EUROPEAN COMMUNITIES (AUTHORIZATION, PLACING ON THE MARKET, USE AND CONTROL OF PLANT PROTECTION PRODUCTS) (AMENDMENT) REGULATIONS 1995

I, IVAN YATES, Minister for Agriculture, Food and Forestry, in exercise of the powers conferred on me by section 3 of the European Communities Act, 1972 (No. 27 of 1972), and for the purpose of giving effect to Council Directive No 94/43/EC of 27 July 19941, Commission Directive 94/37/EC of 22 July 19942, Commission 94/79/EC of 21 December 19943, Commission Regulation (EC) No 933/94 of 27 April 19944 and Commission Regulation (EC) No 491/95 of 3 March 19955, hereby make the following Regulations:

REG 1

1. (1) These Regulations may be cited as the European Communities (Authorization, Placing on the Market, Use and Control of Plant Protection Products) (Amendment) Regulations, 1995.
(2) The European Communities (Authorization, Placing on the Market, Use and Control of Plant Protection Products) Regulations, 1994 (S.I. No. 139 of 1994) and these Regulations may be cited together as the European Communities (Authorization, Placing on the Market, Use and Control of Plant Protection Products) Regulations, 1994 and 1995 and shall be construed together as one.
(3) These Regulations shall come into operation on the first day of August 1995.

REG 2

Interpretation
2. (1) In these Regulations—
"the Directive of 1994" means Council Directive No. 94/43/EC of 27 July 19941;
"the principal Regulations" means the European Communities (Authorization, Placing on the Market, Use and Control of Plant Protection Products) Regulations, 1994 (S.I. No. 139 of 1994).
1O.J. No. L227/31 1/9/1994.
2O.J. No. L194/65 29/7/1994.
3O.J. No. L354/16 31/12/1994.
4O.J. No. L107/8 28/4/1994.
5O.J. No. L49/50 4/3/1995.
(2) In these Regulations, unless otherwise indicated—
(a) a reference to a Regulation is a reference to a Regulation of these Regulations,
(b) a reference to a paragraph or subparagraph is a reference to a paragraph or subparagraph of the provision in which the reference occurs,

(c) a reference to an EEC Method is a reference to a test method described in Commission Directive 92/69/EEC6.
6O.J. No. L383 A/1 29/12/1992
(3) A word or expression that is used in the Directive of 1994 or in any Commission Directive or Regulation of the European Communities mentioned in these Regulations has, unless the contrary intention appears, the meaning in these Regulations that it has in the Directive or Regulation concerned.

REG 3

Amendments
3. The introduction and Part A of Annex II, as set out in Part 1 of the First Schedule to the principal Regulations, is hereby replaced by the text set out in Part 1 of the Schedule to these Regulations.

REG 4

4. The introduction and Part A of Annex III, as set out in Part 2 of the First Schedule to the principal Regulations, is hereby replaced by the text set out in Part 2 of the Schedule to these Regulations.

REG 5

5. Annex IV, as set out in Part 5 of the First Schedule to the principal Regulations, is hereby replaced by the text set out in Part 3 of the Schedule to these Regulations.

REG 6

6. Part 2 of the Second Schedule to the principal Regulations, is hereby replaced by the text set out in Part 4 of the Schedule to these Regulations.

REG 7

7. Section 10 of Part A of the Ninth Schedule to the principal Regulations, is hereby replaced by the text set out in Part 5 of the Schedule to these Regulations.
FIRST SCHEDULE
Part 1
Annex II
(Annex II to the Directive of 1991, as amended by Commission

Directive No 93/71/EEC of 27 July 1993, Commission Directive 94/37/EC and Commission Directive 94/79/EC)

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

Introduction

The information required shall:

1.1.Include a technical dossier supplying the information necessary for evaluating the foreseeable risks, whether immediate or delayed, which the substance may entail for humans, animals and the environment and containing at least the information and results of the studies referred to below;1.2where relevant, be generated using test guidelines referred to or described in this Annex, in the case of studies initiated before the adoption of the modification of this Annex, the information shall be generated using suitable internationally or nationally validated test guidelines or, in the absence thereof, test guidelines accepted by the competent authority;1.3in 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 guideline used;1.4include, 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;1.5include 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;1.6where relevant, have been generated in accordance with the requirements of Directive 86/609/EEC7, 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.

7O.J. No. L358/1 18/12/1986.

2.1Tests and analyses must be conducted in accordance with the principles laid down in Directive 87/18/EEC8 of 18 December 1986, on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their application for tests on chemical substances, where testing is done to obtain data on the properties and/or safety with respect to human or animal health or the environment.2.2Notwithstanding the provisions of point 2.1, during the period to 31 December 1999, tests and analyses done to obtain data on the properties and/or safety with respect to honeybees and beneficial arthropods other than bees may have been conducted by

officially recognized testing facilities or organisations, in accordance with the principles laid down in the Sixth Schedule, or in compliance with Irish/European Standard IS/EN 45001, where they are conducted within the territory of the state, and in accordance with the requirements of points 2.2 and 2.3 of the introduction to Annex III to Directive 93/71/EEC, where they are conducted outside the territory of the state.
8O.J. No. L15/3 17/01/1987.

PART A
Chemical substances

1Identity of the active substanceThe 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.1.1Applicant (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 territory of the State, 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.1.2Manufacturer (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 substance 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.

1.3Common name proposed or ISO-accepted, and synonymsThe 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.1.4Chemical name (IUPAC and CA) nomenclatureThe chemical name as given in Annex I to the Directive of 1967, or, if not included in that Directive, in accordance with both IUPAC and CA nomenclature, must be provided.1.5Manufacturer's development code number(s)Code numbers used to identify the active substance and, where available, formulations containing the active substance, during development work, must be reported. For each code number reported, the material to which it relates, the period for which it was used, and the Member States

or other countries in which it was used and is being used, must be stated.1.6CAS, EEC and CIPAC numbers (if available)Chemical Abstracts, EEC (EINECS or ELINCS), and CIPAC numbers, where they exist, must be reported.1.7Molecular and structural formula, molecular massThe 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.1.8Method of manufacture (synthesis pathway) of the active substancesThe method of manufacturer, 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.1.9Specification of purity of the active substance in g/kgThe 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.
1.10Identity of isomers, impurities and additives (e.g. stabilizers), together with the structural formula and the content expressed as g/kgThe maximum content in g/kg of inactive isomers as well as the ratio of the content of isomers/diastereo-isomers, where relevant, must be provided. In addition, the maximum content in g/kg of each further component other than additives, including by-products, and impurities, must be provided. In the case of additives the content in g/kg must be provided.For each component, present in quantities of 1 g/kg or more, the following information, where relevant, must be provided—— chemical name according to IUPAC and CA nomenclature;— ISO common name or proposed common name if available;— CAS number, EEC (EINECS or ELINCS) number, and CIPAC number if available;— molecular and structural formula;— molecular mass; and— maximum content in g/kg.Where the manufacturing process is such that impurities and by-products which are particularly undesirable because of their toxicological, ecotoxicological or environmental properties could be present in the active substance, the content of each such compound must be determined and reported. In such cases, the analytical methods used and the limits of determination, which must be sufficiently low, for each compound of concern, must be reported. Additionally the following information, where relevant, must be provided—— chemical name according to IUPAC and CA nomenclature;— ISO common name or proposed common name if available;— CAS number, EEC (EINECS or ELINCS) number, and CIPAC number if available;— molecular and structural formula;— molecular mass; and— maximum content in g/kg.Where the information provided relates to a pilot plant

production system, the information required must again be provided once industrial scale production methods and procedures have stabilized, if the 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 substances and other than impurities resulting from the manufacturing process, the function of the component (additive) must be given—antifoaming agentbufferantifreezedispersing agentbinderstabiliserother (specify)1.11Analytical profile of batchesRepresentative samples of the active substance must be analyzed 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 analyzed. 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.2Physical and chemical properties of the active substances (i) The information provided, must describe the physical and chemical properties of active substances and together with other relevant information, must serve to characterize them. In particular, the information provided must permit—
— physical, chemical, and technical hazards associated with active substances, to be identified; — classification of active substance as to hazard; — 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 and technical hazards associated with preparations, to be identified,

permit preparations to be classified, and demonstrate 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 which active substances for 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 used 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.2.1Melting point and boiling point2.1.1The melting point or where appropriate the freezing or solidification point of purified active substance must be determined in accordance with EEC Method A 1 and be reported. Measurements should be taken up to 360°C.2.1.2Where appropriate, the boiling point of purified active substances must be determined in accordance with EEC Method A 2 and be reported. Measurements should be taken up to 360°C. 2.1.3Where 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 densityIn the case of active substances which are liquids or solids, the relative density of the purified active substance must be determined in accordance with EEC Method A3 and be reported.2.3Vapour pressure (In Pa), volatility (e.g. Henry's law constant)2.3.1The vapour pressure of purified active substance must be determined in accordance with EEC Method A4 and be reported. Where vapour pressure is less than 10-5 Pa, the vapour pressure at 20 or 25°C may be estimated using a vapour pressure curve.2.3.2In 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 x m3 x mol-1).2.4Appearances (physical state, colour and odour; if known)2.4.1A description of both the colour, if any, and the physical state of both the active substance as manufactured and the purified active substance, must be provided.2.4.2A description of any odour associated with the active substance as manufactured and with the purified active substance, noted when handling the materials in laboratories or production plants, must be reported.2.5Spectra (UV/VIS, IR, NMR, MS), molecular extinction at relevant wavelengths2.5.1The following spectra including a table of signal characteristics needed for interpretation must be determined and reported: Ultraviolet/Visible (UV/VIS), infrared (IR), nuclear magnetic resonance (NMR), and mass spectra (MS) of purified active substance. 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.2.5.2The UV/visible absorption spectra, IR, NMR and MS spectra, where necessary for the identification of impurities considered to be of toxicological, ecotoxicological or environmental significance, must be determined and reported.
2.6Solubility in water including effect of pH (4 to 10) on solubilityThe water solubility of purified active substances under atmospheric pressure must be determined in accordance with EEC Method A 6 and be reported. 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 substances in aqueous media is such that water solubility cannot be determined, a justification based on test data must be provided.2.7Solubility in organic solventsThe solubility of 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-heptaneAromatic hydrocarbon— preferably xyleneHalogenated hydrocarbon— preferably 1,2-dichlorethaneAlcohol— preferably methanol or isopropyl acetoneKetone— preferably acetoneEster— preferably ethyl acetateIf 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.2.8Partition co-efficient n-octanol/water including effect of pH (4 to 10)The n-octanol/water partition coefficient of purified active substance must be determined in accordance with EEC Method A 8 and be reported. 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).2.9Stability in water, hydrolysis rate, photochemical degradation, quantum yield and identity of breakdown product(s), dissociation constant including effect of pH (4 to 9)2.9.1The hydrolysis rate of purified active substances (usually radio labelled 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 in accordance with EEC Method C 7 and be reported. 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 constant observed, must be reported. The estimated DT50 value must also be

reported.2.9.2For compounds with a molar (decadic) absorption coefficient (e) > 10 (1 x mol-1 x cm-1) at a wavelength x l > 290 nm, direct phototransformation 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 co-solvent or solubilizer. The light source must simulate sunlight and be equipped with filters to exclude radiation at wavelengths l < 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.2.9.3Where necessary to investigate direct phototransformation, 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 methodology to be used is that described by SETAC9.2.9.4Where dissociation in water occurs, the dissociation constant(s) (pKa values) of purified active substances must be determined in accordance with OECD Test Guideline 112 and be reported. 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.2.10Stability in air, photochemical degradation, identity of breakdown product(s)An estimation of the photochemical oxidative degradation (indirect phototransformation) of the active substance(s), must be submitted2.11Flammability including auto-flammability2.11.1The flammability of active substances as manufactured, which are solids, gases, or are substances which evolve highly flammable gases, must be determined in accordance with EEC Methods A 10, A 11 or A 12, as appropriate, and be reported2.11.2The auto-flammability of active substances as manufactured must be determined in accordance with 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, Nr. 14.3.4), and be reported.

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

2.12Flash pointThe flash point of active substances as manufactured with a melting point below 40°C, must be determined in accordance with EEC Method A 9 and be reported; only closed cup methods should be used.2.13Explosive propertiesThe explosive properties of active substances as manufactured, must be determined in accordance with EEC Method A 14, where appropriate, and be reported.2.14Surface tensionThe surface tension of active substances must be determined in accordance EEC Method A 5 and be reported.2.15Oxidizing propertiesThe oxidizing properties of active substances as manufactured, must be

determined in accordance with EEC Method A 17 and be reported, except where examination of their structural formulas, establishes beyond reasonable doubt that the active substance concerned 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.3Further 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 information and data referred to are required for all active substances, except where otherwise specified.
3.1Function, e.g. fungicide, herbicide, insecticide, repellant, growth regulatorThe function must be specified from among the following:acaricideplant growth regulatorbactericiderepellantfungiciderodenticideherbicidesemio-chemicalsinsecticidetalpicidemolluscicideviricidenematicideother (must be specified)3.2Effects on harmful organisms, e.g. contact poison, inhalation poison, stomach poison, fungitoxic or fungistatic, etc. systemic or not in plants3.2.1The nature of the effects on harmful organisms must be stated:contact actionfungitoxic actionstomach actiondisiccantinhalation actionreproduction inhibitorfungistatic actionother (must be specified)3.2.2It must be stated whether or not the active substance is translocated in plants and where relevant whether such translocation is apoplastic, symplastic or both.3.3Field of use envisaged, e.g. field, protected crops, storage of plant products, home gardeningThe field(s) of use, existing and proposed, for preparations containing the active substance must be specified from among the following:Field use— Agriculture— Horticulture— Forestry— ViticultureProtected cropsAmenityWeed control on non-cultivated areasHome gardeningHouse plantsPlant products storage practiceOther (specify)3.4Harmful organisms controlled and crops or products protected or treated3.4.1Details 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.3.4.2Where relevant, details of harmful organisms against which protection is afforded, must be provided.3.4.3Where relevant, effects achieved e.g. sprout suppression, retardation of ripening, reduction in stem length, enhanced fertilization etc., must be reported.

3.5Mode of action3.5.1To the extent that it has been 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 available, the results of relevant experimental studies must be reported.3.5.2Where 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 5.1, 5.10, 6.1, 6.2, 6.8, 7.1, 7.2 and 9, where relevant, must be provided for the active metabolite or degradation product—— chemical name according to IUPAC and CA nomenclature;— ISO common name or proposed common name;— CAS number, EEC (EINECS or ELINCS) number, and CIPAC number if available;— empirical and structural formula; and— molecular mass.3.5.3Available 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; and— environmental and other factors effecting the rate and extent of conversion.3.6Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategiesWhere available, information on the possible occurrence of the development of resistance or cross-resistance, must be provided.3.7Recommended methods and precautions concerning handling, storage, transport or fireA Safety Data Sheet in accordance with Article 27 of the Directive of 1967 must be provided for all active substances.3.8Procedures for destruction or decontamination3.8.1Controlled incinerationIn 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 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. 3.8.2OthersOther 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.3.9Emergence measures in case of an accidentProcedures for the decontamination of water in case of an accident must be provided.4Analytical methods4.1Analytical methods for the determination of pure active substance and, where appropriate, for relevant breakdown products, isomers and impurities of the active substance and additives (e.g. stabilizers)4.2Analytical methods including recovery rates and the limits of determination for residues in, and where relevant on, the following:4.2.1Treated plants, plant products, foodstuffs, feeding stuffs4.2.2Soil4.2.3Water (including

drinking water)4.2.4Air4.2.5Animal and human body fluids and tissues5Toxicological and metabolism studiesIntroduction (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, 1, — specify appropriate conditions or restrictions to be associated with any inclusion in Annex 1, — classify the 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 on 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 no 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 provided. (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 radio labelled 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 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.
(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 those 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 route of administration of the test substance depends on the main exposure routes. In cases where exposure is mainly to the gas phase, it can be more appropriate to perform inhalation studies instead of oral studies.5.1Studies on absorption, distribution, excretion and metabolism in animalsQuite limited data, as described below and restricted to one test species (normally the rat) may be all that is required. These data can provide information useful in the design and interpretation of subsequent toxicity tests. However, it must be remembered that information on inter species 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 testThe 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 of 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 requiredA 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 guidelineCommission Directive 88/302/EEC10, Part B, Toxicokinetics.5.2Acute toxicityThe 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,— the time course and characteristics of the effects with full details of behavioural changes and possible gross

pathological changes at postmortem,— 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 the Directive of 1967. The information generated through acute toxicity testing is of particular value in assessing hazards likely to arise in accident situations.5.2.1OralCircumstances in which requiredThe acute oral toxicity of the active substance must always be reportedTest GuidelineThe test must be carried out in accordance with EEC Method B1 or B1 bis.5.2.2PercutaneousCircumstances in which requiredThe acute percutaneous toxicity of the active substance must always be reported 10O.J. No. L133/1 30/05/1988.

Test GuidelineBoth local and systemic effects must be investigated. The test must be carried out in accordance with EEC Method B 3.5.2.3InhalationCircumstances in which requiredThe inhalation toxicity of the active substance must be reported where the active substance is—— a gas or a liquified gas,— to be used as a fumigant,— to be included in a smoke generating, aerosol or vapour releasing, preparation,— to be used with fogging equipment,— has a vapour pressure > 1 x 10-2 Pa and is to be included in preparations to be used in enclosed spaces such as warehouses or glasshouses,— to be included in preparations which are powders containing a significant proportion of particles of diameter < 50 µm (>1% on a weight basis), or— to be included in preparations to be applied in a manner which generates a significant proportion of particles or droplets of diameter < 50 µm (>1% on a weight basis).Test GuidelineThe test must be carried out in accordance with EEC Method B 2.5.2.4Skin irritationAim of the testThe test will provide information as to the potential for skin irritancy of the active substance, including the potential reversibility of the effects observed.Circumstances in which requiredThe skin irritancy of the active substance must be determined and reported 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 GuidelineThe test must be carried out in accordance with EEC Method B 4.
5.2.5Eye irritationAim of the testThe test will provide information as to the potential for eye irritancy of the active substance, including the potential reversibility of the effects observed.Circumstances in which requiredEye irritation tests must be conducted and reported except where it is likely, as indicated in the test guideline, that severe effects on the eye may be produced.Test GuidelineThe test must be carried out in accordance with EEC Method B 5.5.2.6Skin sensitizationAim of the testThe test will provide sufficient information to assess the potential of the active substance to provoke skin sensitization reactions.Circumstances in which requiredThe test must always be carried out except where the substance is a known sensitizer.Test GuidelineThe test must be carried out in accordance with EEC Method B 6.5.3Short-term

toxicityShort-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 effects of the active substance and the risks to workers who may be exposed over extensive periods. In addition short-term studies provide information which is useful in the design on 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,— the toxicity of the active substance including where possible the NOAEL,
— the 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,— where possible, the mode of toxic action, and— the relative hazard associated with different routes of exposure.5.3.1Oral 28-day studyCircumstances in which requiredAlthough 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 can be of particular value in the identification of adaptive responses which can be masked in chronic toxicity studies.Test GuidelineThe test must be carried out in accordance with EEC Method B 7.5.3.2Oral 90-day studyCircumstances in which requiredThe short-term (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 GuidelineCommission Directive 88/3O2/EEC10, Part B, sub-chronic oral toxicity test.5.3.3Other routesCircumstances in which requiredFor the assessment of the significance of operator exposure, percutaneous studies may be useful.For volatile substances (vapour pressure > 10-2 Pa) expert judgement is required to decide whether the short-term studies have to be performed by the oral inhalation route of exposure.
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Test Guidelines— 28-day dermal: EEC Method B 9,— 90-day dermal: Commission Directive 88/302/EEC10, Part B, sub-chronic dermal toxicity study,— 28-day inhalation: EEC Method B 8,— 90-day inhalation; Commission Directive 88/3O2/EEC10, Part B, sub-chronic inhalation toxicity study.5.4Genotoxicity testingAim of the testThese studies are of value in—— the prediction of genotoxic potential,— the early identification of genotoxic carcinogens, and— 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 dependent upon the interpretation of results obtained at each stage.5.4.1In vitro studiesCircumstances in which requiredIn 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 reported.Test GuidelinesAcceptable test guidelines are—EEC Method B 14 — Salmonella Typhimurium reverse mutation assay,EEC Method B 10—in vitro mammalian cytogenetic test, Commission Directive 88/302/EEC10, Part B — in vitro mammalian cell gene mutation test.

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5.4.2In vivo studies in somatic cellsCircumstances in which requiredIf all the results of the in vitro studies are negative further testing must be done, taking into consideration all 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 for that/those previously used.If the in vitro cytogenetic test is positive, an in vitro 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 GuidelinesAcceptable test guidelines are—EEC Method B 12 — micronucleus test, Commission Directive 88/302/EEC10, Part B — mouse spot test,EEC Method B 11—in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis5.4.3In vivo studies in germ cellsCircumstances in which requiredWhen 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 information regarding toxicokinetics, use and anticipated exposure. Suitable tests involve interaction with DNA (such as the dominant lethal assay), to assess the potential for inherited effects and possibly to make a quantifiable assessment of heritable effects. It is recognized that in view of their complexity, the use of quantitative studies requires strong justification.5.5Long term toxicity and carcinogenicityAim of the testThe 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—

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— 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.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 requiredThe 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 ConditionsA 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 with the active substance, using the mouse as test species, must be conducted.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. Historical control data provided must include—
— the identification of species and strain, the name of the supplier and the specific colony identification, if the supplier has more than one geographical location,— the name of the laboratory and the dates when the study was performed,— a description of the general conditions under which animals were maintained, including the type or brand of diet and, where possible, the amount consumed,— the approximate age, in days, of the control animals at the beginning of the study and at the time of killing or death,— a description of the control group mortality pattern observed during or at the end of the study, and other pertinent observations (e.g. diseases, infections),— the names of the laboratory and of the examining scientists responsible for gathering and interpreting 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 in the carcinogenicity study should elicit signs of minimal toxicity such as slight depression in body-weight (less than 10%), without causing tissue necrosis or metabolic saturation and without

substantially altering the 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.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, unassociated 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 the American Society of Toxicologic Pathologists11, 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 the mechanism of action and available, special histological staining) techniques, histochemical techniques and electron microscope examinations, must be conducted and reported.
11Standardized System of Nomenclature and Diagnostic Criteria — Guides of Toxicologic Pathology.

Test GuidelineCommission Directive 88/3O2/EEC10, Part B, chronic toxicity test, carcinogenicity test or combined chronic toxicity/carcinogenicity test.5.6Reproductive toxicityAdverse reproductive effects are of two main types—— impairment of male or female fertility, and— effects 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 points 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. Historical control data provided must include—— the identification of species and strain, the name of the supplier and the specific colony identification, if the supplier has more than one geographical location,— the name of the laboratory and the dates when the study was performed,— a description of the general conditions under which animals were maintained, including the type of brand of diet and, where possible, the amount consumed,— the approximate age, in days, of the control animals at the beginning of the study and at the time of killing or death,— a 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— the names and the laboratory and of the examining scientists responsible for gathering and interpreting pathological data from the study.5.6.1Multi-generation studiesAim of the testThe studies reported, taken together with other relevant data and information on the active substance, must be sufficient to permit the identification of effects on reproduction, following repeated exposure to the active substance, and in particular must be sufficient—
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— 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 testing),— to establish the dose-response relationship, to identify changes in toxic signs and manifestations observed, and— to establish the NOAEL.Circumstances in which requiredA reproduction toxicity study in rats over at least two generations must always be reported.Test guidelineCommission Directive 88/302/EEC10, Part B, two-generation reproduction toxicity test. In addition organ weight of reproductive organs must be reported.Supplementary studiesWhere necessary for a better interpretation of effects on reproduction and as far as this information is not yet available it could be necessary to perform supplementary studies and information—— separate male and female studies,— three segment design studies,— 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.5.6.2Developmental toxicity studiesAim of the testThe 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,
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— 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 in pregnant animals.Circumstances in which requiredThe tests must always be carried out.Test guidelineCommission Directive 88/302/EEC10, Part B, teratogenicity test — rodent and non-rodent.5.7Delayed neurotoxicity studiesAim of the testThe test will provide sufficient data to establish if the active substance could provoke delayed neurotoxicity after exposure.Circumstances in which requiredThese studies must be carried out for substances of similar or related structures to those known to have been capable of inducing delayed neurotoxicity, such as organophosphates.Test GuidelineThe test must be carried out in accordance with OECD

Guideline 418.5.8Other toxicological studies5.8.1Toxicity studies with 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.5.8.2Supplementary studies on the active substanceIn certain cases it may be necessary to carry out supplementary studies to further clarify the nature of observed effects. Such studies could include—
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— studies on absorption, distribution, excretion and metabolism,— studies on neurotoxic potential,— studies on immunotoxicological potential,— studies using 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.5.9Medical dataWhere available, and without prejudice to the provisions of Article 5 of Council Directive 80/1107/EEC12, on the protection of workers from the risks related to exposure to chemical, physical and biological agents at work, practical data and information relevant to the recognition of the symptoms of poisoning, and on the effectiveness of first aid and therapeutic measures must be submitted. Specific references to the investigations relative to antidotal pharmacology or safety pharmacology using animals, should be provided. Where 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.5.9.1Medical surveillance on manufacturing plant personnelReports of occupational health surveillance programmes, supported with detailed information on the design of the programmes, on exposure to the active substance and exposure to other chemicals, must be submitted. Such reports should, where feasible, 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, the symptoms observed and other relevant clinical information.
12O.J. No. L327/8 3/12/1980.
5.9.2Direct observation, e.g. clinical cases and poisoning incidentsAvailable 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 animals data to man and in identifying unexpected adverse effects which are specific to humans.5.9.3Observations on exposure of the general population and epidemiological studies if appropriateWhere available, and supported with data on levels and duration of exposure, and where conducted in accordance with recognized standards13, epidemiological studies are of particular value and must be submitted.5.9.4Diagnosis of poisoning (determination of active substance, metabolites), specific signs of poisoning, clinical testsA detailed description of the clinical signs 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.5.9.5Proposed treatment: first aid measures, antidotes, medical treatmentThe first aid measures to be used in the event of poisoning (actual and suspected) and in the event of contamination of eyes must be reported.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, particularly those relating to "general medical problems" and conditions, must be described.

13Guidelines for Good Epidemiology Practices for Occupational and Environmental Research, developed by the Chemical Manufacturers Association's Epidemiology Task Force, as part of the Epidemiology Resource and Information Centre (ERIC), Pilot Project, 1991.

5.9.6Expected effects of poisoningWhere known, the expected effects and the duration of these effects following poisoning must be described and include a description of the impact of—— the type, level and duration of exposure, or ingestion, and— varying time periods between exposure, or ingestion, and commencement of treatment.5.11Summary of mammalian toxicology and overall conclusionsA summary of all information provided in accordance with paragraphs 5.1 through 5.9 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 (paragraph 5 (iv)), the relevance of the data as submitted, to 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 estimation of the ADI and AOEL(s) for the active substance must be submitted.6Residues in or on treated products, food and feed6.1Identification of breakdown and reaction products and of metabolites in treated plants or products6.2Behaviour of residue of the active substance and its metabolites from the time of application until harvest or out-loading of stored products — uptake and distribution in, and where relevant on, plants, kinetics of disappearance, binding to plant constituents, etc.6.3Overall material balance for the active substance. Sufficient residue data from supervised trials to demonstrate that residues likely to arise from the proposed treatments would not be or concern for human and animal health6.4Estimation of the potential and actual exposure through diet and other means, such as residue monitoring data for products in the distribution chain, or such as data concerning exposure via air, water, etc.6.5Feeding and metabolism studies in livestock (if residues remain in or on crops or parts of crops used for feed) to permit evaluation of residues in foodstuffs of animal origin
6.6Effects of industrial processing and/or household preparation on the nature and magnitude of residues6.7Summary and evaluation of residue behaviour resulting from data submitted pursuant to points 6.1 to 6.67Fate and behaviour in the environmentIntroduction (i) The introduction provided, taken together with that for one or more preparations containing the active substance, must be sufficient to permit 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. (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 distribution, fate, and behaviour in the environment of the active substance and relevant metabolites, degradation and reaction products 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) 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 radiolabelled 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 radiolabelled test material is used, radiolabels 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 metabolites, 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 must be taken into account. (vi) Where relevant, tests should be designed and data analyzed 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).7.1Fate and behaviour in soilAll 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 at pF = 0 and pF = 2.5 must 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 that as far as possible the same soils be used throughout all laboratory soil studies.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 absorption/desorption studies.The first soil chosen to begin testing 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 must be reported in cases where field studies are conducted.7.1.1Route and rate of degradation7.1.1.1Route of DegradationAim of the testsThe data and information provided, together with other relevant data and information, should be sufficient to—— indentify, where feasible, 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, 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.Non-extractable residues 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 generated through metabolic pathways which form naturally occurring products.

7.1.1.1.1Aerobic degradationCircumstances in which requiredThe 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.Test conditionsThe 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, as well as in the form of balance sheets which show the distribution of radiolabel 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 such residues exceed 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 should normally be 120 days, except where after a shorter

period the levels of non-extractable residues and CO2 are such that they can be extrapolated in a reliable way to 100 days.Test guidelineThe methodology to be used is that described by SETAC9.7.1.1.1.2Supplementary studiesAnaerobic degradationCircumstances in which requiredAn anaerobic degradation study must be reported unless it can be justified that exposure of the active substance, following use of plant protection products containing it, to anaerobic conditions is unlikely to occur,
9Society of Environmental Toxicology and Chemistry (SETAC), 1995, "Procedures for assessing the environmental fate and ecotoxicity of pesticides, ISBN 90-5607-002-9"

Test conditions and test guidelineThe provisions specified under the corresponding paragraph of point 7.1.1.1.1 apply.Soil photolysisCircumstances in which requiredA 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 guidelineThe methodology to be used is that described by SETAC9.7.1.1.2Rate of degradation7.1.1.2.1Laboratory studiesAim of the testsThe soil degradation studies should provide the best possible estimates of the time taken for degradation of 50% and 90% (DT50lab and DT90lab), of the active substance, and of relevant metabolites, degradation and reaction products under laboratory conditions.Aerobic degradationCircumstances in which requiredThe rate of degradation in soil must always be reported, except where the nature and manner of use of plant protection products containing the active substance preclude soil contamination, such as uses on stored products or wound healing treatments for trees.Test conditionsThe rate of aerobic degradation of the active substance in three soil types of 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, until such time as a validated Community calculation model for the extrapolation of degradation rates to low temperatures is available, one additional study at 10 °C has to be performed on one of the soils used for the investigation of degradation at 20 °C.
9Society of Environmental Toxicology and Chemistry (SETAC), 1995, "Procedures for assessing the environmental fate and ecotoxicity of pesticides, ISBN 90-5607-002-9"

The duration of the study should normally be 120 days except where 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 DT50 values were determined from the results obtained with the active substance.Test guidelineThe methodology to be used is that described by SETAC9.Anaerobic degradationCircumstances in which requiredThe rate of anaerobic degradation of the active substance

must be reported where an anaerobic study is required in accordance with point 7.1.1.1.2.Test conditionsThe rate of anaerobic degradation of the active substance must be carried out in the soil used in the anaerobic study performed in accordance with point 7.1.1.1.2.The duration of the study should normally be 120 days except where more than 90% of the active substance is degraded before that period expires.Similar studies using one soil 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 DT50 values were determined from the results obtained with the active substance.Test guidelineThe methodology to be used is that described by SETAC9.7.1.1.2.2Field studiesSoil dissipation studiesAim of the testThe soil dissipation studies should provide estimates of the time taken for dissipation of 50% and 90% (DT50f and DT90f), of the active substance under field conditions. Where relevant, information on relevant metabolites, degradation and reaction products must also be reported.
9Society of Environmental Toxicology and Chemistry (SETAC), 1995, "Procedures for assessing the environmental fate and ecotoxicity of pesticides, ISBN 90-5607-002-9"

Circumstances in which required.Tests must be conducted where DT50lab, determined at 20 °C and at a soil moisture content pF value of 2 - 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 DT50lab determined at 10 °C and at a soil moisture content pF value of 2 - 2.5 (suction pressure) is greater than 90 days.Test conditionsIndividual studies on a range of representative soils (normally 4 different types) must be continued until > 90% of the amount applied has dissipated. The maximum duration of such studies is 24 months.Test guidelineThe methodology to be used is that described by SETAC9.Soil residue studiesAim of the testSoil residue studies should provide estimates of the soil residue levels at harvest or at time of sowing or planting succeeding crops.Circumstances in which requiredSoil residue studies must be reported where the DT50lab is greater than one third of the period between the time of application and time of harvest and where absorption by the succeeding crop is possible, except where soil residues at time of sowing or planting of a succeeding crop can be reliably estimated from the data generated in 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 conditionsIndividual studies must be continued until harvest or time of sowing or planting succeeding crops, unless > 90% of the amount applied has dissipated at earlier date.Test guidelineThe methodology to be used is that described by SETAC9.
9Society of Environmental Toxicology and Chemistry (SETAC), 1995, "Procedures for assessing the environmental fate and ecotoxicity of

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Soil accumulation studiesAim of the testsThe tests should provide sufficient data to evaluate the possibility of accumulation in soil of residues of the active substance and of relevant metabolites, degradation and reaction products.Circumstances in which requiredWhere on the basis of soil dissipation studies it is established that DT90f > 1 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 conditionsLong term field studies must be done on two relevant soils and involve multiple applications.Before performing these studies the applicant must seek the agreement of the competent authorities on the type of study to be performed.7.1.2Adsorption and desorption.Aim of the testThe data and information provided, together with other relevant data and information, should be sufficient to establish the adsorption coefficient of the active substance and of relevant metabolites, degradation and reaction products.Circumstances in which required.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 treatments for trees.Test conditionsStudies on the active substance must be reported for four soil types.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 guidelineThe test must be carried out in accordance with OECD Guideline 106.7.1.3Mobility in the soil7.1.3.1Column leaching studiesAim of the testTesting should provide sufficient data to evaluate the mobility and leaching potential of the active substance and if possible of relevant metabolites, degradation and reaction products.Circumstances in which requiredStudies in 4 soils must be carried out where in the adsorption and desorption studies provided for under point 7.1.2 it is not possible to obtain reliable adsorption coefficient values.Test guidelineThe methodology to be used is that described by SETAC9.7.1.3.2Aged residue column leachingAim of the testTesting should provide sufficient data to estimate the mobility and leaching potential of relevant metabolites, degradation and reaction products.Circumstances in which requiredThe 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 with point 7.1.2 or 7.1.3.1 was performed.Test conditionsThe period(s) of ageing should be determined on the basis of the degradation patterns of active

substance and metabolites and be such as to ensure that a relevant spectrum of metabolites is present and the time of leaching.
9Society of Environmental Toxicology and Chemistry (SETAC), 1995, "Procedures for assessing the environmental fate and ecotoxicity of pesticides, ISBN 90-5607-002-9"

Test guidelineThe methodology to be used is that described by SETAC9.7.1.3.3Lysimeter Studies or Field leaching studiesAim of the testsThe test should provide data with respect to—— mobility in soil,— potential for leaching to ground water,— the potential distribution in soil.Circumstances in which requiredExpert judgement is 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 (PECGW) 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 conditionsGreat care is necessary in the design of both experimental installations and of individual studies, to ensure that results obtained can be used for assessment purposes. Studies should cover the realistic worst case situation likely to arise, taking into account soil type, climatic conditions, application rate and frequency and period of application.Water percolating from soil columns must be analysed at suitable intervals, while residues in plant material must be determined at harvest. Residues in the soil profile, in at least 5 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 removal of soil cores influences the leaching process.Precipitation, soil and air temperatures must be recorded at regular intervals (at least on a weekly base).Lysimeter studiesTest conditionsThe minimal depth of the lysimeters should be 100 cm and their maximal depth should be 130 cm. The soil cores must not be disturbed. 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 to a depth of more than 25 cm.
9Society of Environmental Toxicology and Chemistry (SETAC), 1995, "Procedures for assessing the environmental fate and ecotoxicity of pesticides, ISBN 90-5607-002-9"

Field leaching studiesTest conditionsInformation relative to the groundwater table in the fields used for experimental purposes 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 guidelineThe methodology to be used is that described by SETAC9.7.2Fate and behaviour in water and airAim of the testsThe 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, and— potential for contamination of surface water and groundwater.7.2.1Route and rate of degradation in aquatic systems (as far as not covered by point 2.9)Aim of the testsThe 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),
9Society of Environmental Toxicology and Chemistry (SETAC), 1995, "Procedures for assessing the environmental fate and ecotoxicity of pesticides, ISBN 90-5607-002-9"

— 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.7.2.1.1Hydrolytic degradationCircumstances in which requiredThe 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 guidelineThe same provisions as provided under the corresponding paragraphs of point 2.9.1 apply.7.2.1.2Photochemical degradationCircumstances in which requiredThe 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 guidelinesThe same provisions as provided under the corresponding paragraphs of points 2.9.2 and 2.9.3 apply.7.2.1.3Biological degradation7.2.1.3.1Ready biodegradabilityCircumstances in which requiredThe test must always be performed unless it is not required in accordance with the provisions of Annex VI of the Directives of 1967, for the classification of the active substance.Test guidelineThe test must be carried out in accordance with EEC Method C 4. 7.2.1.3.2Water/sediment studyCircumstances in which requiredThe test must be reported unless it can be justified that contamination of surface water will not occur.Test guidelineThe methodology to be used is that described by SETAC9.7.2.1.4Degradation in the saturated zoneCircumstances in which requiredTransformation 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 groundwater.Test conditionsExpert judgement is required to decide whether, or not, this information is necessary. Before performing these studies the applicant must seek the agreement of the competent authorities on the type of study to be performed.7.2.2Route and rate of degradation in air (as far as not covered by point 2.10)Guidance under development.7.3Definition of the residueIn the light of the chemical composition of residues that occur in soil, water or air, resulting from use, or proposed use, of plant protection products 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.7.4Monitoring dataAvailable monitoring data concerning fate and behaviour of the active substance and relevant metabolites, degradation and reaction products must be reported."8Ecotoxicological studies on the active substance8.1Effects on birds8.1.1Acute oral toxicity8.1.2Short-term toxicity — eight-day dietary study in at least one species (other than chicken)
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8.1.3Effects on reproduction8.2Effects on aquatic organisms8.2.1Acute toxicity to fish8.2.2Chronic toxicity to fish8.2.3Effects on fish reproduction and growth rate8.2.4Bio-accumulation in fish8.2.5Acute toxicity for Daphnia magna8.2.6Daphnia magna reproduction and growth rate8.2.7Effects on algal growth8.3Effects on other non-target organisms8.3.1Acute toxicity to honeybees and other beneficial arthropods (e.g. predators)8.3.2Toxicity to earthworms and to other soil non-target macro-organisms8.3.3Effects on soil non-target micro organisms8.3.4Effects on other non-target organisms (flora and fauna) believed to be at risk8.3.5Effects on biological methods for sewage treatment9Summary and evaluation of points 7 and 810Proposals 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 phrases11A dossier as referred to in Annex III, part A, for a representative plant protection product

Part 2

Annex III

(Annex III to the Directive of 1991, as amended by Commission Directive No 93/71/EEC of 27 July 1993, Commission Directive 94/37/EC and Commission Directive 94/79/EC)

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

INTRODUCTION

The information required shall:

1.1include a technical dossier supplying the information necessary for evaluating efficacy and the foreseeable risks, whether immediate or

delayed, which the plant protection product may entail for humans, animals and the environment and containing at least the information and results of the studies referred to below;1.2where relevant, be generated using test guidelines referred to or described in this Annex; in the case of studies initiated before the adoption of the modification of this Annex, the information shall be generated using suitable internationally or nationally validated test guidelines or, in the absence thereof, test guidelines accepted by the competent authority;1.3in the event of a test guideline being inappropriate or not described, or where another one than those referred to in this annex has been used, include a justification, which is acceptable to the competent authority for the guidelines used;1.4include, 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;1.5include 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.1.6where relevant, have been generated in accordance with the requirements of Directive 86/609/EEC.2.1Tests 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 health or the environment. 2.2Tests and analyses, required under the provisions of section 6 points 6.2 to 6.6 of this annex, shall, where they are conducted outside the territory of the state, be conducted by official or officially recognised testing facilities or organisations in the Member State concerned, which satisfy at least the requirements specified in points 2.2 and 2.3 of the introduction to Annex III to Directive 93/71/EEC.2.3Tests and analyses, required under the provisions of section 6 points 6.2 to 6.6 of this annex, shall, where they are conducted within the territory of the state, be conducted in accordance with the Principles of Good Experimental Practice set out in the Sixth Schedule, or in compliance with Irish/European Standard IS/EN 45001 and in accordance with the authorisation for trials or trials permit concerned.2.4Notwithstanding the provisions of point 2.1, during the period to 31 December 1999, tests and analyses done to obtain data on the properties and/or safety with respect to honeybees and beneficial arthropods other than bees may have been conducted by officially recognised testing facilities or organisations, in accordance with the principles laid down in the Sixth Schedule, or in compliance with Irish/European Standard IS/EN 45001, where they are conducted within the territory of the state, and in accordance with the requirements of points 2.2 and 2.3 of the introduction to Annex III to Directive 93/71/EEC, where they are conducted outside the territory of the state.3The

information required shall include the proposed classification and labelling of the plant protection product in accordance with relevant Community Directives.4In individual 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 possibly new studies have to be performed, all information on the formulant, made available to the competent authority, shall 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 of 27 June 1967, on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.

PART A

Chemical preparations

1Identity of the plant protection productThe information provided, taken together with that provided for the active substance(s), must be sufficient to identify preparations, with precision, and to define them in terms of their specification and nature. The information and data referred to, unless otherwise specified, are required for all plant protection products.1.1Applicant (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 territory of the State, 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.1.2Manufacturer 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 (preferably 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 as required in Annex II must be provided.1.3Trade name or proposed trade name, and manufacturer's development code number of the preparation if appropriateAll 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 obsolete), full details of the differences, must be provided. (The proposed trade name may not give rise to confusion with the trade name of plant protection products already authorised).1.4Detailed

quantitative and qualitative information on the composition of the preparation (active substance(s), and formulant(s)
1.4.1For preparations the following information must be reported—— the content of both technical active substance(s) and pure active substance(s); and— the content of formulants.The concentrations must be expressed in terms as provided for in Article 6(2) of the Directive of 1978.1.4.2For 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.1.4.3Formulants must where possible, be identified both by their chemical name as given in Annex I to the Directive of 1967, or, if not included in that Directive, in accordance with both IUPAC and CA nomenclature. Their structure or structural formula must be provided. For each component of 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.1.4.4For formulants the function must be given:adhesive (sticker)preservativeantifoaming agentodourantantifreezeperfumebinderpropellantbufferrepellentcarriersafenerdeodorantsolventdispersing agentstabiliserdyesynergistemeticthickeneremulsifierwetting agent fertilisermiscellaneous (specify)1.5Physical state and nature of the preparation (emulsifiable concentrate, wettable powder, solution etc.)1.5.1The type and code of preparation must be designated in accordance with 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 that 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.1.6Function (herbicide, insecticide, etc.)The function must be specified from among the following:acaricideplant growth regulatorbactericiderepellentfungiciderodenticideherbicidesemio-chemicalsinsecticidetalpicidemolluscicideviricidenematicideother (must be specified)
2Physical, chemical and technical properties of the plant protection productThe 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 Specifications, of the FAO Panel of Experts on Pesticide Specifications, Registration Requirements and Application Standards, must be stated. Divergences from FAO specifications must be described in detail, and justified.2.1Appearance (colour and odour)A description of both the colour and odour, if any, and the physical state of the preparation, must be provided.2.2Explosivity and oxidising properties2.2.1The explosive properties of preparations must be

determined in accordance with EEC Method A 14 and be reported. 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.2.2.2The oxidising properties of preparations which are solids, must be determined in accordance with EEC Method A 17 and be reported. For other preparations the method used must be justified. Oxidising 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.2.3Flash point and other indications of flammability or spontaneous ignitionThe flash point of liquids which contain flammable solvents, must be determined in accordance with EEC Method A 9 and be reported. The flammability of solid preparations and gasses must be determined in accordance with EEC Method A 10, A 11 or A 12, as appropriate, and be reported. The auto-flammability of preparations, determined in accordance with EEC Method A 15 or A 16 as appropriate, and/or, where necessary, in accordance with the UN-Bowes-Cameron-Cage-Test (UN-Recommendations on the Transport of Dangerous Goods, Chapter 14, Nr 14.3.4), must be reported.2.4Acidity/alkalinity and if necessary pH value2.4.1In the case of preparations which are acidic (pH < 4) or alkaline (pH >10) the acidity or alkalinity and the pH value must be determined in accordance with CIPAC Method MT31 and MT75 respectively, and be reported.2.4.2Where relevant (if to be applied as aqueous dilution) the pH of a 1% aqueous dilution, emulsion or dispersion of the preparation, must be determined in accordance with CIPAC Method MT75 and be reported. 2.5Viscosity and surface tension2.5.1In the case of liquid preparations for Ultra Low Volume use (ULV) the kinematic viscosity must be determined in accordance with OECD Test Guideline 14 and be reported.2.5.2For non newtonian liquids the viscosity must be determined and reported together with the test conditions.2.5.3In the case of liquid preparations the surface tension must be determined in accordance with EEC Method A 5 and be reported.2.6Relative density and bulk density2.6.1The relative density of liquid preparations must be determined in accordance with EEC Method A 3 and be reported.2.6.2The bulk (tap) density of preparations which are powders or granules, must be determined in accordance with CIPAC Methods MT33, MT159 or MT169, as appropriate, and be reported.2.7Storage stability — stability and shelf-life. Effects of light, temperature and humidity on technical characteristics of the plant protection product2.7.1The stability of the preparation after storage for 14 days at 54°C must be determined in accordance with CIPAC Method MT46 and be reported.Other storage times and/or temperatures may be needed (e.g. 8 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 initial determined content, the minimum content must be declared and information on the degradation

products must be supplied.2.7.2Additionally in the case of liquid preparations, the effect of low temperatures on stability, must be determined in accordance with CIPAC Methods MT39, MT48, MT51 or MT54, as appropriate, and be reported.2.7.3The shelf life of the preparation at ambient temperatures must be reported. Where shelf life is less than two years, the shell life in months, with appropriate temperature specifications, must be reported. Useful information relating to such testing is contained in GIFAP Monograph No 17.2.8Technical characteristics of the plant protection productThe technical characteristics of the preparation must be determined to permit a decision to be made as to its acceptability.2.8.1WettabilityThe 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 in accordance with CIPAC Method MT53.3 and be reported. 2.8.2Persistent foamingThe persistence of foaming of preparations to be diluted with water, must be determined in accordance with CIPAC Method MT47 must be reported.2.8.3Suspensibility and suspension stability2.8.3.1The suspensibility of water dispersible products (e.g. wettable powders, water dispersible granules, suspension concentrates) must be determined in accordance with CIPAC Method MT15, MT161 or MT168, as appropriate and be reported.2.8.3.2The spontaneity or dispensability of water dispersible products (e.g. suspension concentrates and water dispersible granules) must be determined in accordance with CIPAC Methods MT160 or MT174, as appropriate, and be reported.2.8.4Dilution stabilityThe dilution stability of water soluble products must be determined in accordance with CIPAC Method MT41 and be reported.2.8.5Dry sieve test and wet sieve testIn order to ensure that dustable powders have a suitable particle size distribution for ease of application, a dry sieve test must be conducted in accordance with CIPAC Method MT59.1 and be reported.In the case of water dispersible products, a wet sieve test must be conducted in accordance with CIPAC Method MT59.3 or MT167, as appropriate, must be reported.2.8.6Particle size distribution (dustable and wettable powders, granules), content of dust/fines (granules), attrition and friability (granules)2.8.6.1The size distribution of particles in the case of powders, must be determined in accordance with OECD Method 110 and be reported.The nominal size range of granules for direct application must be determined in accordance with CIPAC MT58.3 and for water dispersible granules and in accordance with CIPAC MT170, and be reported.2.8.6.2The dust content of granular preparations, must be determined in accordance with CIPAC Method MT171 and be reported. If relevant for operator exposure the particle size of dust must be determined in accordance with OECD Method 110 and be reported.2.8.6.3The friability and attrition characteristics of granules, must be determined and reported once internationally agreed methods are available. Where relevant data are available they must be reported together with details of the method used. 2.8.7Emulsifiability, Re-emulsifiability, emulsion stability2.8.7.1The emulsifiability, emulsion stability and re-emulsifiability of

preparations which form emulsions, must be determined in accordance with CIPAC Methods MT36 or MT173, as appropriate, and be reported.2.8.7.2The stability of dilute emulsions and of preparations which are emulsions, must be determined in accordance with CIPAC Method MT20 or MT173, as appropriate, and be reported.2.8.8Flowability, pourability (rinsability) and dustability2.8.8.1The flowability of granular preparations must be determined in accordance with CIPAC Method MT172 and be reported.2.8.8.2The pourability (including rinsed residue) of suspensions (e.g. suspension concentrates, suspo-emulsions), must be determined in accordance with CIPAC Method MT148 and be reported.2.8.8.3The dustability of dustable powders following accelerated storage as specified in paragraph 2.7.1 must be determined in accordance with CIPAC Method MT34 or another suitable method and be reported.2.9Physical and chemical compatibility with other products including plant protection products with which its use is to be authorized2.9.1The physical compatibility of tank mixes must be determined using in-house test methods and be reported. A practical test is an acceptable alternative.2.9.2The chemical compatibility of tank mixes must be determined and reported except where examination of the individual properties of the preparations establishes 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 determining chemical compatibility.2.10Adherence and distribution to seedsIn the case of preparations for seed treatment, both distribution and adhesion must be investigated and reported; in the case of distribution in accordance with CIPAC Method MT175.2.11Summary and evaluation of data presented under points 2.1 to 2.103Data on application3.1Field of use envisaged, e.g. field, protected crops, storage of plant products, home gardeningThe field(s) of use, existing and proposed, for preparations containing the active substance must be specified from among the following:
Field use— Agriculture— Horticulture— Forestry— ViticultureProtected cropsAmenityWeed control on non-cultivated areasHome gardeningHouse plantsPlant products storage practiceOther (specify)3.2Effects on harmful organisms, e.g. contact, inhalation or stomach poison, fungitoxic or fungistatic, etc., systemic or not in plants3.2.1The nature of the effects on harmful organisms must be stated:contact actionstomach actioninhalation actionfungitoxic actionfungistatic actiondesiccantreproduction inhibitorother (must be specified)It must be stated whether or not the active substance is translocated in plants and where relevant whether such translocation is apoplastic, symplastic or both.3.3Details of intended use e.g. types of harmful organisms controlled and/or plants or plant products to be protectedDetails of the intended use must be provided.Where relevant, effects achieved e.g. sprout suppression, retardation of ripening, reduction in stem length, enhanced fertilisation etc. must be reported.3.4Application rateFor each method of application and each use, the rate of application per unit (ha, m 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/m³ and where appropriate in g or kg/tonne; for protected crops and home gardening use rates shall be expressed in g or kg/100m or g or kg/m³.3.5Concentration 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.3.6Method of applicationThe 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.
3.7Number and timing of applications and duration of protectionThe 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.3.8Necessary waiting periods or other precautions to avoid Phytotoxic effects on succeeding cropsWhere 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.3.9Proposed instructions for useThe proposed instructions for use of the preparation, to be printed on labels and leaflets, must be provided.4Further information on the plant protection product4.1Packaging (type, materials, size etc.), compatibility of the preparation with proposed packaging materials4.1.1Packaging 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".4.1.2The suitability of the packaging, including closures, in terms of its strength, leakproofness and resistance to normal transport and handling, must be determined in accordance with ADR Methods 3552, 3553, 3560, 3554, 3555, 3556 and 3558, or ADR methods for intermediate bulk containers, as appropriate, and where child resistant closures are required, in accordance with ISO Standard 8317, and be reported.4.1.3The resistance of the packaging material to its contents must be determined in accordance with GIFAP Monograph No. 17, and be reported.
4.2Procedures for cleaning application equipmentCleaning procedures for both application equipment and protective clothing must be described in detail. The effectiveness of the cleaning procedure, must be fully investigated and reported.4.3Re-entry periods, necessary waiting periods or other precautions to protect man, livestock and the environmentThe information provided must follow from and be supported by the data provided for the active substance(s) and that provided

under sections 7 and 8.4.3.1Where 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 or on 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.4.3.2Where necessary, in the light of 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.4.4Recommended methods and precautions concerning: handling, storage, transport or fireThe 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 must be conducted in accordance with ISO-TR 9122.Where relevant, the nature and characteristics of protective clothing and equipment proposed must be reported. The data provided must be sufficient to permit an evaluation to be made of the suitability and effectiveness of the protective clothing under realistic conditions of use (e.g. shield or glasshouse circumstances).

4.5Emergency measures in the case of an accidentWhether arising during transport, storage or use, detailed procedures to be followed in the event of an emergency, must be provided, and include procedures for—— containment of spillages;— decontamination of areas, vehicles and buildings;— disposal of damaged packaging, adsorbents and other materials;— protection of emergency workers and bystanders; and— first aid measures.4.6Procedures for destruction or decontamination of the plant protection product and its packagingProcedures 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.4.6.1Possibility of neutralisationNeutralisation 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 neutralisation should be identified (through analysis or on the basis of theoretical considerations) and be reported.4.6.2Controlled incinerationIn many cases the preferred or sole means to safely dispose of active

substances as well as plant protection products containing them, contaminated materials, or contaminated packaging, is through controlled incineration in a licensed 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 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.4.6.3OthersOther 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.5Analytical methods5.1Analytical methods for determining the composition of the plant protection product
5.2In so far as not covered by Annex II, Part A, point 4.2, analytical methods including recovery rates and the limits of determination for residues and where relevant on, the following:5.2.1Treated plants, plant products, foodstuffs, feeding-stuffs5.2.2Soil5.2.3Water (including drinking water)5.2.4Air5.2.5Animal and human body fluids and tissues6Efficacy dataGeneralThe 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 active 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 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 products 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 in 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 seasons 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.
6.1Preliminary testsReports 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 protection product. Where this information is not submitted a justification which is acceptable to the competent authority must be provided.6.2Testing effectivenessAim of the testsThe 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 conditionsNormally 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 authorised plant protection product which has proved to have 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 or 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 show the level of effects on the species to be treated, and include investigation of differences in the response of a representative sample of the range of cultivars on which its use is proposed.
In order to clarify the dose response, dose rates lower than the recommended one must be included in some trials in order to enable

to assess whether the recommended rate is the minimum necessary to achieve the desired effect.The duration of the effects of treatment must be investigated in relation to the control of the target organism or effect on the treated plants or plant products, as appropriate. When more than one application is recommended, trials must be reported which establish the duration of the effects of an application, the number of applications necessary and the desired intervals between them.Evidence must be submitted to show that the dose, timing and method 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 product is unlikely to be affected to a significant degree by environmental factors, such as temperature or rain, an investigation of the effects of such factors on performance must be carried out and reported, particularly where it is known that the performance of chemically related products is 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 guidelineTrials 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 Organisation (EPPO) guidelines 152 and 181. The report shall include a detailed and critical assessment of the data.When conducted within the territory of the state, the trials must be carried out in accordance with specific EPPO guidelines, where available. When conducted within the territory of another Member State, the trials must be carried out in accordance with specific EPPO guidelines, where available or when the Member State concerned so requires, in accordance with guidelines satisfying at least the requirements of the corresponding EPPO guidelines.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.6.3Information on the occurrence or possible occurrence of the development of resistanceLaboratory 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 active substances, must be provided. Where such information is not directly relevant to the uses for which authorisation is sought or to be renewed (different species of harmful organism or different crops), it must, if available, nevertheless be provided, as it may provide an 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.6.4Effects on the yield of treated plants or plant products in terms of quantity and/or quality6.4.1Effects on the quality of plants or plant productsAim of the testsThe 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 requiredThe possibility of the occurrence of taint or odour in food crops must be investigated and be reported where:— the nature of the product or its use is such that a risk of occurrence of taint or odour might be expected, or— other products based on the same or a closely similar active substance 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 its use could have an adverse influence on other quality aspects (for example in the case of use of plant growth regulators close to harvest), or— other products based on the same or a closely similar active substance 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 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 and methods of processing the crops, if relevant, are similar. It is generally sufficient to perform the test with the main formulation type to be authorized.

6.4.2Effects on transformation processesAim of the testsThe 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 requiredWhen 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 substance 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 authorised.6.4.3Effects on the yield of treated plants or plant

productsAim of the testsThe tests shall provide sufficient data to permit an evaluation of the performance of the plant protection product and of the possible occurrence of yield reduction or loss in storage of treated plants or plant products.Circumstances in which requiredThe effects of plant protection products on the yield or yield components of treated plants or 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 storage life must be determined where relevant.This information will normally be available from the tests required under the provisions of point 6.2.
6.5Phytotoxicity to target plants (including different cultivars), or to target plant productsAim of the testsThe tests 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 requiredFor 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 to be transient, evidence to support this claim is required. If necessary yield measurements 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 growth stage, vigour, and other factors which may influence susceptibility 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) or adjuvant(s), the provision of the previous paragraphs apply for the mixture.Test guidelineObservations concerning phytotoxicity must be recorded and reported 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, where testing is conducted within the territory of the state. When conducted within the territory of another Member State, the trials must be carried out in accordance with EPPO Guideline 135, or when the Member State concerned so requires, in accordance with guidelines satisfying at least the requirements of EPPO Guideline 135.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.6.6Observations 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)
6.6.1Impact on succeeding cropsAim of the information requiredSufficient 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 requiredWhere data, generated in accordance with section 9, point 9.1, shows that significant 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 succeeding crops.6.6.2Impact on other plants, including adjacent cropsAim of the information requiredSufficient 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 requiredObservations 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.6.6.3Impact on treated plants or plant products to be used for propagationAim of the information requiredSufficient 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 to be used for propagation.Circumstances in which requiredObservations 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 guidelineFor seeds testing shall be done according to ISTA methods14.6.6.4Effects on beneficial and other non-target organismsAny 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.6.7Summary and evaluation of data presented under 6.1 to 6.6A summary of all data and information 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.7Toxicological studiesFor the evaluation of the toxicity of preparations, sufficient information concerning the acute toxicity, irritancy and sensitizing properties of their active substance(s) is necessary. Where possible, additional

information on mode of toxic action, toxicological profile and all other known toxicological aspects of the active substance(s) 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 to be authorized.7.1Acute toxicityThe 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,— the toxicity of the plant protection product relative to that of the active substance,— the time course and characteristics of the effects with full details of behavioural changes and possible gross pathological changes at postmortem,— where possible mode of toxic action, and— the relative hazard associated with the different routes of exposure.
14International Rules for Seed Testing, 1985, Proceedings of the International Seed Testing Association, Seed Science and Technology, Volume 13, Number 2, 1985.

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 the Directive of 1978. The information generated through acute toxicity testing is of particular value in assessing hazards likely to arise in accident situations.7.1.1OralCircumstances in which requiredAn acute oral toxicity test should always be carried out unless the applicant can establish to the satisfaction of the competent authority that Article 3.2 of the Directive of 1978 can be invoked.Test GuidelineThe test must be carried out in accordance with EEC Method B 1 or B 1 bis.7.1.2PercutaneousCircumstances in which requiredAn acute percutaneous toxicity test should always be carried out unless the applicant can establish to the satisfaction of the competent authority that Article 3.2 of the Directive of 1978 can be invoked.Test GuidelineThe test must be carried out in accordance with EEC Method B
3.7.1.3InhalationAim of the testThe test will provide information concerning the inhalation toxicity to rats of the plant protection product or of smoke generated from it.Circumstances in which requiredThe test must be carried out where the plant protection product—— is a gas or liquified gas,— is a smoke generating formulation or a 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 x 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).Test

GuidelineThe test must be carried out in accordance with EEC Method B 2.7.1.4Skin irritationAim of the testThe test will provide information as to the potential for skin irritancy of the plant protection product, including the potential reversibility of the effects observed.Circumstances in which requiredThe skin irritancy of the plant protection product must be determined and reported 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 GuidelineThe test must be carried out in accordance with EEC Method B 4.7.1.5Eye irritationAim of the testThe test will provide information as to the potential for eye irritancy of the plant protection product, including the potential reversibility of the effects observed.Circumstances in which requiredEye irritation tests must be conducted and reported except where it is likely, as indicated in the test guideline, that severe effects on the eye may be produced.Test GuidelineThe test must be carried out in accordance with EEC Method B 5.
7.1.6Skin sensitizationAim of the testThe test will provide sufficient information to assess the potential of the plant protection product to provoke skin sensitization reactions.Circumstances in which requiredThe test must always be carried out except where the active substance(s) or co-formulants are known to have sensitizing properties.Test GuidelineThe test must be carried out in accordance with EEC Method B 6.7.1.7Supplementary studies for combinations of plant protection productsAim of the testIn certain cases it may be necessary to carry out the tests as referred to in 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 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.7.2Data on exposure7.2.1Operator exposureThe risks for those using plant protection products depend on the physical, chemical and toxicological properties of the plant protection product as well as the form of the product (undiluted/diluted), and the route, degree and duration of exposure. Sufficient information and data must be generated and reported to permit an assessment to be made 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 for its use. The data and information provided 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.
7.2.1.1Estimation of operator exposureAim of the estimationAn estimation shall be made, using where available a suitable calculation model, in order to permit an evaluation to be made of

the degree of operator exposure likely to arise under the proposed conditions of use.Circumstances in which requiredAn estimation of operator exposure must always be completed.Estimation conditionsAn 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 arising from the application of the classification and labelling provisions of the Directive of 1978. The estimation made shall relate to exposure arising from handling the undiluted and diluted product, taking into account the different types and sizes of containers to be used, mixing and loading operations, application of the plant protection product, climatic conditions and cleaning and the routine maintenance of application equipment.A first estimation shall be made on the basis of the assumption that the operator does not use any personal protective equipment.Where appropriate, a second estimation shall be made on the basis of an assumption that the operator uses that effective and readily obtainable protective equipment which it is feasible for the operator to use. Where personal protective measures are specified on the label, the estimation shall take these into account.7.2.1.2Measurement of operator exposureAim of the testThe test shall provide sufficient data to permit an evaluation to be made of the degree of operator exposure likely to arise under the proposed conditions of use.Circumstances in which requiredActual exposure data for relevant exposure route(s) must be reported where risk assessment indicates that a health-based limit value may be exceeded. That will 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 the inclusion of the active substance(s) in Annex 1, and/or
— the Limit Values established for the active substance(s) and/or toxicologically relevant compound(s) contained in the plant protection product, in accordance with Council Directive 80/1107/EEC12 and Council Directive 90/394/EEC15, on the protection of workers from the risks related to exposure to carcinogens at work,may be exceeded.Actual exposure data must also be reported when an appropriate calculation model or appropriate data are not available to permit an estimation to be made as provided for in 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 to be used in refining the estimation made in accordance with point 7.2.1.1Test conditionsThe test must be conducted under realistic exposure conditions taking into account the proposed conditions of use.7.2.2Bystander exposureBystanders 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 for the protection of bystanders, including the exclusion of bystanders from treatment areas and separation distances.Aim of the estimationAn estimation shall be made, using where available a suitable

calculation model, in order to permit an evaluation to be made of the degree of bystander exposure likely to arise under the proposed conditions of use.Circumstances in which requiredAn estimation of bystander exposure must always be completed.Estimation conditionsAn estimation of bystander exposure shall be made for each type of application method. The estimation shall be made on the basis of the assumption that bystanders do not use any personal protective equipment.
12O.J. No. L327/8 3/12/1980.
15O.J. No. L196/1 26/7/1990.

Measurement of bystander exposure may be required when estimates made indicate that there is cause for concern.7.2.3Worker exposureWorkers can be exposed following application of plant protection products, when entering treated fields or premises or when 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 protection measures, including waiting and re-entry periods.7.2.3.1Estimation of worker exposureAim of the estimationAn estimation shall be made, using where available a suitable calculation model, in order to permit an evaluation to be made of the degree of worker exposure likely to arise under the proposed conditions of use.Circumstances in which requiredAn estimation of worker exposure must always be completed.Estimation conditionsAn estimation of worker exposure must be made for each crop and task to be carried out.A first estimation made with the benefit of available data on the exposure likely to arise shall be made on the basis of the assumption that the worker does not use any personal protective equipment.Where appropriate, a second estimation shall be made on the basis of an assumption that the worker uses that effective and readily obtainable protective equipment which it is feasible for the worker to use.Where appropriate, a further estimation shall be made using data generated relating to the amounts of dislodgeable residues that occur under the proposed conditions of use.7.2.3.2Measurement of worker exposureAim of the testThe test shall provide sufficient data to permit an evaluation to be made of the degree of worker exposure likely to arise under the proposed conditions of use.
Circumstances in which requiredActual exposure data for relevant exposure route(s) must be reported where risk assessment indicates that a health-based limit value be exceeded. That will be the case when the results of the estimation of worker exposure provided for under point 7.2.3.1 indicate that—— the AOELs established in the context of the inclusion of the active substance(s) in Annex 1, and/or— the Limit Values established for the active substance(s) and/or toxicologically relevant compound(s) contained in the plant protection product, in accordance with Council Directive 80/1107/EEC12 and Council Directive 90/394/EEC15,may be exceeded.Actual exposure data must also be reported when an appropriate calculation model or appropriate data are not available to permit an estimation to be

made as provided for in point 7.2.3.1.In cases 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 to be used in refining the estimation made in accordance with point 7.2.3.1.Test conditionsThe test must be conducted under realistic exposure conditions taking into account the proposed conditions of use.7.3Dermal absorptionAim of the testThe test shall provide a measurement of the absorption of the active substance and of toxicologically relevant compounds through the skin.Circumstances in which requiredThe study must be conducted when dermal exposure is a significant route and where the risk assessment indicates that a health-based limit value may be exceeded. That will be the case when 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 AOELs established in the context of the inclusion of the active substance(s) in Annex I, and/or— the Limit Values established for the active substance(s) and/or toxicologically relevant compound(s) contained in the plant protection product, in accordance with Council Directive 80/1107/EEC12 and Council Directive 90/394/EEC15,
1212O.J. No. L327/8 3/12/1980.
15O.J. No. L196/1 26/7/1990.

may be exceeded.Test conditionsIn principle data generated through in vivo skin absorption testing must be reported. If when the results of the estimation made using in vivo skin absorption testing are incorporated in the risk assessment, there nevertheless is an indication of excessive exposure, it may be necessary to perform an in vitro comparative absorption study using rat and human skin.Test guidelineAppropriate elements of OECD Guideline 417 should be used. The results of skin absorption studies conducted with the active substance(s) should be taken into account in designing individual studies.7.4Available toxicological data relating to non-active substancesWhere available a copy of the notification and the safety data sheet submitted in the context of the Directive of 1967 must be submitted for each formulant. All other available information should be submitted.8Residues in or on treated products, food and feed8.1Data from supervised trials in crops, food or feeding stuffs, for which authorized use is sought, giving all experimental conditions and details, including residue data concerning the active substance, relevant metabolites and relevant other constituents of the plant protection product, from time of application until harvest, or in the case of post-harvest treatment, breakdown of residues during storage and levels of residues at time of release from storage for marketing. Data should be available for the range of climatic and agronomic conditions likely to be encountered in the proposed area of use.8.2Effects of industrial processing and/or household preparation on the nature and magnitude of residues8.3Effects on taint, odour, taste or other quality aspects due to residues in or on fresh or processed products8.4Estimation of residues in products of animal origin resulting from ingestion of feeding stuffs or resulting from

contact with bedding, on the basis of residue data referred to in point 8.1 and studies in livestock referred to in Annex II, Part A, point 6.58.5Residue data in succeeding or rotational crops where presence of residues might be expected
12O.J. No. L327/8 3/12/1980.
15O.J. No. L196/1 26/7/1990.

8.6Proposed pre-harvest intervals for envisaged uses, or withholding periods or storage periods, in the case of post-harvest uses8.7Proposed maximum residue levels (MRLs) and justification of the acceptability of these residues8.8Summary and evaluation of the residue behaviour on the basis of the data submitted under points 8.1 to 8.79Fate and behaviour in the environmentIntroduction (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 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 radiolabelled 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 metabolites, reaction and degradation products in the environment. (iv) Where relevant, tests should be designed and data analyzed 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).
Predicted environmental concentrations in soil (PECs), water (PECsw and PECGw) and air (PECA)Estimates must be made and justified relevant to 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 (PECs)" 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 (PECsw)" 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 (PECGW)" the level of residues in groundwater "Predicted environmental concentration in air (PECA)" 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 that provided in the EPPO schemes for environmental risk assessment16. Where relevant the parameters provided for in this section should be used.When models are used for estimation of predicted environmental concentrations they must——
provide 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, and

16OEPP/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.

— be relevant to conditions in the area of use of proposed use for the plant protection product.The information provided must, where relevant, include that referred to in Annex II, Part A, point 7: and9.1Fate and behaviour in soilWhere 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 7.1.9.1.1Rate of Degradation in Soil9.1.1.1Laboratory studiesAim of the testThe soil degradation studies should provide best possible estimates of the time taken for degradation of 50% and 90% (DT50lab and DT90lab) of the active substance under laboratory conditions.Circumstances in which requiredThe 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 with the requirements of Annex II, section 7, point 7.1.1.2. Such extrapolation is for example not possible for slow release formulations.Test conditionsThe rate of aerobic and/or anaerobic degradation in soil must be reported. The duration of the study should normally be 120 days except where more than 90% of the active substance is degraded before that period expires.Test guidelineThe methodology to be used is that described by SETAC9.9.1.1.2Field studiesSoil dissipation studiesAim of the testThe soil dissipation studies should provide best possible estimates of the time taken for dissipation of 50% and 90% (DT50f and DT90f) of the active substance, under field conditions. Where relevant, information on relevant metabolites, degradation and reaction products also must be reported.

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

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, section 7, point 7.1.1.2. Such extrapolation is for example not possible for slow release formulations.Test conditionsIndividual studies on a range of representative soils (normally 4 different types) must be continued until > 90% of the amount applicable has dissipated. The maximum duration of such studies is 24 monthsTest guidelineThe methodology to be used is that described by SETAC9.Soil residue studiesAim of the testSoil residue studies should provide estimates of the soil residue levels at harvest or at time of sowing or planting succeeding crops.Circumstances in which requiredSoil 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, section 7, point 7.1.1.2.2. Such extrapolation is for example not possible for slow release formulations.Test conditionsIndividual studies must be continued until harvest or time of sowing or planting succeeding crops, unless > 90% of the amount applies has dissipated at earlier date.Test guidelineThe methodology to be used is that described by SETAC9.Soil accumulation studiesAim of the tests
9Society of Environmental Toxicology and Chemistry (SETAC), 1995, "Procedures for assessing the environmental fate and ecotoxicity of pesticides, ISBN 90-5607-002-9"

The tests should provide sufficient data to evaluate the possibility of accumulation in soil of residues of the active substance and of relevant metabolites, degradation and reaction products.Circumstances in which requiredSoil 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 provided in accordance with the requirements of Annex II, section 7, point 7.1.1.2.2. Such extrapolation is for example not possible for slow release formulations.Test conditionsLong term field studies must be done on two relevant soils and involve multiple applications.Before performing these studies the applicant must seek the agreement of the competent authorities on the type of study to be performed.Test guidelineThe methodology to be used is that described by SETAC9.9.1.2Mobility in the SoilAim of the testTesting should provide sufficient data to evaluate the mobility and leaching potential of the active substance and relevant metabolites, degradation and reaction products.9.1.2.1Laboratory studiesCircumstances in which requiredThe 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, sections 7, points 7.1.2 and 7.1.3.1. Such extrapolation is for example not possible for slow release formulations.Test guidelineThe methodology to be used

is that described by SETAC9.9.1.2.2Lysimeter Studies or Field leaching studiesAim of the testsThe test should provide data with respect to—
9Society of Environmental Toxicology and Chemistry (SETAC), 1995, "Procedures for assessing the environmental fate and ecotoxicity of pesticides, ISBN 90-5607-002-9"

— the mobility of the plant protection product in soil,— the potential for leaching to ground water,— the potential distribution in soil.Circumstances in which requiredExpert 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 PECGW. The type and conditions of the 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 to the requirements of Annex II, section 7, point 7.1.3. Such extrapolation is for example not possible for slow release formulations.Test conditionsGreat care is necessary in the design of both experimental installations and of individual studies, to ensure that results obtained can be used for assessment purposes. Studies should cover the realistic worst case situation likely to arise, taking into account soil type, climate conditions, application rate and 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 5 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 removal of soil cores influences the leaching process.Precipitation, soil and air temperatures must be recorded at regular intervals (at least on a weekly base).9.1.3Estimation of expected concentrations in soilPECs estimations provided 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. Estimations must be made for each relevant soil tested, and be 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 PECs estimations include both direct and indirect application to soil — drift, run off, and leaching. The estimations made must take account of processes such as volatilization, adsorption, hydrolysis, photolysis and aerobic and anaerobic degradation.
For the purposes of PECs calculations, the bulk density of soils can be assumed to be 1.5 g/cm³ dry weight, while the depth of the soil layer should be 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 should be assumed that 50% (minimum) of the applied dose reaches the soil

surface unless actual experimental data provide more reliable information.Initial, short-term and long-term PECs calculations (time weighted averages) must be provided—Initial:immediately after applicationShort-term:24 hours, 2 days and 4 days after last applicationLong-term:7, 28, 50 and 100 days after last application, where relevant.9.2Fate and behaviour in water9.2.1Estimation of concentrations in GroundwaterGround water contamination routes must be defined taking into account relevant agricultural, plant health, and environmental (including climatic) conditions.Estimations (calculations) of predicted environmental concentration in groundwater PECGW, for active substance and relevant metabolites, degradation and reaction products, must be made and submitted.PECGW estimations made must relate to the maximum number and highest rates of application, for which authorization is sought.Expert judgement is required to decide whether, or not, additional field tests could provide further useful information. Before undertaking such studies, applicants must seek the approval of the competent authorities for the type of study to be performed.9.2.2Impact on water treatment proceduresIn those instance in which such information is necessary for the purposes of a conditional authorization pursuant to Annex VI, Part C, point 2.5.1.2 (b), the information provided should serve to establish or to provide an estimate of the effectiveness of water treatment procedures (drinking water and sewage treatment), and any impact on such procedures.Before conducting studies applicants must seek the approval of the competent authorities for the type of studies to be performed.
9.2.3Estimation of concentrations in Surface WaterSurface water contamination routes must be defined taking into account relevant agricultural, plant health, and environmental (including climatic) conditions.Suitable estimations (calculations) of predicted environmental concentration in surface water PECsw, of active substance and relevant metabolites, degradation and reaction products, must be made and submitted.PECsw estimations made must relate to the maximum number and highest rates of application, for which authorization is sought, and be relevant and lakes, ponds, rivers, canals, streams, irrigation/drainage canals and drains.The factors to be considered in making PECsw estimations include direct application to water, drift, run-off, discharge via drains and atmospheric deposition, and must take account of the effects of processes such as volatilization, adsorption, advection, hydrolysis, photolysis, biodegradation, sedimentation and re-suspension.Initial, short-term and long-term PECsw 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 applicationLong-term:7, 14, 21, 28 and 42 days after last application, where relevant.Expert judgement is required to decide whether, or not, additional field tests could provide further useful information. Before undertaking such studies, applicants must seek the approval of the competent authorities for the type of study to be performed.9.3Fate and behaviour in air pro memoria10Ecotoxicological

studies10.1Effects on birds10.1.1Acute oral toxicity10.1.2Supervised trials to assess risks to avian species under field conditions10.1.3If appropriate, studies on acceptance of bait, granules, or treated seeds by birds10.2Effects on aquatic organisms10.2.1Acute toxicity to fish10.2.2Acute toxicity to Daphnia magna
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Part 3

Annex VI

(Annex VI to the Directive of 1991, as amended by Commission Directive No 94/43/EC of 27 July 1994

UNIFORM PRINCIPLES FOR EVALUATION AND AUTHORIZATION OF PLANT PROTECTION PRODUCTS

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AINTRODUCTION1The principles developed in this Annex are intended to ensure that evaluations and decisions with regard to the authorization of plant protection products, provided they are chemical preparations, result in the implementation of the requirements of Article 4 (1) (b), (c), (d) and (e) of the Directive of 1991, by the competent authority, in a manner that achieves a high level of protection of human and animal health and the environment are achieved.2In evaluating applications and granting authorizations the competent authority shall: (a) — without prejudice to the provisions of subparagraph (3) (a) of Regulation 8 and paragraph (3) of Regulation 10 of the principal Regulations, 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 purposes of decision-making, — ensure that the data submitted are acceptable in terms of quantity, quality, consistency and reliability and are sufficient to permit a proper evaluation of the dossier, — evaluate, where relevant, justifications submitted by the applicant for not supplying certain data; (b) without prejudice, where relevant, to the provisions of subparagraphs (3) (b) and (5) (a) of Regulation 8, paragraphs (1) and (2) of Regulation 10 of the principal Regulations, 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; and (c) take into consideration other relevant technical or scientific information that it possesses 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.3Where 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).
4Where the data and information provided are sufficient to permit completion of the evaluation for one of the proposed uses, applications shall be evaluated and a decision made for the proposed

use.Taking account of justifications provided and with the benefit of any subsequent clarifications, the competent authority 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.5During the process of evaluation and decision-making, the competent authority shall cooperate with applicants, to resolve any questions relating to the dossier quickly, to identify at an early stage any additional studies necessary for a proper evaluation of the dossier, 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 the Regulations.The competent authority shall normally come to a reasoned decision within 12 months of receiving a technically complete dossier. A technically complete dossier is one that satisfies all the requirements of Annex III.6The judgements made by the competent authority during the evaluation and decision-making process shall be based on scientific principles, preferably recognized at international level (for example, by the EPPO), and be made with the benefit of the expert advice available to it.BEVALUATION1General principles1.1Having regard to current scientific and technical knowledge, the competent authority shall evaluate the information referred to in Part A, point 2, and in particular: (a) assess the performance in terms of efficacy and phytotoxicity of the plant protection product for each use for which authorization is sought, and (b) identify the hazards arising, assess their significance and make a judgement as to the likely risks to humans, animals or the environment.1.2 In accordance with the terms of Article 4 of the Directive of 1991, which inter alia specifies that Member States shall have regard to all normal conditions under which the plant protection product may be used, and to the consequences of its use, the competent authority 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 the competent authority shall also take into account the principles of integrated control.
1.3In the evaluation of applications submitted, the competent authority shall have regard to the agricultural, plant health or environmental (including climatic) conditions in the area of use.1.4In interpreting the results of evaluations, the competent authority shall take into consideration possible elements of uncertainty in the information obtained during the evaluation, in order to ensure that the chances of failing to detect adverse effects or of under-estimating their importance are reduced to a minimum. The decision-making process shall be examined to identify critical decision points or items of data for which uncertainties could lead to a false classification of risk.The first evaluation made shall be based on the best available data or estimates reflecting 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 the range of use conditions that are likely to occur, resulting in a realistic worst-case approach, to determine whether it is possible that the initial evaluation could have been significantly different.1.5Where the 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, and— be relevant to the conditions in the area of use.1.6Where metabolites, degradation or reaction products are referred to in the specific principles, only those that are relevant for the criterion concerned shall be taken into account.2Specific principlesThe competent authority 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.2.1Efficacy2.1.1Where the proposed use concerns the control of or protection against an organism, the competent authority 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.

2.1.2Where the proposed use concerns an effect other than the control of or protection against an organism, the competent authority 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.2.1.3The competent authority shall evaluate the efficacy data on the plant protection product as provided for in Annex III having regard to the degree of control or the extent of the effect desired and having regard to the relevant experimental conditions such as—— the choice of the crop or cultivar,— the agricultural and environmental (including climatic) conditions,— the presence and density of the harmful organism,— the development stage of crop and organism,— the amount of the plant protection product used,— if required on the label, the amount of adjuvant added,— the frequency and timing of the applications, and— the type of application equipment.2.1.4The competent authority 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; and (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, the competent

authority 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.2.1.5Where 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, the competent authority 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 conduct label includes recommendations for use of the plant protection product with other plant protection and/or with adjuvants as a tank mix, the competent authority shall evaluate the appropriateness of the mix and of its conditions of use.2.2Absence of unacceptable effects on plants or plant products2.2.1The competent authority 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; and (iii) all relevant information on the active substance as provided for in Annex II, including mode of action, vapour pressure, volatility and water solubility. (b) This evaluation will include: (i) the nature, frequency, level and duration of observed phytotoxic effects and the agricultural, plant health and environmental (including climatic) conditions that affect these; (ii) the differences between main cultivars with regard to their sensitivity to phytotoxic effects; (iii) the part of the treated crop or plant products where phytotoxic effects are observed; (iv) the adverse impact on the yield of the treated crop or plant products in terms of quantity and/or quality; (v) the adverse impact on treated plants or plant products to be used for propagation, in terms of viability, germination, sprouting, rooting and establishment; and (vi) where volatile products are concerned, the adverse impact on adjacent crops.2.2.2Where the available data indicate that the active substance or significant metabolites, degradation and reaction products persist in soils and/or in or on plant debris in significant quantities after use of the plant protection product according to the proposed conditions of use, the competent authority shall evaluate the degree of adverse effects on subsequent crops. This evaluation shall be carried out as specified in point 2.2.1.
2.2.3Where the product label includes requirements for use of the plant protection product with other plant protection products or with adjuvants as a tank mix, the evaluation as specified in point 2.2.1 shall be carried out in relation to the information supplied for the tank mix.2.3Impact on vertebrates to be controlledWhere the proposed use of the plant protection product is intended to have an effect on vertebrates, the competent authority 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 it 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; and (ii) all relevant information on the plant protection product as provided for in Annex III, including toxicological studies and efficacy data.2.4Impact on human or animal health2.4.1Arising from the plant protection product2.4.1.1The competent authority 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 shall 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; and (iv) other relevant information as provided for in Annex III such as— — composition of the preparation, — nature of the preparation, — size, design and type of packaging, — field of use and nature of crop or target, — method of application including handling, loading and mixing of product, — exposure reduction measures recommended, — protective clothing recommendations, — maximum application rate, — minimum spray application volume stated on the label, — number and timing of applications. (b) This evaluation shall be made for each type of application method and application equipment proposed for use of the plant protection product as well as for the different types and sizes of containers to be used, taking account of mixing, loading operations, application of the plant protection product and cleaning and routine maintenance of application equipment.2.4.1.2The competent authority shall examine the 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, and—

its resistance to and compatibility with the contents.2.4.1.3 The competent authority shall examine the nature and characteristics of the protective clothing and equipment proposed with particular reference to the following aspects—
— obtainability and suitability, and— ease of wearing taking into account physical stress and climatic conditions.2.4.1.4The competent authority 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 shall 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; and (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, and— further activities whereby workers are exposed.2.4.2Arising from residues2.4.2.1The competent authority 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, and— 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.
2.4.2.2Prior to evaluating the residue levels in the reported trials or in products of animal origin, the competent authority 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, and— analytical methods and the residue definition.2.4.2.3On the basis of suitable statistical models the competent authority shall evaluate the residue levels observed in the trials reported. 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 result of the evaluation thereof; and (iv) realistic possibilities of

extrapolating data from one crop to another.2.4.2.4The competent authority 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.2.4.2.5The competent authority shall estimate the potential exposure of consumers through diet and, where relevant, other means of exposure, using a suitable calculation model. This evaluation shall 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.2.4.2.6The competent authority 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.2.5Influence on the environment2.5.1Fate and distribution in the environmentIn the evaluation of the fate and distribution of the plant protection product in the environment, the competent authority shall have regard to all aspects of the environment, including biota, and in particular to the following.
2.5.1.1The competent authority shall evaluate the possibility that the plant protection product may reach the soil under the proposed conditions of use; if this possibility exists it shall estimate the rate and the route of degradation in the soil, mobility in the soil and the change in the total concentration (extractable and non-extractable17) of the active substance and of relevant metabolites, degradation and reaction products that could be expected in the soil in the area of envisaged use after use of the plant protection product according to the proposed conditions of use.This evaluation shall 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; and (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.2.5.1.2the competent authority shall evaluate the possibility that the plant protection product may reach groundwater intended for the production of drinking water under the proposed conditions of use; if this possibility exists, it 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.
17Non-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 considered to include fragments through metabolic pathways leading to natural products.

If there is not a validated Community calculation model, the competent authority shall base its evaluation on the results of studies on mobility and persistence in soil as provided for in Annexes II and III.This evaluation shall also take into consideration the following information: (i) the specific information on fate and behaviour in soil and water as provided for in Annex II and the results of the evaluation thereof; (ii) other relevant information on the active substance such as— — molecular weight, — solubility in water, — octanol/water partition coefficient, — vapour pressure, — volatilization rate, — hydrolysis rate in relation to pH and identity of breakdown products, — dissociation constant; (iii) all information on the plant protection product as provided for in Annex III, including the information on distribution and dissipation in soil and water; (iv) where relevant, other authorized uses of plant protection products in the area of envisaged use containing the same active substance or which give rise to the same residues; (v) where relevant, data on dissipation including transformation and sorption in the saturated zone; (vi) where relevant, data on the procedures for drinking water abstraction and treatment in the area of envisaged use; (vii) where relevant, monitoring data on the presence or absence of the active substance in groundwater as a result of previous use of plant protection products containing the same active substance or which give rise to the same residues.2.5.1.3The competent authority shall evaluate the possibility that the plant protection product may reach surface water under the proposed conditions of use; if this possibility exists it 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 not a validated Community calculation model, the competent authority shall base its evaluation on the results of the studies on mobility and persistence in soil and the information on run-off and drift as provided for in Annexes II and III. This evaluation shall 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 via 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; and (vi) where relevant, data on the procedures for drinking water abstraction and treatment in the area of envisaged use.

2.5.1.4The competent authority shall evaluate the possibility that the plant protection product may be dissipated in the air under the proposed conditions of use; if this possibility exists it 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 shall take into consideration the following information: (i) the specific information on fate and behaviour in soil, water and air as provided for in Annex II and the results of the evaluation thereof; (ii) other relevant information on the active substance such as— — vapour pressure, — solubility in water, — hydrolysis rate in relation to pH and identity of breakdown products, — photochemical degradation in water and air and identity of breakdown products, — octanol/water partition coefficient; (iii) all relevant information on the plant protection product as provided for in Annex III, including the information on distribution and dissipation in air.2.5.1.5 The competent authority shall evaluate the procedures for destruction or decontamination of the plant protection product and its packaging.2.5.2Impact on non-target speciesWhen calculating toxicity/exposure ratios the competent authority shall take into consideration toxicity to the most sensitive relevant organism used in the tests.2.5.2.1The competent authority shall evaluate the possibility of exposure of birds and other terrestial vertebrates to the plant protection product under the proposed conditions of use; if this possibility exists it shall evaluate the extent of the short-term and long-term risks to be expected for these organisms, including reproductive effects, after use of the plant protection product according to the proposed conditions of use. (a) This evaluation shall 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; and (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 shall 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 ratios. The toxicity/exposure ratios are defined as, respectively, the quotient of LD50, LC50 or NOEC expressed on an active substance basis and the estimated exposure expressed on mg/kg body weight.2.5.2.2The competent authority shall evaluate the possibility that exposure of aquatic organisms to the plant protection product may occur under the proposed conditions of use; if this possibility exists it shall evaluate the degree of short-term and long-term risks to be expected for aquatic organisms after use of the plant protection product according to the proposed conditions of use. (a) This evaluation shall 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 shall 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 ratios for fish and Daphnia. These ratios are defined as the quotient of respective acute LC50 or EC50 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 EC50 and the predicted short-term environmental concentration; (iv) a calculation of the long-term toxicity/exposure ratios for fish and Daphnia. The long-term toxicity/exposure ratios are defined as the quotient of the NOEC and the predicted long-term environmental concentration; (v) where relevant, bioconcentration in

fish and possible exposure of predators of fish, including humans; and
(vi) if the plant protection product is to be applied directly to surface water, effects on surface water quality, such as pH or dissolved oxygen content.2.5.2.3The competent authority shall evaluate the possibility that exposure of honeybees may occur to the plant protection product under the proposed conditions of use; if this possibility exists it shall evaluate the short-term and long-term risks to be expected for honeybees after use of the plant protection product according to the proposed conditions of use. (a) This evaluation shall take into consideration the following information: (i) the specific information on toxicity to honeybees as provided for in Annex II and the results of the evaluation thereof; (ii) other relevant information on the active substance such as— — solubility in water, — octanol/water partition coefficient, — vapour pressure, — 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; and (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 shall include: (i) the ratios between the maximum application rate expressed in grammes of active substance per hectare and the contact and oral LD50 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; and (ii) where relevant, effects on honeybee larvae, honeybee behaviour, colony survival and development after use of the plant protection product according to the proposed conditions of use.
2.5.2.4The competent authority 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 it shall assess expected lethal and sublethal effects on these organisms and the reduction in their activity after use of the plant protection product according to the proposed conditions of use.This evaluation shall take into consideration the following information: (i) the specific information on toxicity to honeybees and other beneficial arthropods as provided for in Annex II and the results of the evaluation thereof; (ii) other relevant information on the active substance such as— — solubility in water, — octanol/water partition coefficient, — vapour pressure, — photodegradation rate and identity of breakdown products, — mode of action (e.g. insect growth regulating activity); (iii) all relevant information on the plant protection product as provided for in Annex III such as— — effects on beneficial arthropods other than bees, — toxicity to honeybees, — available data from biological primary screening, — maximum application rate, — maximum number and timetable of applications; (iv) where relevant, other authorized uses of plant protection products in the area of envisaged use, containing the

same active substance or which give rise to the same residues.2.5.2.5The competent authority shall evaluate the possibility that 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 it shall evaluate the degree of short-term and long-term risks to be expected to these organisms after use of the plant protection product according to the proposed conditions of use. (a) This evaluation shall 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 absorption, — vapour pressure, — hydrolysis rate in relation to pH and identity of breakdown products; — photodegradation rate and identity of breakdown products, DT50 and DT90 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; and (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 shall include:
(i) lethal and sublethal effects; (ii) predicted initial and long-term environmental concentration: (iii) a calculation of the acute toxicity/exposure ratio (defined as the quotient of LC50 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); and (iv) where relevant, bioconcentration and the persistence of residues in earthworms.2.5.2.6The competent authority 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 impact on microbial activity such as impact on nitrogen and carbon mineralization processes in the soil after use of the plant protection product according to the proposed conditions of use. (a) This evaluation shall take into consideration the following information:
(i) all relevant information on the active substance, including the specific information relating to the effects on non-target soil micro-organisms as provided 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 envisaged use, containing the same active substance or which give rise to the same residues; and (iv) all available information from biological primary screening.2.6Analytical methodsThe competent authority shall evaluate the analytical methods proposed for post-registration control and monitoring purposes, to determine:2.6.1for formulation

analysisthe 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 shall take into consideration the following information: (i) data on analytical methods as provided for in Annex II and the results of the evaluation thereof; (ii) data on analytical methods as provided for in Annex III, 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); and (iii) the limit of detection and determination of the proposed methods for impurities.2.6.2for residue analysisthe 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 shall take into consideration the following information: (i) data on analytical methods as provided for in Annex II and the results of the evaluation thereof; (ii) data on analytical methods as provided for in Annex III, 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; and (iv) the limit of determination of the proposed methods.2.7Physical and chemical properties2.7.1The competent authority shall evaluate the actual content of the active substance in the plant protection product and its stability during storage.2.7.2The competent authority 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 shall take into consideration the following information: (i) data on the physical and chemical properties of the active substance as provided for in Annex II and the results of the evaluation thereof; and (ii) data on the physical and chemical properties of the plant protection product as provided for in Annex III.2.7.3Where 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 shall be evaluated.

CDECISION-MAKING1General principles1.1Where appropriate, the competent authority shall impose conditions or restrictions on authorizations which it grants. The nature and severity of these measures shall be selected on the basis of, and to be appropriate to, the nature and extent of the expected advantages and the risks likely to arise.1.2The competent authority shall ensure that, where necessary,

decisions taken with respect to the granting of authorizations take account of the agricultural, plant health and environmental (including climatic) conditions in the areas of envisaged use. Such considerations may result in specific conditions and restrictions on use, and, where necessary, may result in authorization being granted for some but not other areas within the territory of the state.1.3The competent authority 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 shall be differentiated according to, and be appropriate to the agricultural, plant health and environmental (including climatic) conditions in the various areas for which an authorization is granted. However, the rates and the number of applications shall not give rise to undesirable effects such as the development of resistance.1.4The competent authority shall ensure that decisions taken respect the principles of integrated control if the product is intended to be used in conditions where these principles are relied on.1.5Since the evaluation is to be based on data concerning a limited number of representative species, the competent authority shall ensure that use of plant protection products does not have any long-term repercussions for the abundance and diversity of non-target species.1.6Before issuing an authorization, the competent authority shall ensure that the label of the product—— fulfils the requirements of Regulation 24 of the principal Regulations,— 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 1.1, 1.2, 1.3, 1.4 and 1.5 above.
The authorization shall mention the particulars specified in subparagraph (2) (g), (h), (ii), (iii), and (iv) of Regulation 24 of the principal Regulations.1.7Before issuing authorizations, the competent authority shall: (a) ensure that the proposed packaging is in accordance with the provisions of Regulation 23 of the principal Regulations; and (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, — the procedures for the decontamination and destruction of the packagings,and in accordance with the relevant regulatory provisions.1.8No 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 outweigh the possible adverse effects of its use. Any restrictions on use of the product relating to non-compliance with some of the aforementioned requirements shall be mentioned on

the label, and non-compliance with the requirements referred to in point 2.7 shall 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 shall be reviewed on expiry of the time limit accorded to the applicant;
(c) where the reproducibility of the submitted analytical methods referred to in Part C, point 2.6, has only been verified in two laboratories, an authorization shall be granted for one year to permit the applicant to demonstrate the reproducibility of those methods in accordance with agreed criteria.1.9Where an authorization has been granted according to the requirements provided for in this Annex, the competent authority may, by virtue of subparagraph (6) (b) of Regulation 19 of the principal Regulations: (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.The competent authority 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.2Specific principlesThe specific principles shall apply without prejudice to the general principles referred to in Section 1.2.1 Efficacy2.1.1 Where the proposed uses include recommendations for the control of or protection against organisms which are not considered to be harmful on the basis of experience acquired or scientific evidence under normal agricultural, plant health and environmental (including climatic) conditions in the areas of proposed use or where the other intended effects are not considered to be beneficial under those conditions, no authorization shall be granted for those uses.2.1.2The level, consistency and duration of control or protection or other intended effects shall be similar to those resulting from the use of suitable reference products. If no suitable reference product exists, the plant protection product shall 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.
2.1.3Where relevant, yield response when the product is used and reduction of loss in storage shall 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 shall 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.2.1.4Conclusions as to the performance of the preparation shall be valid for all areas of the territory of the state, and shall 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).2.1.5Where proposed label claims include requirements for use of the preparation with other specified plant protection products or adjuvants as a tank mix, the mixture shall 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 other specified plant protection products or adjuvants as a tank mix, the competent authority shall not accept the recommendations unless they are justified.2.2Absence of unacceptable effects on plants or plant products2.2.1There shall be no relevant phytotoxic effects on treated plants or plant products except where the proposed label indicates appropriate limitations of use.2.2.2There shall 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.2.2.3There shall 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.2.2.4There shall 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.
2.2.5There shall 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.2.2.6There shall 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.2.2.7Where proposed label claims include requirements for use of the preparation with other plant protection products or adjuvants,

as a tank mix, the mixture shall comply with the principles referred to in points 2.2.1 to 2.2.6.2.2.8The proposed instructions for cleaning the application equipment shall 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.2.3Impact on vertebrates to be controlledAn 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.2.4Impact on human or animal health2.4.1Arising from the plant protection product2.4.1.1No authorization shall be granted if the extent of operator exposure in handling and using the plant protection product under the proposed conditions of use, including dose and application method, exceeds the acceptable operator exposure level (AOEL).Moreover, the conditions of the authorization shall be in compliance with the limit value established for the active substance and/or toxicologically relevant compound(s) of the product in accordance with Council Directive 80/1107/EEC of 27 November 198012 and Council Directive 90/394/EEC of 28 June 199015.2.4.1.2Where 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 m particular.

12O.J. No. L327/8 3/12/1980.

15O.J. No. L196/1 26/7/1990.

2.4.1.3Plant protection products which because of particular properties or if mishandled or misused could lead to a high degree of risk, shall 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 shall not be authorized for use by non-professional users.2.4.1.4Waiting and re-entry safety periods or other precautions shall 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 provisions referred to in point 2.4.1.1.2.4.1.5Waiting and re-entry safety periods of other precautions shall be established in such a way that no adverse impact on animals occurs.2.4.1.6Waiting and re-entry periods or other precautions to ensure that the AOEL levels and limit values are respected shall be realistic; if necessary special precautionary measures shall be

prescribed.2.4.2Arising from residues2.4.2.1Authorizations shall ensure that residues occurring reflect the minimum quantities of the plant protection product necessary to achieve adequate control corresponding to good agricultural practice, applied in such a manner (including pre-harvest intervals or withholding periods or storage periods) that the residues at harvest, slaughter or after storage, as appropriate, are reduced to a minimum.2.4.2.2Where no Community MRL18 or provisional MRL (at national or at Community level) exists, the competent authority shall establish a provisional MRL in accordance with subparagraph (1) (c) of Regulation 13, subparagraph (2) (b) of Regulation 18 of the principal Regulations; conclusions as to the levels fixed shall 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.2.4.2.3Where 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, the competent authority shall not grant an authorization for the plant protection product unless the applicant can provide evidence that the recommended use will not exceed that MRL or unless a new provisional MRL has been established by the competent authority, or by the Commission in accordance with Article 4 (1) (f) of the Directive of 1991.

18A Community MRL means an MRL established pursuant to Council Directive 76/895/EEC of 23 November 1976 on the fixing of maximum levels for pesticide residues in or on fruit or vegetables (O.J. No. L340/26 9/12/1976), Council Directive 86/362/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in or on cereals (O.J. No. L221/37 7/8/1986, Council Directive 86/363/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in or on foodstuffs of animal origin (O.J. No. L221/43 7/8/1986), Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin (O.J. No. L224/1 18/8/1990), Council Directive 90/642/EEC of 27 November 1990 on the fixing of maximum levels for pesticide residues in or on certain products of plant origin, including fruit and vegetables (O.J. No. L350/71 14/12/1990), or Council Directive 91/132/EEC of 4 March 1991 amending Directive 74/63/EEC on undesirable substances and products in feedingstuffs (O.J. No. L66/16 13/3/1991).

2.4.2.4Where a Community MRL exists the competent authority shall not grant an authorization for the plant protection product unless the applicant can provide evidence that the recommended use will not exceed that MRL, or unless a new Community MRL has been established in accordance with the procedures provided for in the relevant Community legislation.2.4.2.5In the cases referred to in points 2.4.2.2 and 2.4.2.3, each application for an authorization shall be accompanied by a risk assessment, taking into account worst-case potential exposure of consumers in the territory of the state, on

the basis of good agricultural practice.Taking into account all registered uses, the proposed use shall not be authorized if the best possible estimate of dietary exposure exceeds the acceptable daily intake (ADI).2.4.2.6Where the nature of residues is affected during processing, a separate risk assessment may be carried out under the conditions provided for in point 2.4.2.5.2.4.2.7Where the treated plants or plant products are intended to be fed to animals, residues occurring shall not have an adverse effect on animal health.2.5Influence on the environment2.5.1Fate and distribution in the environment2.5.1.1No 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. DT90 > 1 year and DT50 > 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 phytoloxic effects on succeeding crops occur and/or that there is an unacceptable impact on the environment, in accordance with the relevant requirements provided for in points 2.5.1,2, 2.5.1.3, 2.5.1.4, and 2.5.2.2.5.1.2 (a) An authorization shall be granted only in the following cases: (1) where adequate monitoring data relevant to the proposed conditions of use of the plant protection product are not available and on the basis of the evaluation it appears that, after use of the plant protection product under the conditions proposed, the foreseeable concentration of the active substance or of relevant metabolites or breakdown or reaction products in groundwater intended for the production of drinking water does not exceed the lower of the following concentrations: (i) the maximum permissible concentration laid down by Council Directive 80/778/EEC of 15 July 198019 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; (2) where adequate monitoring data relevant to the proposed conditions of use of the plant protection product are available and support the conclusion that in practice, after use of the plant protection product under the conditions proposed, the concentration of the active substance or of relevant metabolites or breakdown or reaction products in groundwater intended for the production of drinking water has not exceeded or no longer exceeds and is not in danger of exceeding the appropriate maximum concentration as referred to in (1) above. (b) Irrespective of the provisions in (a)

above, where the concentration referred to in (a) (1) (ii) is greater than that referred to in (a) (1) (i), a conditional authorization, which is not an authorization within the meaning of Article 10 (1) of this Directive and which is for a limited period of not more than 5 years, shall be issued only in those cases in which the conditions specified in (1) or (2) below are fulfilled: (1) where adequate monitoring data relevant to the proposed conditions of use of the plant protection product are not available, every conditional authorization issued shall be subject to the following requirements:
19 O.J. No. L229/11 30/8/1980.

(i) it appearing on the basis of the evaluation that, after use of the plant protection product under the conditions proposed, the foreseeable concentration of the active substance or of relevant metabolites or breakdown or reaction products in groundwater intended for the production of drinking water does not exceed the maximum concentration referred to in (a) (1) (ii) above; and (ii) it being ensured that an adequate monitoring programme covering areas liable to be contaminated is introduced or continued in the territory of the state, using suitable methods of sampling and analysis, so that it can be estimated whether the maximum concentration referred to in (a) (1) (i) above will be exceeded; it is for the competent authority to decide who is to bear the cost of that monitoring programme; (iii) where appropriate, attaching to the authorization of the conditions for or restrictions on the use of the product concerned, to appear on the label, having regard to agricultural plant health, and environmental (including climatic) conditions in the envisaged area of use; (iv) if necessary, amendment or withdrawal of the conditional authorization, in accordance with paragraph (6) of Regulation 19 of the principal Regulations, where monitoring results show that, despite the imposing of the conditions or restrictions referred to in (iii) above, after use of the plant protection product under the conditions proposed, the concentration of the active substance or of relevant metabolites or breakdown or reaction products in groundwater intended for the production of drinking water will exceed the concentration referred to in (a) (1) (i) above; (2) where adequate monitoring data relevant to the conditions of use of the plant protection product are available and support the conclusion that in practice, after use of the plant protection product under the conditions proposed, there is no risk that the concentration of the active substance or of relevant metabolites or breakdown or reaction products in groundwater intended for the production of drinking water will exceed the maximum concentration referred to in (a) (1) (ii) above, every conditional authorization issued shall be subject to the following requirements; (i) prior investigation of the significance of the risk of the maximum concentration referred to in (a) (1) (i) being exceeded and of the factors involved; (ii) it being ensured that an adequate programme, consisting of measures referred to in (b) (1) (ii), (iii) and (iv) above, is introduced

or continued in the territory of the state so as to make sure that in practice the concentration does not exceed the maximum permissible concentration referred to in (a) (1) (i) above. (c) If, upon expiry of the conditional authorization, monitoring results show that in practice the concentration of the active substance or of relevant metabolites or breakdown or reaction products, as a result of the use of the plant protection product under the proposed conditions of use, in groundwater intended for the production of drinking water has been reduced to a level approaching the maximum permissible concentration referred to in (a) (1) (i) above and if other amendments to the proposed conditions of use could be expected to ensure that the foreseeable concentration will be reduced below the maximum concentration, a further conditional authorization including those new amendments may be issued for a single period of not more than 5 years. (d) The competent authority may at any time introduce appropriate conditions for or restrictions on the product's use, having regard to local agricultural, plant health and environmental (including climatic) conditions, in order to comply with the concentration referred to in (a) (1) (i) above in water intended for human consumption, in accordance with Directive 80/778/EEC.192.5.1.3No 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—

19O.J. No. L229/11 30/8/1980.

— 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 75/44O/EEC of 16 June 197520 concerning the quality required of surface water intended for the abstraction of drinking water in the Member States, 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, shall be such that the likelihood of accidental contamination of surface water is reduced to a minimum.2.5.1.4No authorization shall be granted if the airborne concentration of the active substance under the proposed conditions of use is such that either the AOEL or the limit values for operators, bystanders or workers as referred to in Part C, point 2.4.1, are exceeded.2.5.2Impact on non-target species2.5.2.1Where 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 LD50 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.2.5.2.2Where 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 1000 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.
20O.J. No. L194/34 25/7/1975.

2.5.2.3Where 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.2.5.2.4Where 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.2.5.2.5Where 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.2.5.2.6Where there is a possibility of non-target soil micro-organisms being exposed, no authorization shall be granted if the nitrogen or carbon mineralization processes in laboratory studies are affected by more than 25% after 100 days, unless it is clearly established through an appropriate risk assessment that under field conditions there is no unacceptable impact on microbial activity

after use of the plant protection product according to the proposed conditions of use, taking account of the ability of micro-organisms to multiply.2.6Analytical methodsThe methods proposed shall reflect the state of the art. The following criteria shall be met in order to permit validation of the analytical methods proposed for post-registration control and monitoring purposes:2.6.1for formulation analysisthe method shall be suitable for the determination and to identification of the active substance(s) and where appropriate any toxicologically, ecotoxicologically or environmentally significant impurities and co-formulants;
2.6.2for residue analysis (i) the method shall be suitable for the determination and confirmation of residues of toxicological, ecotoxicological or environmental significance; (ii) mean recovery rates should be between 70% and 110% with a relative standard deviation of < 20%; (iii) repeatability shall be less than the following values for residues in foodstuffs:

Residue level
mg/kgDifference
mg/kgDifference
in %0010.005500.10.0252510.12512.5>112.5

Intermediate values are determined by interpolation from a log-log graph; (iv) reproducibility shall be less than the following values for residues in foodstuffs:

Residue level mg/kgDifference mg/kgDifference in %0.010.011000.10.055010.2525>125

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 shall satisfy the following criteria; Limit of determination in relation to the proposed provisional or Community MRL:
MRL (mg/kg)limit of determination (mg/kg)> 0.50.10.5 - 0.050.1 - 0.2
< 0.05MRL x 0.5

2.7Physical and chemical properties2.7.1Where an appropriate FAO specification exists, that specification shall be met.2.7.2Where no appropriate FAO specification exists, the physical and chemical properties of the product shall 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 shall not exceed the following values:

Declared content in g/kg or g/l at 20°CToleranceup to 25 15%
homogeneous formulation 25% non-homogeneous formulationmore 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 shall 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".2.7.3Where 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 shall be physically and chemically compatible in the tank mix.

Part 4

FORMAT AND PRESENTATION OF DOCUMENTATION

1The format for the presentation of the documentation referred in paragraph (2) of Regulation 8 of the principal Regulations is that described in the "Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Annex I of Directive 91/414/EEC (Article 5.3 and 8.2)"21.2Those guidelines should be adapted as necessary in the case of documentation submitted in support for applications for the authorization of plant protection products.3Where in accordance with Regulation 10 of the principal Regulations, it is claimed that the dossiers, or part of the information contained in them, be protected, the owner of the dossiers and/or the studies concerned must be indicated. Where ownership is shared, all of the joint owners must be identified.4Where in accordance with sub-paragraphs (1) (a) and (3) (a) of Regulation 10 of the principal Regulations, agreement to the use of information submitted by other parties is claimed, an original signed and notarized letter, confirming such agreement, and submitted by the owner of the information, must be provided. Each such letter must include the following information: (i) the identity of those to whom agreement for the use of information submitted has been granted; (ii) the purposes for which such agreement has been granted (a particular product, a group of products, or all relevant products); and (iii) the period for which the agreement given is valid.5 In the case of existing active substances being reviewed for possible inclusion in Annex I, or being reviewed in the context of applications for authorization of preparations in accordance with Regulation 18 of the principal Regulations, where the information qualifies for protection pursuant to Regulation 10 of the principal Regulations, the following must be provided: (i) for each study referred to in sub-paragraph (1) (c) of Regulation 10 of the principal Regulations, a list of the Member States in which one or more preparations containing the active substance was on the market on 24 July 1993, and the dates on which authorization of the first such preparation was granted by each such Member State — in the case of preparations placed on the market prior to 2 December 1985 in Ireland and prior to 6 October

1986 in the UK, the dates of first placing on the market — and the date of expiry of the period of protection for each Member State;
21European Commission Document 1663/VI/94 Rev 6, 31 January, 1995.

(ii) for each study referred to in sub-paragraph (1)(d) of Regulation 10 of the principal Regulations, a statement that the study was generated for the purposes of achieving inclusion in Annex I or has not been previously submitted to the competent authorities of any of the Member States for the authorization of a plant protection product; (iii) for each study referred to in sub-paragraph (3) (b) of Regulation 10 of the principal Regulations, the identity of the first Member State to authorise the preparation, the date of authorization and the date of expiry of the period of protection for the Community; and (iv) for each study referred to in sub-paragraph (3) (c) of Regulation 10 of the principal Regulations, a list of the Member States in which the preparation was authorised, and the dates on which such authorization was granted by each such Member State — in the case of preparations placed on the market prior to 2 December 1985 in Ireland and prior to 6 October 1986 in the UK, the dates of first placing on the market — and the date of expiry of the period of protection for each Member State.

Part 5

DATA REQUIREMENTS RELATING TO TOXICITY IN SUPPORT OF APPLICATIONS FOR AUTHORIZATIONS FOR TRIALS PURPOSES

10Toxicological studies10.1Acute toxicity (i) The studies, data and information to be provided and evaluated, must be sufficient to permit the hazards for humans, following a single exposure to the plant protection product, to be assessed, and in particular to establish, or indicate: — the relationship between dose and morbidity and mortality; — the toxicity of the active substance relative to other substances; — the toxicity of the preparation; — the time course and characteristics of poisoning with full details of behavioural changes and possible gross pathological findings at post-mortem; and — the relative hazard associated with the different routes of exposure. (ii) While the emphasis must be on estimating the toxicity ranges involved, the information generated must also permit the active substance(s) and the preparation to be classified. The information generated through acute toxicity testing is of particular value in assessing hazards likely to arise and in accident situations. (iii) The vehicle chosen for administration of the test material must be selected such that it is not itself toxic and such that the test substance is bio-available. Where feasible, aqueous solutions are preferred. Other options include solution/suspension in 0.5% carboxymethyl cellulose or solution/suspension in non-polar non-toxic solvents. Where a novel or unusual vehicle is used, the bio-availability of the test substance

in the vehicle used must be established and reported — a comparative 7 day test using radiolabelled material with different vehicles.10.1.1Oral10.1.1.1The acute oral toxicity to the rate of each active substance in the preparation, determined in accordance with the EEC Method B 1 (Fixed Dose Method), must be reported.10.1.1.2The acute oral toxicity to the rat of the preparation, determined in accordance with the EEC Method B 1 (Fixed Dose Method), must be reported, except where:— for plant protection products containing one active substance, Article 3.2 of the Directive of 1978 can in principle be invoked; or— for plant protection products containing more than one active substance, Article 3.3 of the Directive of 1978 can in principle be invoked;and relevant information and documentation is submitted, or is available to the competent authority, which shows that there are valid grounds for assuming that the classification resulting from the calculation would not vary substantially from that obtainable by biological testing i.e. the composition of the preparation is similar to that of a preparation for which a biological test is available, and the toxicity of the tested preparation is similar to its predicted toxicity, or the composition of the preparation is similar to that of two or more preparations for which biological tests are available, and the toxicity of the tested preparations varies in a consistent manner from their predicted toxicities.10.1.2Percutaneous10.1.2.1Since knowledge of percutaneous toxicity is necessary for the evaluation of operator hazard and the specification of suitable protective clothing, the acute percutaneous toxicity to rats of each active substance in the preparation, determined in accordance with EEC Method B 3, must be reported. Both local and systemic effects must be investigated.10.1.2.2The acute percutaneous toxicity to rats of the preparation, determined in accordance with EEC Method B 3, must be reported. Both local and systemic effects must be investigated. However, testing of the preparation should not be carried out, where:— for plant protection products containing one active substance, Article 3.2 of the Directive of 1978 can in principle be invoked; or— for plant protection products containing more than one active substance, Article 3.3 of the Directive of 1978 can in principle be invoked; andrelevant information and documentation is submitted, or is available to the competent authority, which shows that there are valid grounds for assuming that the classification resulting from the calculation would not vary substantially from that obtainable by biological testing i.e. the composition of the preparation is similar to that of a preparation for which a biological test is available, and the toxicity of the tested preparation is similar to its predicted toxicity, or the composition of the preparation is similar to that of two or more preparations for which biological tests are available, and the toxicity of the tested preparations varies in a consistent manner from their predicted toxicities.10.1.3Inhalation10.1.3.1The inhalation hazard of a plant protection product is dependant not only on its toxic properties, physical state, manner of use and where relevant particle size, but

also on the vapour pressure and solubility of its components. Accordingly, the inhalation toxicity to rats of each active substance in the preparation, determined in accordance with EEC Method B 2, must be reported where the preparation is:
— a gas or liquified gas;— to be used as a fumigant;— to be used with fogging equipment;— a smoke generating, aerosol or vapour releasing preparation;— contains an active substance with a vapour pressure > 1 x 10-2 Pa and is to be used in enclosed spaces such as warehouses or glasshouses.— a powder containing a significant proportion of particles of diameter < 5µ (>1% on a weight basis); or— to be applied in a manner which produces a spray, mist or aerosol containing a significant proportion of particles of diameter 5µ (> 1% on a weight basis).10.1.3.2The inhalation toxicity to rats of the preparation, determined in accordance with EEC Method B 2, must be reported where the preparation is:— a gas or liquified gas;— a smoke generating formulation or a fumigant;— a vapour releasing preparation;— to be used with fogging equipment;— an aerosol;— contains an active substance(s) having a vapour pressure > 1 x 10-2 Pa and is to be used in enclosed spaces such as warehouses or glasshouses;— to be applied from aircraft in cases where inhalation exposure is relevant;— a powder containing a significant proportion of particles of diameter < 5µ (>1% on a weight basis), or— to be applied in a manner which produces a spray, mist or aerosol containing a significant proportion of particles of diameter < 5µ (>1% on a weight basis).10.1.3.3However, testing of the preparation should not be carried out, where:— for plant protection products containing one active substance, Article 3.2 of the Directive of 1978 can in principle be invoked; or— for plant protection products containing more than one active substance, Article 3.3 of the Directive of 1978 can in principle be invoked; andrelevant information and documentation is submitted, or is available to the competent authority, which shows that there are valid grounds for assuming that the classification resulting from the calculation would not vary substantially from that obtainable by biological testing i.e. the composition of the preparation is similar to that of a preparation for which a biological test is available, and the toxicity of the tested preparation is similar to its predicted toxicity, or the composition of the preparation is similar to that of two or more preparations for which biological tests are available, and the toxicity of the tested preparations varies in a consistent manner from their predicted toxicities.
10.1.4Skin and where appropriate eye irritation10.1.4.1The possible effects of accidental contamination of skin and eyes, must be investigated, as contact may occur in handling preparations containing the active substance, in either concentrated or dilute form, or in cleaning application equipment.10.1.4.2The skin irritancy of each active substance, and of the preparation, determined using a single application to intact skin of rabbits, in accordance with EEC Method B 4, must be reported, except where:— positive results can be predicted on the basis of the acidity or alkalinity of aqueous

solutions of the active substance (pH < 2 or >11.5), or on the basis of the acidity or alkalinity of the preparation (pH < 2 or >11.5), as appropriate;— no irritation is seen at the limit test dose level in acute percutaneous studies; or— where the active substance, or preparation, as appropriate, is highly toxic in an acute percutaneous study.10.1.4.3Eye irritation tests must not be conducted for active substances or preparations known, or found, to be corrosive. Similarly eye irritation tests must not be conducted for substances or preparation known or found to be skin irritants, unless there is particular reason to believe otherwise. For other active substances contained in the preparation, as well as for the preparation, eye irritancy, determined in accordance with EEC Method B 5, using healthy adult albino rabbits, must be determined and reported, except where it is known, on the basis of other available information that the active substance or preparation, as appropriate, is likely to produce severe effects on the eyes.10.1.5Skin sensitization10.1.5.1Allergic sensitization, following exposure, occurs in a significant proportion of the human population. The potential of each active substance in the preparation, to provoke skin sensitization reactions, must be assessed in accordance with the EEC Method B 6, using the Guinea-pig Maximization Test (GPMT), and be reported.10.1.5.2The potential of preparations which contain an active substance found to provoke skin sensitization reactions, or which contain other components known to lead to such reactions, must be assessed in accordance with the EEC Method B 6, and be reported.10.2Short-term toxicity (i) 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 effects of the active substance and the risks to workers who may be exposed over extensive periods. In addition short-term studies provide information which is useful in the design on chronic toxicity studies.
(ii) 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, — the toxicity of the active substance including where possible the NOAEL, — the 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, — where possible, the mode of toxic action, and — the relative hazard associated with different routes of exposure.10.2.1Oral 28-day studyCircumstances in which requiredAlthough 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 can be of particular value in the identification of adaptive responses which can be masked in chronic toxicity studies.Test GuidelineThe test must be carried out in accordance with EEC Method B 7.10.2.2Oral 90-day studyCircumstances in which requiredThe short-term (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 GuidelineCommission Directive 88/302/EEC10, Part B, sub-chronic oral toxicity test.10.3Genotoxicity testingAim of the testThese studies are of value in—— the prediction of genotoxic potential,— the early identification of genotoxic carcinogens, and— 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 of 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 the interpretation of results obtained at each stage.10.3.1In vitro studiesCircumstances in which requiredIn vitro mutagencity tests (bacterial assay for gene mutation, test for clastogenicity in mammalian cells and test for gene mutation in mammalian cells) must always be reported.Test GuidelinesAcceptable test guidelines are—EEC Method B 14 — Salmonella Typhimurium reverse mutation assay,EEC Method B 10—in vitro mammalian cytogenetic test, Commission Directive 88/302/EEC10 Part B - in vitro mammalian cell gene mutation test.10.3.2In vivo studies in somatic cellsCircumstances in which requiredIf all the results of the in vitro studies are negative further testing must be done, taking into consideration all 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 vitro test using somatic cells (metaphase analysis in rodent bone marrow or micronucleus test in rodents) must be conducted.
10O.J. No. L133/1 30/05/1988.

If either of the in vitro gene mutation tests are positive, an in vitro test to investigate unscheduled DNA synthesis or a mouse spot test must be conducted.Test GuidelinesAcceptable test guidelines are—EEC Method B12 — micronucleus test, Commission Directive 88/302/EEC10, Part B — mouse spot test,EEC Method B 11 — in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis10.3.3In vivo studies in germ cellsCircumstances in which requiredWhen 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 information regarding toxicokinetics,

use and anticipated exposure. Suitable tests involve interaction with DNA (such as the dominant lethal assay), to assess the potential for inherited effects and possibility to make a quantifiable assessment of heritable effects. It is recognized that in view of their complexity, the use of quantitative studies requires strong justification.

GIVEN under my Official Seal, this 24th day of July, 1995.
IVAN YATES,
Minister for Agriculture, Food and Forestry.

EXPLANATORY NOTE.
These Regulations, amend the European Communities (Authorization, Placing on the Market, Use and Control of Plant Protection Products) Regulations, 1994 (S.I. No. 139 of 1994).
The amendments, inter alia, specify the criteria to be applied in the examination of applications for the authorization of plant protection products and also lay down the detailed requirements to be submitted in support of applications.