessed, if it has been demonstrated that the test animals are actually exposed to these metabolites/toxins;

(b) other relevant information on the micro-organism, the metabolites/toxins, residual growth medium, contaminants and co-formulants in the plant protection product, such as their biological, physical and chemical properties (e.g. survival of the micro-organism at the body temperature of humans and animals, ecological niche, behaviour of the micro-organism and/or metabolites/toxins during application);

(c) the toxicological studies provided for in Annex IIIB;

(d) other relevant information on the plant protection product as provided for in Annex IIIB 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,

— minimum spray application volume,

— composition of the preparation,

— excess remaining on plants and plant products after treatment, taking into account the influence of factors such as temperature, UV light, pH and the presence of certain substances,

— further activities whereby workers are exposed.

2.6.2. Effects on human or animal health arising from residues

In the evaluation, non-viable and viable residues must be addressed separately. Viruses and viroids should be considered as viable residues since they are capable of transferring genetic material, although strictly speaking they are not living.

2.6.2.1. Non-viable residues

(a) Member States shall evaluate the possibility of exposure of humans or animals to non-viable residues and their degradation products via the food chain due to the possible

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occurrence of such residues in or on edible parts of treated crops. In particular, the following information should be taken into account:

— the stage of development of the micro-organism at which non-viable residues are produced,

— the development stages/life cycle of the micro-organism under typical environmental conditions; in particular, attention shall be paid to the assessment of the likelihood of survival and multiplication of the micro-organism in or on crops, food or feed, and, as a consequence, the likelihood of the production of non-viable residues,

— the stability of relevant non-viable residues (including the effects of factors such as temperature, UV light, pH and the presence of certain substances),

— any experimental study showing whether or not relevant non-viable residues are translocated in plants,

— data concerning the proposed good agricultural practice (including number and timing of applications, maximum application rate and minimum spray application volume, proposed pre-harvest intervals for envisaged uses, or withholding periods or storage periods, in the case of post-harvest uses) and additional data on application as provided for in Annex IIIB,

— where relevant, other authorised uses of plant protection products in the area of envisaged use, i.e. containing the same residues, and

— the natural occurrence of non-viable residues on edible plant parts as a consequence of naturally occurring micro-organisms.

(b) Member States shall evaluate the toxicity of non-viable residues and their degradation products having regard in particular to the specific information provided in accordance with Annex IIB and IIIB.

(c) Where non-viable residues or their degradation products are considered toxicologically relevant for humans and/or animals and when exposure is not considered negligible, the actual levels in or on the edible parts of treated crops should be determined, taking into consideration:

— analytical methods for the non-viable residues,

— the growth curves of the micro-organism under optimal conditions,

— the production/formation of non-viable residues at relevant moments (e.g. at the anticipated harvest time).

2.6.2.2. Viable residues

(a) Member States shall evaluate the possibility of exposure of humans or animals to viable residues via the food chain due to the possible occurrence of such residues in or on edible parts of treated crops. In particular, the following information should be taken into account:

— the likelihood of survival, the persistence and multiplication of the micro-organism in or on crops, food or feed. The various development stages/life cycle of the micro-organism should be addressed,

— information concerning its ecological niche,

— information on fate and behaviour in the various parts of the environment,

— the natural occurrence of the micro-organism (and/or a related micro-organism),

— data concerning the proposed good agricultural practice (including number and timing of applications, maximum application rate and minimum spray application volume, proposed pre-harvest intervals for envisaged uses, or withholding periods or storage periods in the case of

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post-harvest uses) and additional data on application as provided for in Annex IIIB,

— where relevant, other authorised uses of plant protection products in the area of envisaged use, i.e. containing the same micro-organism or which result in the same residues.

(b) Member States shall evaluate the specific information concerning the ability of viable residues to persist or grow in the host and the ability of such residues to cause effects/reactions in the host. In particular, the following information should be taken into account:

— the medical data and toxicity, infectivity and pathogenicity studies provided for in Annex IIB, and the results of the evaluation thereof,

— the development stages/life cycle of the micro-organism under typical environmental conditions (e.g. in or on the treated crop),

— the mode of action of the micro-organism,

— the biological properties of the micro-organism (e.g. host specificity).

The various development stages/life cycle of the micro-organism should be addressed.

(c) In the event that viable residues are considered to be toxicologically relevant for humans and/or animals and if exposure is not considered negligible, the actual levels in or on the edible parts of treated crops should be determined, taking into consideration:

— analytical methods for the viable residues,

— the growth curves of the micro-organism under optimal conditions,

— the possibilities of extrapolating data from one crop to another.

2.7. *Fate and behaviour in the environment*

The biocomplexity of the ecosystems and interactions in the microbial communities concerned must be taken into account.

Information on the origin and properties (e.g. specificity) of the micro-organism/its residual metabolites/toxins and its intended use forms the basis for an assessment of environmental fate and behaviour. The mode of action of the micro-organism should be taken into consideration.

An assessment shall be made of the fate and behaviour of any known relevant metabolite that is produced by the micro-organism. The assessment shall be made for each environmental compartment, and shall be triggered on the basis of the criteria specified in section 7 (iv) of Annex IIB.

In the assessment of the environmental fate and behaviour of plant protection products, Member States shall have regard to all aspects of the environment, including biota. The potential for persistence and multiplication of micro-organisms has to be assessed in all environmental compartments unless it can be justified that particular micro-organisms will not reach a specific compartment. The mobility of micro-organisms and their residual metabolites/toxins must be considered.

2.7.1. Member States shall evaluate the possibility of contamination of ground water, surface water and drinking water under the proposed conditions of use of the plant protection product.

In the overall assessment, Member States should pay particular attention to potential adverse effects on humans through groundwater contamination, when the active substance is applied in regions with vulnerable conditions, such as drinking water abstraction areas.

2.7.2. Member States shall evaluate the risk for the aquatic compartment where the possibility of the exposure of aquatic organisms has been established. A micro-organism may give

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rise to risks because of its potential through multiplication to establish itself in the environment and can therefore have a long-lasting or permanent impact on microbial communities or their predators.

This evaluation will take into consideration the following information:

(a) the biological properties of the micro-organism,

(b) the survival of the micro-organism in the environment,

(c) its ecological niche,

(d) the natural background level of the micro-organism, where it is indigenous,

(e) information on fate and behaviour in the various parts of the environment,

(f) where relevant, information on potential interference with analytical systems used for the control of the quality of drinking water as provided for in Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption ([1]),

(g) where relevant, other authorised uses of plant protection products in the area of envisaged use, e.g. containing the same active substance or which gives rise to the same residues.

2.7.3. Member States shall evaluate the possibility of exposure of organisms in the atmosphere to the plant protection product under the proposed conditions of use; if this possibility exists they shall evaluate the risk for the atmosphere. The transport, short-range and long-range, of the micro-organism in the atmosphere should be taken into account.

2.7.4. Member States shall evaluate the possibility of exposure of organisms in the terrestrial compartment to the plant protection product under the proposed conditions of use; if this possibility exists they shall evaluate the risks arising for the terrestrial compartment. A micro-organism may give rise to risks because of its potential through multiplication to establish itself in the environment and can therefore have a long-lasting or permanent impact on microbial communities or their predators.

This evaluation will take into consideration the following information:

(a) the biological properties of the micro-organism,

(b) the survival of the micro-organism in the environment,

(c) its ecological niche,

(d) the natural background level of the micro-organism, where it is indigenous,

(e) information on fate and behaviour in the various parts of the environment,

(f) where relevant, other authorised uses of plant protection products in the area of envisaged use, e.g. containing the same active substance or which gives rise to the same residues.

2.8. *Effects on and exposure of non-target organisms*

Information on the ecology of the micro-organism and effects on the environment should be assessed as well as possible exposure levels and the effects of its relevant metabolites/toxins. An overall assessment of the environmental risks that the plant protection product may cause, taking into account the normal levels of exposure to micro-organisms both in the environment as well as in the body of organisms, is necessary.

Member States shall evaluate the possibility of exposure of non-target organisms under the proposed conditions of use and if

([1]) OJ L 330, 5.12.1998, p. 32. Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

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this possibility exists they shall evaluate the risks arising for the non-target organisms concerned.

Where applicable, an assessment of infectivity and pathogenicity is necessary, unless it can be justified that non-target organisms will not be exposed.

To assess the possibility of exposure the following information should also be taken into consideration:

(a) the survival of the micro-organism in the respective compartment,

(b) its ecological niche,

(c) the natural background level of the micro-organism, where it is indigenous,

(d) information on fate and behaviour in the various parts of the environment,

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

2.8.1. Member States shall evaluate the possibility of exposure of and effects on terrestrial wildlife (non-domestic birds, mammals and other terrestrial vertebrates).

2.8.1.1. A micro-organism may give rise to risks because of its potential to infect and multiply in avian and mammalian host systems. Whether or not identified risks could be changed due to the formulation of the plant protection product shall be assessed, taking into account the following information on the micro-organism:

(a) its mode of action,

(b) other biological properties,

(c) studies on mammalian toxicity, pathogenicity and infectivity,

(d) studies on avian toxicity, pathogenicity and infectivity.

2.8.1.2. A plant protection product may give rise to toxic effects due to the action of toxins or co-formulants. For the assessment of such effects, the following information should be taken into consideration:

(a) studies on mammalian toxicity,

(b) studies on avian toxicity,

(c) information on fate and behaviour in the various parts of the environment.

If mortality or signs of intoxication are observed in the tests the evaluation must include a calculation of toxicity/exposure ratios based on the quotient of the LD_{50} value and the estimated exposure expressed in mg/kg body weight.

2.8.2. Member States shall evaluate the possibility of exposure of and effects on aquatic organisms.

2.8.2.1. A micro-organism may give rise to risks because of its potential to infect and multiply in aquatic organisms. Whether or not identified risks could be changed due to the formulation of the plant protection product shall be assessed, taking into account the following information on the micro-organism:

(a) its mode of action,

(b) other biological properties,

(c) studies on toxicity, pathogenicity and infectivity.

2.8.2.2. A plant protection product may give rise to toxic effects due to the action of toxins or co-formulants. For the assessment of such effects the following information should be taken into consideration:

(a) studies on toxicity to aquatic organisms,

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(b) information on fate and behaviour in the various parts of the environment.

If mortality or signs of intoxication are observed in the tests the evaluation must include a calculation of toxicity/exposure ratios based on the quotient of the EC_{50} value and/or the NOEC value and the estimated exposure.

2.8.3. Member States shall evaluate the possibility of exposure of and effects on bees.

2.8.3.1. A micro-organism may give rise to risks because of its potential to infect and multiply in bees. Whether or not identified risks could be changed due to the formulation of the plant protection product shall be assessed, taking into account the following information on the micro-organism:

(a) its mode of action,

(b) other biological properties,

(c) studies on toxicity, pathogenicity and infectivity.

2.8.3.2. A plant protection product may give rise to toxic effects due to the action of toxins or co-formulants. For the assessment of such effects the following information should be taken into consideration:

(a) studies on toxicity to bees,

(b) information on fate and behaviour in the various parts of the environment.

If mortality or signs of intoxication are observed in the tests the evaluation must include a calculation of the hazard quotient, based on the quotient of the dose in g/ha and the LD_{50} value in µg/bee.

2.8.4. Member States shall evaluate the possibility of exposure of and effects on arthropods other than bees.

2.8.4.1. A micro-organism may give rise to risks because of its potential to infect and multiply in arthropods other than bees. Whether or not identified risks could be changed due to the formulation of the plant protection product shall be assessed, taking into account the following information on the micro-organism:

(a) its mode of action,

(b) other biological properties,

(c) studies on toxicity, pathogenicity and infectivity to honeybees and other arthropods.

2.8.4.2. A plant protection product may give rise to toxic effects due to the action of toxins or co-formulants. For the assessment of such effects the following information should be taken into consideration:

(a) studies on toxicity to arthropods,

(b) information on fate and behaviour in the various parts of the environment,

(c) available data from biological primary screening.

If mortality or signs of intoxication are observed in the tests the evaluation must include a calculation of toxicity/exposure ratios based on the quotient of the ER_{50} value (effective rate) and the estimated exposure.

2.8.5. Member States shall evaluate the possibility of exposure of and effects on earthworms.

2.8.5.1. A micro-organism may give rise to risks because of its potential to infect and multiply in earthworms. Whether or not identified risks could be changed due to the formulation of the plant protection product shall be assessed, taking into account the following information on the micro-organism:

(a) its mode of action,

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(b) other biological properties,

(c) studies on earthworm toxicity, pathogenicity and infectivity.

2.8.5.2. A plant protection product may give rise to toxic effects due to the action of toxins or co-formulants. For the assessment of such effects the following information should be taken into consideration:

(a) studies on earthworm toxicity,

(b) information on fate and behaviour in the various parts of the environment.

If mortality or signs of intoxication are observed in the tests the evaluation must include a calculation of toxicity/exposure ratios based on the quotient of the LC_{50} value and the estimated exposure expressed in mg/kg dry weight soil.

2.8.6. Member States shall evaluate the possibility of exposure of and effects on soil micro-organisms.

2.8.6.1. A micro-organism may give rise to risks because of its potential to interfere with nitrogen and carbon mineralisation in the soil. Whether or not identified risks could be changed due to the formulation of the plant protection product shall be assessed, taking into account the following information on the micro-organism:

(a) its mode of action,

(b) other biological properties.

Experimental data are not normally required, i.e. where it can be justified that a proper risk assessment can be performed with the available information.

2.8.6.2. Member States shall evaluate the impact of exotic/non-indigenous micro-organisms on non-target micro-organisms and on their predators following use of the plant protection product according to the proposed conditions of use. Experimental data are not normally required, i.e. where it can be justified that a proper risk assessment can be performed with the available information.

2.8.6.3. A plant protection product may give rise to toxic effects due to the action of toxins or co-formulants. For the assessment of such effects the following information should be taken into consideration:

(a) information on fate and behaviour in the various parts of the environment,

(b) all available information from biological primary screening.

2.9. *Conclusions and proposals*

Member States shall draw conclusions on the need for further information and/or testing and the need for measures to limit the risks arising. Member States shall justify proposals for the classification and labelling of plant protection products.

C. **DECISION-MAKING**

1. **General principles**

1.1. Where appropriate, Member States shall impose conditions or restrictions on the authorisations they grant. The nature and severity of these conditions or restrictions 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.

1.2. Member States shall ensure that decisions taken to grant authorisations, 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 on use, and, in authorisation being granted for some but not other areas within the Member State in question.

1.3. Member States shall ensure that the authorised amounts, in terms of rates and number of applications, are the minimum

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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 authorised 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 authorisation is granted. However, the rates and the number of applications may not give rise to undesirable effects such as the development of resistance.

1.4. Member States shall ensure that decisions respect the principles of integrated pest control if the plant protection product is intended for use in conditions where these principles are relied on.

1.5. 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.

1.6. Before issuing an authorisation, Member States shall ensure that the label of the plant protection product:

(a) fulfils the requirements of Article 16 of this Directive,

(b) also contains the information on protection of users required by Community legislation on worker protection,

(c) specifies in particular the conditions or restrictions under which the plant protection product may or may not be used as referred to in points 1.1 to 1.5,

(d) The authorisation shall mention the particulars indicated in Article 16(1)(g) and (h) of this Directive and Article 10 (1.2), (2.4), (2.5) and (2.6) of Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations ([1]).

1.7. Before issuing authorisations, Member States shall:

(a) ensure that the proposed packaging is in accordance with the provisions of Directive 1999/45/EC;

(b) ensure that:

— the procedures for destruction of the plant protection product,

— the procedures for neutralisation of any adverse effects of the plant protection product if it is accidentally dispersed, and

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

are in accordance with the relevant regulatory provisions.

1.8. No authorisation shall be granted unless all the requirements referred to in point 2 are satisfied. However, when one or more of the specific decision-making requirements referred to in point 2.4 are not fully satisfied, authorisations shall be granted only where 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 plant protection product relating to non-compliance with some of the requirements referred to in point 2.4 must be mentioned on the label. These advantages can be in terms of:

(a) advantages for and compatibility with integrated control measures or organic farming,

(b) facilitating strategies to minimise the risk of development of resistance,

([1]) OJ L 200, 30.7.1999, p. 1. Directive as last amended by Directive 2004/66/EC (OJ L 168, 1.5.2004, p. 35).

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(c) reduced risk for operators and consumers,

(d) reduced contamination of the environment and reduced impact on non-target species.

1.9. Where an authorisation 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 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.

1.10. Member States shall ensure, as far as is practically possible, that for all micro-organisms that are considered for an authorisation, the applicant has taken into account all available relevant knowledge and information in literature at the time of submission.

1.11. Where the micro-organism has been genetically modified, as defined in Directive 2001/18/EC, no authorisation shall be granted unless the evaluation conducted in accordance with Directive 2001/18/EC has been submitted, as required under Article 1(3) of that Directive. The relevant decision taken by the competent authorities in accordance with Directive 2001/18/EC must be provided.

1.12. In accordance with Article 1(3) of this Directive, no authorisation shall be granted for a plant protection product containing a genetically modified organism unless authorisation is granted according to the provisions in Directive 2001/18/EC, part C, under which that organism can be released into the environment.

1.13. No authorisation shall be granted if relevant metabolites/toxins (i.e. those expected to be of concern for human health and/or the environment) known to be formed by the micro-organism, and/or by microbial contaminants are present in the plant protection product, unless it can be shown that the amount present is at an acceptable level before and after its proposed use.

1.14. Member States shall ensure that adequate quality control measures are applied to ensure the identity of the micro-organism and contents of the plant protection product. Such measures must include a Hazard Analysis Critical Control Point (HACCP) system or equivalent system.

2. **Specific principles**

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

2.1. *Identity*

For each authorisation granted the Member States shall ensure that the micro-organism concerned is deposited at an internationally recognised culture collection and has an accession number. Each micro-organism must be identified and named at the species level and characterised at the strain level. There must also be information as to whether or not the micro-organism is a wild type or a spontaneous or induced mutant, or a genetically modified organism.

2.2. *Biological and technical properties*

2.2.1. There must be sufficient information to permit assessment of the minimum and maximum content of the micro-organism in the material used for the manufacturing of plant protection products, as well as in the plant protection product. The

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content of other components and formulants in the plant protection product and contaminating micro-organisms derived from the production process must to the extent possible be defined. Member States shall ensure that the level of contaminating organisms is controlled to an acceptable level. In addition: the physical nature and state of the plant protection product must be specified, preferably according to the 'Catalogue of pesticide formulation types and international coding system (CropLife International Technical Monograph No 2, 5th Edition, 2002)'.

2.2.2. No authorisation shall be granted if, at any stage in the development of a microbial plant protection product, it becomes apparent, on the basis of a build-up of resistance, or transfer of resistance, or other mechanism, that there may be interference with the effectiveness of an anti-microbial agent used in human or animal medicine.

2.3. *Further information*

No authorisation shall be granted unless full information is provided on the continuous quality control of the production method, production process and plant protection product. In particular, the occurrence of spontaneous changes in major characteristics of the micro-organism and the absence/presence of contaminating organisms shall be considered. The quality assurance criteria for production and the techniques used to ensure a uniform plant protection product must to the extent possible be described and specified.

2.4. *Efficacy*

2.4.1. Performance

2.4.1.1. No authorisation shall be granted 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.

2.4.1.2. 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.

2.4.1.3. Where relevant, yield response when the plant protection 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.

2.4.1.4. Conclusions as to the performance of the preparation must be valid for all areas of the Member State in which it is to be authorised, and 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).

2.4.1.5. 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 2.4.1.1 to 2.4.1.4.

Where proposed label claims include recommendations for use of the preparation with specified plant protection products or

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adjuvants as a tank mix, Member States shall not accept the recommendations unless they are justified.

2.4.1.6. If there is evidence of a development of resistance of pathogens towards the plant protection product, the Member State shall decide if the submitted resistance management strategy addresses this adequately and sufficiently.

2.4.1.7. Only plant protection products containing non-viable micro-organisms may be authorised for use to control vertebrate species. The intended effect on vertebrates to be controlled shall be obtained without unnecessary suffering and unnecessary pain for these animals.

2.4.2. Absence of unacceptable effects on plants and plant products

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

2.4.2.2. 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.

2.4.2.3. 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.

2.4.2.4. 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.

2.4.2.5. 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.

2.4.2.6. 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.

2.4.2.7. Where proposed label claims include requirements for use of the preparation with other plant protection products or adjuvants, as a tank mix, the mixture must comply with the principles referred to in points 2.4.2.1 to 2.4.2.6.

2.4.2.8. 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.

2.5. *Identification/detection and quantification methods*

The methods proposed must reflect the latest techniques. Methods for post-authorisation monitoring should involve the use of commonly available reagents and equipment.

2.5.1. No authorisation shall be granted unless there is an adequate method of sufficient quality to identify and quantify the micro-organism and non-viable components (e.g. toxins, impurities and co-formulants) in the plant protection product. In the case of a plant protection product containing more than one micro-organism, the recommended methods should be capable of identifying and determining the content of each one.

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2.5.2. No authorisation shall be granted unless there are adequate methods for post-registration control and monitoring of viable and/or non-viable residues. Methods must be available for analysis of:

(a) plants, plant products, foodstuffs of plant and animal origin and feedingstuffs if toxicologically relevant residues occur. Residues are considered relevant if a maximum residue level (MRL) or a waiting or re-entry safety period or other such precaution is required,

(b) soil, water, air and/or body tissues if toxicologically, ecotoxicologically or environmentally relevant residues occur.

2.6. *Impact on human and animal health*

2.6.1. Effects on human and animal health arising from the plant protection product

2.6.1.1. No authorisation shall be granted if on the basis of the information provided in the dossier it appears that the micro-organism is pathogenic to humans or non-target animals under the proposed conditions of use.

2.6.1.2. No authorisation shall be granted if the micro-organism and/or the plant protection product containing the micro-organism might, under the recommended conditions of use, including a realistic worst case scenario, colonise or cause adverse effects in humans or animals.

When making a decision on the authorisation of the microbial plant protection product, Member States shall consider possible effects on all human populations, namely professional users, non-professional users and humans exposed directly or indirectly though the environment and at work, and animals.

2.6.1.3. All micro-organisms should be regarded as potential sensitisers, unless it is established by means of relevant information that there is no risk of sensitisation, taking into account immuno-compromised and other sensitive individuals. Authorisations granted shall therefore specify that protective clothing and suitable gloves be worn and that the plant protection product containing the micro-organism should not be inhaled. Moreover, the proposed conditions of use may require use of additional items of protective clothing and equipment.

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

2.6.1.4. No authorisation shall be granted if it is known that transfer of genetic material from the micro-organism to other organisms may lead to adverse effects on human and animal health, including resistance to known therapeutic substances.

2.6.1.5. Plant protection products which, because of particular properties, or which, 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. Moreover, plant protection products which are classified as very toxic may not be authorised for use by non-professional users.

2.6.1.6. Waiting and re-entry safety periods or other precautions must be established in such a way that no colonisation of or adverse effects on bystanders or workers exposed after application of the plant protection product are expected.

2.6.1.7. Waiting and re-entry safety periods or other precautions must be established in such a way that no colonisation of or adverse effects on animals are expected.

2.6.1.8. Waiting and re-entry periods or other precautions to ensure that no colonisation or adverse effects are expected must be realistic; if necessary, special precautionary measures must be prescribed.

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2.6.1.9. The conditions of authorisation shall be in compliance with Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work ([1]), and Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work ([2]). The experimental data and information relevant to the recognition of the symptoms of infection or pathogenicity and on the effectiveness of first aid and therapeutic measures provided shall be considered. The conditions of authorisation shall also be in compliance with Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work ([3]). The conditions of authorisation shall also be in compliance with Council Directive 89/656/EEC of 30 November 1989 on the minimum health and safety requirements for the use by workers of personal protective equipment at the workplace ([4]).

2.6.2. Effects on human and animal health arising from residues

2.6.2.1. No authorisation shall be granted unless there is sufficient information for plant protection products containing the micro-organism, to decide that there is no harmful effect on human or animal health arising from exposure to the micro-organism, its residual traces and metabolites/toxins remaining in or on plants or plant products.

2.6.2.2. No authorisation shall be granted unless viable residues and/or non-viable 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 viable residues and/or toxins at harvest, slaughter or after storage are reduced to a minimum.

2.7. *Fate and behaviour in the environment*

2.7.1. No authorisation shall be granted if the available information indicates that there may be unacceptable adverse environmental effects due to the fate and behaviour of the plant protection product in the environment.

2.7.2. No authorisation shall be granted if contamination of ground water, surface water or drinking water expected as a result of the use of a plant protection product under the proposed conditions of use, may cause interference with the analytical systems for the control of the quality of drinking water provided for in Directive 98/83/EC.

2.7.3. No authorisation shall be granted if the contamination of groundwater expected as a result of the use of a plant protection product under the proposed conditions of use contravenes or exceeds whichever of the following is the lower:

(a) the parameters or maximum permissible concentrations laid down by Directive 98/83/EC, or

(b) the parameters or maximum permissible concentrations laid down for components in the plant protection product such as relevant metabolites/toxins in accordance with Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy ([5]), or

(c) the parameters for the micro-organism or the maximum concentration laid down by the Commission for components in the plant protection product such as relevant metabolites/toxins when including the micro-

([1]) OJ L 131, 5.5.1998, p. 11.
([2]) OJ L 262, 17.10.2000, p. 21.
([3]) OJ L 158, 30.4.2004 p. 50.
([4]) OJ L 393, 30.12.1989, p. 18.
([5]) OJ L 327, 22.12.2000, p. 1. Directive as amended by Decision No 2455/2001/EC.

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organism 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 1/10 of the acceptable daily intake (ADI) laid down when the micro-organism was included in Annex I,

unless it is scientifically demonstrated that under relevant field conditions the lower of the parameters or concentrations is not contravened or exceeded.

2.7.4. No authorisation shall be granted if the contamination of surface water expected as a result of the use of a plant protection product under the proposed conditions of use:

(a) exceeds, where the surface water in or from the area of envisaged use is intended for the extraction of drinking water, the parameters or values established in accordance with 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

(b) exceeds the parameters or values for components in the plant protection product, such as relevant metabolites/toxins, established in accordance with Directive 2000/60/EC or

(c) has an impact deemed unacceptable on non-target species, including animals, according to the relevant requirements provided for in point 2.8.

The proposed instruction 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.

2.7.5. No authorisation shall be granted if it is known that transfer of genetic material from the micro-organism to other organisms, may lead to unacceptable effects on the environment.

2.7.6. No authorisation shall be granted unless there is sufficient information on the possible persistence/competitiveness of the micro-organism and relevant secondary metabolites/toxins in or on the crop under the environmental conditions prevailing at and following the intended use.

2.7.7. No authorisation shall be granted if it can be expected that the micro-organism and/or its possible relevant metabolites/toxins will persist in the environment in concentrations considerably higher than the natural background levels, taking into account repeated applications over the years, unless a robust risk assessment indicates that the risks from accumulated plateau concentrations are acceptable.

2.8. *Effects on non-target organisms*

Member States shall ensure that the available information is sufficient to permit a decision to be taken as to whether or not there may be unacceptable effects on non-target species (flora and fauna), due to exposure to the plant protection product containing the micro-organism following its intended use.

Member States shall pay special attention to possible effects on beneficial organisms used for biological control and organisms playing an important role in integrated control.

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

(a) the micro-organism is pathogenic to birds and other non-target terrestrial vertebrates,

(b) in case of toxic effects due to components in the plant protection product, such as relevant metabolites/toxins, the toxicity/exposure ratio is less than 10 on the basis of the acute LD_{50} value or the long-term toxicity/exposure ratio is

([1]) OJ L 194, 25.7.1975, p. 26. Directive to be repealed from 22.12.2007 by Directive 2000/60/EC (OJ L 327, 22.12. 2000, p. 1).

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less than 5, 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.

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

(a) the micro-organism is pathogenic to aquatic organisms,

(b) in case of toxic effects due to components in the plant protection product such as relevant metabolites/toxins, the toxicity/exposure ratio is less than 100 in case of acute toxicity (EC_{50}) to daphnia and fish and 10 for long-term/chronic toxicity to algae (EC_{50}), daphnia (NOEC) and fish (NOEC), unless it is clearly established through an appropriate risk assessment that under field conditions no unacceptable impact on the viability of exposed species occurs — directly or indirectly — after use of the plant protection product according to the proposed conditions of use.

2.8.3. Where there is a possibility of bees being exposed, no authorisation shall be granted:

(a) if the micro-organism is pathogenic to bees,

(b) in case of toxic effects due to components in the plant protection product such as relevant metabolites/toxins, 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.

2.8.4. Where there is a possibility of arthropods other than bees being exposed, no authorisation shall be granted if:

(a) the micro-organism is pathogenic to arthropods other than bees,

(b) in case of toxic effects due to components in the plant protection product such as relevant metabolites/toxins, unless it is clearly established through an appropriate risk 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.

2.8.5. Where there is a possibility of earthworms being exposed, no authorisation shall be granted if the micro-organism is pathogenic to earthworms or in the case of toxic effects due to components in the plant protection product such as relevant metabolites/toxins, the acute toxicity/exposure ratio 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.

2.8.6. Where there is a possibility of non-target soil micro-organisms being exposed, no authorisation shall be granted if the nitrogen or carbon mineralisation 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 the microbial community after use of the plant protection product according to the proposed conditions of use, taking account of the ability of micro-organisms to multiply.