EUROPEAN COMMUNITIES (AUTHORISATION, PLACING ON THE MARKET, USE AND CONTROL OF PLANT PROTECTION PRODUCTS) (AMENDMENT) REGULATIONS 1996

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), for the purpose of giving effect to Commission Directive 95/35/EC of 14 July 19951, Commission Directive 95/36/EC of 14 July 19952, and Commission Directive 96/12/EC of 8 March 19963, hereby make the following Regulations:

1 O.J. No. L172/6 22/7/1995
2 O.J. No, L172/8 22/7/1995
3 O.J. No, L 65/20 15/3/1996

REG 1

1. (1) These Regulations may be cited as the European Communities (Authorisation, Placing on the Market, Use and Control of Plant Protection Products) (Amendment) Regulations, 1996.
(2) The European Communities (Authorisation, Placing on the Market, Use and Control of Plant Protection Products) Regulations, 1994 and 1995 and these Regulations may be cited together as the European Communities (Authorisation, Placing on the Market, Use and Control of Plant Protection Products) Regulations, 1994 to 1996 and shall be construed together as one.
(3) These Regulations shall come into operation on the first day of July 1996.

Interpretation

REG 2

2. (1) In these Regulations —
"the principal Regulations" mean the European Communities (Authorisation, Placing on the Market, Use and Control of Plant Protection Products) Regulations, 1994 and 1995;
"permission to market" means a permission granted by the competent authority to market and use a plant protection product pursuant to paragraph (3) of Regulation 5 of the Principal Regulations.
(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 a Schedule is a reference to a Schedule of the Principal Regulations as amended by these Regulations.
(3) A word or expression that is used in the Directive of 1991 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.
Amendments

REG 3

3. The provisions of paragraph (2) of Regulation 5 of the Principal Regulations are hereby revoked and are replaced by the following:
"(2) Plant protection products which are pesticides referred to in paragraph (1) (a) of Regulation 3 of the Regulations of 1994 and which are on the market prior to the first day of October 1994, may continue to be placed on the market for use in accordance with the Regulations of 1994, until such time as:
(a) approval of the record of the studies, conducted and the information, documentation and materials submitted for approval in accordance with the provisions of Regulation 6 of the Regulations of 1994, has been refused and as a consequence, clearance in accordance with those Regulations has been refused, or
(b) they are authorized in accordance with these Regulations, or are refused such authorization."

REG 4

4. The provisions of Regulation 28 of the Principal Regulations are hereby revoked and are replaced by the following:
"28. (1) The Minister may from time to time specify the maximum levels of residues of plant protection products which may be contained in specified controlled products.
(2) The maximum levels of residues of plant protection products specified in accordance with paragraph (1) shall be those established by the competent authority pursuant to subparagraph (1) (c) of Regulation 13, subparagraph (2) (b) of Regulation 15 or subparagraph (3) (b) of Regulation 18 and shall remain in force until —
(a) replaced by maximum levels subsequently specified to give effect to provisional maximum levels established by the Community in accordance with Article 4 (1) (f) of the Directive of 1991, or
(b) replaced by maximum levels established pursuant to the procedures provided in Council Directive 76/895/EEC4, Council Directive 90/642/EEC5 or Council Directive 86/362/EEC6
4 O.J. No. L340/26 9/12/1976
5 O.J. No. L350/71 14/12/1990
6 O.J. No. L221/36 7/8/1986

REG 5

5. The provisions of Regulation 32 of the Principal Regulations are hereby revoked and are replaced by the following:
"32 (1) A person who contravenes Regulation 4, 6 or 7 shall be guilty of an offence and shall be liable on summary conviction to

a fine not exceeding £1,000, to imprisonment for a term not exceeding 6 months, or to both.
(2) A person who —
(a) fails to comply with the requirements of Regulations 7, 8, 9, 17, 23, 24, 25 (1), 26 (4) and (5), 27, 30 (2) and (3), 31 (3), or 36 (4), or
(b) obstructs or interferes with an authorised officer in the course of exercising a power conferred on him by Regulations 30, 31 or 37, or
(c) in the context of Regulation 8, 11 (1), 16 (2) (b), 17, 19 (3), 25 (5), 26 (2) (a) or 27, submits false or misleading information, or who gives false information when requested to provide information under Regulation 37,
shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding £1.000, to imprisonment for a term not exceeding six months, or to both."

REG 6

6. The introduction to Annex II, as set out in Part 1 of the First Schedule of the Principal Regulations is hereby revoked and replaced by the following:
"INTRODUCTION
The information required shall:
1.1 Include a technical dossier supplying the information necessary for evaluating the foreseeable risks, whether immediate or delayed, which the substance may entail for humans, animals and the environment and containing at least the information and results of the studies referred to below;
1.2 where relevant, be generated using test guidelines referred to or described in this Annex, in the case of studies initiated before the adoption of the modification of this Annex, the information shall be generated using suitable internationally or nationally validated test guidelines or, in the absence thereof, test guidelines accepted by the competent authority;
1.3 in the event of a test guideline being inappropriate or not described, or where one other than those referred to in this Annex has been used, include a justification, which is acceptable to the competent authority for the guideline used;
1.4 include, when required by the competent authority, a full description of test guidelines used, except if they are referred to or described in this Annex, and a full description of any deviations from them including a justification, which is acceptable to the competent authority, for these deviations;
1.5 include a full and unbiased report of the studies conducted as well as a full description of them or a justification, which is acceptable to the competent authority where —
· particular data and information which would not be necessary owing to the nature of the product or its proposed uses, are not provided, or

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

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

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

2.1 Tests 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.

8 O.J. No. L15/3, 17/01/1987

2.2 Notwithstanding the provisions of point 2.1, tests and analyses started on or before the 31 December 1999 and performed 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.

2.3 Notwithstanding the provisions of point 2.1, supervised residue trials conducted in accordance with the provisions of point 6, relating to plant protection products containing active substances already on the market prior to 25 July 1993 and started on or before the 31 December 1997, 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 lit to Directive 93/71/EEC, where they are conducted outside the territory of the state."

REG 7

7. The introduction to Annex III, as set out in Part 2 of the First Schedule of the Principal Regulations is hereby revoked and replaced by the following:

"INTRODUCTION

The information required shall:

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

or delayed, which the plant protection product may entail for humans, animals and the environment and containing at least the information and results of the studies referred to below;
1.2 where relevant, be generated using test guidelines referred to or described in this Annex; in the case of studies initiated before the adoption of the modification of this Annex, the information shall be generated using suitable internationally or nationally validated test guidelines or, in the absence thereof, test guidelines accepted by the competent authority;
1.3 in the event of a test guideline being inappropriate or not described, or where one other than those referred to in this Annex has been used, include a justification, which is acceptable to the competent authority for the guidelines used;
1.4 include, a full description of test guidelines used, except if they are referred to or described in this Annex, and a full description of any deviations from them including a justification, which is acceptable to the competent authority, for these deviations;
1.5 include a full and unbiased report of the studies conducted as well as a full description of them or a justification, which is acceptable to the competent authority where —
· particular data and information which would not be necessary owing to the nature of the product or its proposed uses, are not provided, or
· it is not scientifically necessary, or technically possible to supply information and data;
1.6 where relevant, have been generated in accordance with the requirements of Directive 86/609/EEC.
2.1 Tests and analyses must be conducted in accordance with the principles laid down in Directive 87/IS/EEC, where testing is done to obtain data on the properties and/or safety with respect to human health or the environment.
2.2 Tests 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 recognized 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.
2.3 Tests and analyses, required under the provisions of section 6 points 6.2 to 6.8 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 authorization for trials or trials permit concerned.
2.4 Notwithstanding the provisions of point 2.1, tests and analyses started on or before the 31 December 1999 and performed 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.
2.5 Notwithstanding the provisions of point 2.1, supervised residue trials conducted in accordance with the provisions of point 6, relating to plant protection products containing active substances already on the market prior to 25 July 1993 and started on or before the 31 December 1997, 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.
3 The information required shall include the proposed classification and labelling of the plant protection product in accordance with relevant Community Directives.
4 In 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."

REG 8

8. Point 7 of Part A of Annex II, as set out in Part 1 of the First Schedule of the Principal Regulations is hereby revoked and replaced by the following:
"7. FATE AND BEHAVIOUR IN THE ENVIRONMENT
Introduction
(i) The information provided, taken together with that for one or more preparations containing the active substance, must be sufficient to 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, must 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 minimise contamination of the environment and impact on non-target species.
(iii) A detailed description (specification) of the material used, as provided for under Section 1, point 11 must be provided. Where testing is done using active substance the material used should be of that specification that will be used in the manufacture of preparations to be authorized except where radio-labelled material is used.
Where studies are conducted using active substance produced in the laboratory or in a pilot plant production system, the studies must be repeated using active substance as manufactured, unless it can be justified that the test material used is essentially the same for the purposes of environmental testing and assessment.
(iv) Where radio-labelled test material is used, radio-labels should be positioned at sites (one or more as necessary), to facilitate elucidation of metabolic and degradative pathways and to facilitate investigation of the distribution of the active substance and of its metabolite, reaction and degradation products in the environment.
(v) It may be necessary to conduct separate studies for metabolites, degradation or reaction products, where these products can constitute a relevant risk to non-target organisms or to the quality of water, soil and air and where their effects cannot be evaluated by the available results relating to the active substance. Before such studies are performed the information from Sections 5 and 6 must be taken into account.
(vi) Where relevant, tests must be designed and data analyzed using appropriate statistical methods.
Full details of the statistical analysis must be reported (e.g. all point estimates must be given with confidence intervals, exact p-values must be given rather than stating significant/non significant).
7.1 Fate and behaviour in soil
All relevant information on the type and the properties of the soil used in the studies, including pH, organic carbon content, cation

exchange capacity, particle size distribution and water holding capacity. Particle size distribution and water holding capacity at pF = 0 and pF = 2.5 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 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 adsorption/desorption studies.
The soil chosen to commence the programme of studies required should not have extreme characteristics with respect to parameters such as particle size distribution, organic carbon content and pH.
Soils should be collected and handled in accordance with ISO 10381-6 (Soil quality - Sampling - Guidance on the collection, handling and storage of soil for the assessment of microbial processes in the laboratory). Any deviations must be reported and justified.
Field studies should be carried out in conditions as close to normal agricultural practice as possible on a range of soil types and climatic conditions representative of the area(s) of use. Weather conditions shall be reported in cases where field studies are conducted.
7.1.1 Route and rate of degradation
7.1.1.1 Route of degradation
Aim of the tests
The data and information provided, together with other relevant data and information, should be sufficient to:
· identify, where 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 also individual components present which account for less than 10% of the amount of active substance added,

· establish the relative proportions of the components present (mass balance), and
· permit the soil residue of concern and to which non-target species are or may be exposed, to be defined.

Where a reference is made to non-extractable residues these are defined as chemical species originating from pesticides used according to good agricultural practice that cannot be extracted by methods which do not significantly change the chemical nature of these residues. These non-extractable residues are not considered to include fragments generated through metabolic pathways leading to natural products.

7.1.1.1.1 Aerobic degradation

Circumstances in which required

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

Test conditions

The degradation pathway or pathways must be reported for one soil. Results obtained must be presented in the form of schematic drawings showing the pathways involved, and in the form of balance sheets which show the distribution of radio-label as a function of time, as between:

· active substance,
· CO_2,
· volatile compounds other than CO_2,
· individual identified transformation products,
· extractable substances not identified, and
· non-extractable residues in soil.

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

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

Test guideline

SETAC - Procedures for assessing the environmental fate and ecotoxicity of pesticides9.

9 Society of Environmental Taxicology and Chemistry (SETAC), 1995. Procedures for assessing the environmental fate and ecotoxioty of pesticides, ISBN 90-5607-002-9

7.1.1.1.2 Supplementary studies

Anaerobic degradation

Circumstances in which required

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

Test conditions and test guideline
The same provisions as provided for under the corresponding paragraph of point 7.1.1.1.1 apply.
Soil photolysis
Circumstances in which required
A soil photolysis study must be reported unless it can be justified that deposition of the active substance at the soil surface is unlikely to occur.
Test guideline
SETAC - Procedures for assessing the environmental fate and ecotoxicity of pesticides.
7.1.1.2 Rate of degradation
7.1.1.2.1 Laboratory studies
Aim of the tests
The soil degradation studies should provide 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 degradation
Circumstances in which required
The rate of degradation in soil must always be reported, except where the nature and manner of use of plant protection products containing the active substance preclude soil contamination such as uses on stored products or wound healing treatments for trees.
Test conditions
The rate of aerobic degradation of the active substance in three soil types additional to that referred to in paragraph 7.1.1.1.1 must be reported.
In order to investigate the influence of temperature on degradation, one additional study at 10°C must be performed on one of the soils used for the investigation of degradation at 20°C unless a validated Community calculation model for the extrapolation of degradation rates to low temperatures is available.
The duration of the study is normally 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 of the degradation studies with the active substance.
Test guideline
SETAC - Procedures for assessing the environmental fate and ecotoxicity of pesticides.
Anaerobic degradation
Circumstances in which required
The rate of anaerobic degradation of the active substance must be reported where an anaerobic study has to be performed according to point 7.1.1.1.2.

Test conditions
The rate of anaerobic degradation of the active substance must be determined in the soil used in the anaerobic study performed according to point 7.1.1.1.2.
The duration of the study is normally 120 days except where more than 90% of the active substance is degraded before that period expires.
Similar studies for 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 of the degradation studies with the active substance.
Test guideline
SETAC - Procedures for assessing the environmental fate and ecotoxicity of pesticides.
7.1.1.2.2. Field studies
Soil dissipation studies
Aim of the test
The soil dissipation studies should provide estimates of the time taken for dissipation of 50% and 90% (DT50f and DT90f), of the active substance under field conditions. Where relevant, information on relevant metabolites, degradation and reaction products must be reported.
Circumstances in which required
The tests have to be conducted in those conditions were DT50lab ,determined at 20 °C and at a moisture content of the soil related to a 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 moisture content of the soil related to a pF value of 2-2.5 (suction pressure) is greater than 90 days.
Test conditions
Individual studies on a range of representative soils (normally four different types) must be continued until > 90% of the amount applied has dissipated. The maximum duration of the studies is 24 months.
Test guideline
SETAC - Procedures for assessing the environmental fate and ecotoxicity of pesticides.
Soil residue studies
Aim of the test
Soil residue studies should provide estimates of the soil residue levels at harvest or at time of sowing or planting succeeding crops.
Circumstances in which required
Soil residue studies must be reported where the DT50lab is greater than one-third of the period between application and harvest and

where absorption by the succeeding crop is possible, except where soil residues at sowing or planting of a succeeding crop can be reliably estimated from the data of the soil dissipation studies or where it can be justified that these residues can not be phytotoxic to or leave unacceptable residues in rotational crops.
Test conditions
Individual studies must be continued until harvest or time of sowing or planting succeeding crops, unless > 90 % of the amount applied has dissipated.
Test guideline
SETAC - Procedures for assessing the environmental fate and ecotoxicity of pesticides.
Soil accumulation studies
Aim of the tests
The tests should provide sufficient data to evaluate the possibility of accumulation of residues of the active substance and of relevant metabolites, degradation and reaction products.
Circumstances in which required
Where on the basis of soil dissipation studies it is established that DT90f > one year and where repeated application is envisaged, whether in the same growing season or in succeeding years, the possibility of accumulation of residues in soil and the level at which a plateau concentration is achieved must be investigated except where reliable information can be provided by a model calculation or another appropriate assessment.
Test conditions
Long term field studies must be done on two relevant soils and involve multiple applications.
Before performing these studies the applicant shall seek the agreement of the competent authorities on the type of study to be performed.
7.1.2 Adsorption and desorption
Aim of the test
The data and information provided, together with other relevant data and information, must be sufficient to establish the adsorption coefficient of the active substance and of relevant metabolites, degradation and reaction products.
Circumstances in which required
The studies must always be reported except where the nature and manner of use of preparations containing the active substance, preclude soil contamination such as uses on stored products or wound healing treatments for trees.
Test conditions
Studies 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 guideline

OECD method 106.
7.1.3. Mobility in the soil
7.1.3.1. Column leaching studies
Aim of the test
The test should provide sufficient data to evaluate the mobility and leaching potential of the active substance and if possible of relevant metabolites, degradation and reaction products.
Circumstances in which required
Studies in four soils must be carried out where in the absorption and desorption studies provided for under point 7.1.2 it is not possible to obtain reliable absorption coefficient values.
Test guideline
SETAC - Procedures for assessing the environmental fate and ecotoxicity of pesticides.
7.1.3.2 Aged residue column leaching
Aim of the test
The test should provide sufficient data to estimate the mobility and leaching potential of relevant metabolites, degradation and reaction products.
Circumstances in which required
The studies must be performed except:
· where the nature and manner of use of preparations containing the active substance, preclude soil contamination such as uses on stored products or wound healing treatments for trees, or
· where a separate study for the metabolite, degradation or reaction product in accordance with point 7.1.2 or 7.1.3.1 was performed.
Test conditions
The period(s) of ageing should be determined from inspection of the degradation patterns of active substance and metabolites to ensure that a relevant spectrum of metabolites is present at the time of leaching.
Test guideline
SETAC - Procedures for assessing the environmental fate and ecotoxicity of pesticides.
7.1.3.3 Lysimeter studies or field leaching studies
Aim of the tests
The test should provide data on:
· mobility in soil,
· potential for leaching to ground water,
· potential distribution in soil.
Circumstances in which required
Expert judgement will be necessary to decide whether lysimeter studies or field leaching studies should be carried out, taking into account the results of degradation and other mobility studies and the predicted environmental concentrations in ground water (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 conditions
Great care is necessary in design of both experimental installations

and individual studies, to ensure that results obtained can be used for assessment purposes. Studies should cover the realistic worst case situation, taking into account the soil type, climatic conditions, the application rate and the frequency and period of application.
Water percolating from soil columns must be analyzed at suitable intervals, while residues in plant material must be determined at harvest. Residues in the soil profile in at least five layers must be determined on termination of experimental work. Intermediate sampling must be avoided, since removal of plants (except for harvesting according to normal agricultural practice) and soil cross influences the leaching process.
Precipitation, soil and air temperatures must be recorded at regular intervals (at least on a weekly base).
Lysimeter studies
Test conditions
The minimal depth of the lysimeters should be 100 cm; their maximal depth should be 130 cm. The soil cross must be undisturbed. Soil temperatures must be similar to those pertaining in the field. Where necessary, supplementary irrigation must be provided to ensure optimal plant growth and to ensure that the quantity of infiltration water is similar to that in the regions for which authorization is sought. When during the study the soil has to be disturbed for agricultural reasons it must not be disturbed to a depth deeper than 25 cm.
Field leaching studies
Test conditions
Information on the ground water table in the experimental fields must be submitted. If soil cracking is observed during the study this must be fully described.
Great attention should be given to the number and the location of water collection devices. The placement of these devices in the soil must not result in preferential flow paths.
Test guideline
SETAC - Procedures for assessing the environmental fate and ecotoxicity of pesticides.
7.2 Fate and behaviour in water and air
Aim of the tests
The information and data provided, taken together with that provided for one or more preparations containing the active substance, and other relevant information, should be sufficient to establish, or permit estimation of:
· persistence in water systems (bottom sediment and water, including suspended particles),
· the extent to which water, sediment organisms and air are at risk,
· potential for contamination of surface water and ground water.
7.2.1 Route and rate of degradation in aquatic systems (as far as not covered by point 2.9)
Aim of the tests

The data and information provided, together with other relevant data and information, must be sufficient to:
· identify the relative importance of the types of processes involved (balance between chemical and biological degradation),
· where possible, identify the individual components present,
· establish the relative proportions of the components present and their distribution as between water, including suspended particles, and sediment, and
· permit the residue of concern and to which non-target species are or may be exposed, to be defined.

7.2.1.1 Hydrolytic degradation

Circumstances in which required

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

Test conditions and test guideline

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

7.2.1.2 Photochemical degradation

Circumstances in which required

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

Test conditions and test guideline

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

7.2.1.3 Biological degradation

7.2.1.3.1 "Ready biodegradability "

Circumstances in which required

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

Test guideline

EEC method C4.

7.2.1.3.2 Water/sediment study

Circumstances in which required

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

Test guideline

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

7.2.1.4 Degradation in the saturated zone

Circumstances in which required

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

water.
Test conditions
Expert judgement is required to decide whether this information is necessary. Before performing these studies the applicant shall seek the agreement of the competent authorities on the type of study to be performed.
7.2.2 Route and rate of degradation in air (as far as not covered by point 2. 10)
Guidance under development.
7.3 Definition of the residue
In the light of the chemical composition of residues 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.
7.4 Monitoring data
Available monitoring data concerning fate and behaviour of the active substance and relevant metabolites, degradation and reaction products must be reported."

REG 9

9. Point 9 of Part A of Annex III, as set out in Part 2 of the First Schedule of the Principal Regulations is hereby revoked and replaced by the following:
"9 Fate and behaviour in the environment
Introduction
(i) The information provided, taken together with that for the active substance as provided for in Annex II, must be sufficient to permit an assessment of the fate and behaviour of the plant protection product in the environment, and of the non-target species likely to be at risk from exposure to it.
(ii) In particular, the information provided for the plant protection product, together with other relevant information, and that provided for the active substance, should be sufficient to:
· specify the hazard symbols, the indications of danger, and relevant risk and safety phrases for the protection of the environment, which are to be included on packaging (containers),
· predict the distribution, fate, and behaviour in the environment as well as the time courses involved,
· identify non-target species and populations for which hazards arise because of potential exposure, and
· identify measures necessary to minimize contamination of the environment and impact on non-target species.
(iii) Where radio-labelled test material is used, the provisions of Annex II, Chapter 7, introduction, point (iv) apply.
(iv) Where relevant, tests should be designed and data 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).

(v) Predicted environmental concentrations in soil (PECs), water (PECsw and PECGW) and air (PECA).

Justified estimates must be made of the expected concentrations of the active substance and relevant metabolites, degradation and reaction products, in soil, ground water, 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 concentrations 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 concentrations in ground water (PECGW)

The level of residues in ground water.

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 assessment10, Where relevant the parameters provided for in this section should be used.

10 OEPP/EPPO (1993). Decision-making schemes for the environmental risk assessment of plant protection products. Bulletin OEPP/EPPO, Bulletin 23: 1-154 and Bulletin 24: 1-87

When models are used for estimation of predicted environmental concentrations they must:

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

· where possible be reliably validated with measurements carried out under circumstances relevant for the use of the model, and

· be relevant to conditions in the area of use.

The information provided must, where relevant, include that referred to in Annex II, Part A, point 7: and

9.1. Fate and behaviour in soil

Where appropriate, the same provisions relating to the information to be provided on the soil used and on its selection apply as provided for under Annex II, point 7.1.

9.1.1 Rate of degradation in soil

9.1.1.1 Laboratory studies

Aim of the test

The soil degradation studies must 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 required

The persistence and behaviour of plant protection products in soil must be investigated unless it is possible to extrapolate from data obtained on the active substance and relevant metabolites, degradation and reaction products in accordance to the requirements of Annex II, point 7.1.1.2. This extrapolation is, for example, not possible for slow release formulations.

Test conditions

The rate of aerobic and/or anaerobic degradation in soil must be reported.

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

Test guideline

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

9.1.1.2 Field studies

Soil dissipation studies

Aim of the test

The soil dissipation studies should provide best-possible estimates of the time taken for dissipation of 50 and 90% (DT50lab and DT90lab) of the active substance under field conditions. Where relevant, information on relevant metabolites, degradation and reaction products must be collected.

Circumstances in which required.

The dissipation and behaviour of plant protection products in soil must be investigated unless it is possible to extrapolate from data obtained on the active substance and relevant metabolites, degradation and reaction products in accordance to the requirements of Annex U, point 7.1.1.2. This extrapolation is, for example, not possible for slow release formulations.

Test conditions and test guideline

The same provisions as provided under the corresponding paragraph of Annex II, point 7.1.1.2.2 apply.

Soil residue studies

Aim of the test

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

Circumstances in which required

Soil residue studies must be reported unless it is possible to extrapolate from data obtained on the active substance and relevant metabolites, degradation and reaction products in accordance with the requirements of Annex II, point 7.1.1.2.2. This extrapolation is, for example, not possible for slow- release formulations.

Test conditions

The same provisions as provided under the corresponding paragraph of Annex II, point 7.1.1.2.2, apply.

Test guideline
SETAC - Procedures for assessing the environmental fate and ecotoxicity of pesticides.
Soil accumulation studies
Aim of the tests
The tests should provide sufficient data to evaluate the possibility of accumulation of residues of the active substance and of relevant metabolites, degradation and reaction products.
Circumstances in which required
Soil accumulation studies must be reported unless it is possible to extrapolate from data obtained on the active substance and relevant metabolites, degradation and reaction products in accordance with the requirements of Annex II, point 7.1.1.2.2. This extrapolation is, for example, not possible for slow-release formulations.
Test conditions
The same provisions as provided under the corresponding paragraph of Annex II, point 7.1.1.2.2. apply.
Test guideline
SETAC - Procedures for assessing the environmental fate and ecotoxicity of pesticides.
9.1.2 Mobility in the soil
Aim of the test
The test should provide sufficient data to evaluate the mobility and leaching potential of the active substance and relevant metabolites, degradation and reaction products.
9.1.2.1. Laboratory studies
Circumstances in which required
The mobility of plant protection products in soil must be investigated unless it is possible to extrapolate from data obtained in accordance with the requirements of Annex II, points 7.1.2 and 7.1.3.1. This extrapolation is, for example, not possible for slow-release formulations.
Test guideline
SETAC - Procedures for assessing the environmental fate and ecotoxicity of pesticides.
9.1.2.2 Lysimeter studies or field leaching studies
Aim of the tests
The test should provide data on:
• mobility of the plant protection product in soil,
• potential for leaching to ground water,
• potential distribution in soils.
Circumstances in which required
Expert judgement will be necessary to decide whether field leaching studies or lysimeter studies should be carried out, taking into account the results of degradation and mobility studies and the calculated PECGW. The type of study to be conducted must 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, point 7.1.3. Such extrapolation is, for example, not possible for slow release formulations.
Test conditions
The same provisions as provided for under the corresponding paragraph of Annex II, point 7.1.3.3. apply.
9.1.3 Estimation of expected concentrations in soil
PECs estimations must relate both to a single application at the highest rate of application for which authorization is sought, and to the maximum number and highest rates of application for which authorization is sought, for each relevant soil tested, and are expressed in terms of mg of active substance and of relevant metabolites, degradation and reaction products per kg of soil.
The factors to be considered in making PECs estimations relate to direct and indirect application to soil, drift, run off, and leaching and include processes such as volatilization, adsorption, hydrolysis, photolysis, aerobic and anaerobic degradation. For the purposes of 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 is to be assumed that 50% (minimum) of the applied dose reaches the soil surface unless actual experimental data give more specific information.
Initial, short-term and long-term PECs calculations (time weighted averages) must be provided:

Initial:immediately after application Short-term:24 hours, 2 days and 4 days after last application Long-term: 7,28, 50 and 100 days after last application, where relevant.
9.2 Fate and behaviour in water
9.2.1 Estimation of concentrations in ground water
The ground 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 ground water PECGW, of active substance and relevant metabolites, degradation and reaction products, must be submitted.
PEC estimations must relate to the maximum number and highest rates of application, for which authorization is sought.
Expert judgment is required to decide if additional field tests could provide useful information. Before performing these studies the applicant shall seek the agreement of the competent authorities on the type of study to be performed.
9.2.2 Impact on water treatment procedures
In cases where this information is necessary in the framework of a conditional authorization in accordance with Annex VI, Part C, point 2.5.1.2 (b), the information provided should permit establishment or estimation of the effectiveness of water treatment procedures (drinking water and sewage treatment), and impact on such procedures.

Before performing any studies the applicant shall seek the agreement of the competent authorities on the type of information to be provided.
9.2.3 Estimation of concentrations in surface water
The surface water contamination routes 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 submitted.
PEC estimations must relate to the maximum number and highest rates of application, for which authorization is sought, and be relevant to lakes, ponds, rivers, canals, streams, irrigation/drainage canals and drains.
The factors to be considered in making PECSW estimations relate to direct application to water, drift, run-off, discharge via drains and atmospheric deposition, and include processes such as volatilization, adsorption, advection, hydrolysis, photolysis, biodegradation, sedimentation and re-suspension.
Initial, short-term and long-term 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 application Long term:7, 14, 21, 28, and 42 days after last application, where relevant.
Expert judgment is required to decide if additional field tests could provide useful information. Before performing these studies the applicant shall seek the agreement of the competent authorities on the type of study to be performed.
9.3 Fate and behaviour in air
Guidance under development."

REG 10

10. Point 8 of Part A of Annex II, as set out in Part 1 of the First Schedule of the Principal Regulations is hereby revoked and replaced by the following:
"8 ECOTOXICOLOGICAL STUDIES
Introduction
(i) The information provided, taken together with that for one or more preparations containing the active substance, must be sufficient to permit an assessment of the impact on non-target species (flora and fauna), likely to be at risk from exposure to the active substance, its metabolites, degradation and reaction products, where they are of environmental significance. Impact can result from single, prolonged or repeated exposure and can be reversible or irreversible.

(ii) In particular, the information provided for the active substance, together with other relevant information, and that provided for one or more preparations containing it, should be sufficient to:
· decide whether, or not, the active substance can be included in Annex I,
· specify appropriate conditions or restrictions to be associated with any inclusion in Annex I,
· permit an evaluation of short and long-term risks for non-target species-populations, communities, and processes-as appropriate,
· classify the active substance as to hazard,
· specify the precautions necessary for the protection of non-target species, and
· specify the hazard symbols, the indications of danger, and relevant risk and safety phrases for the protection of the environment, to be mentioned on packaging (containers).
(iii) There is a need to report all potentially adverse effects found during routine ecotoxicological investigations and to undertake and report, where required by the competent authorities, such additional studies which may be necessary to investigate the probable mechanisms involved and assess the significance of these effects. All available biological data and information which is relevant to the assessment of the ecotoxicological profile of the active substance must be reported.
(iv) The information on fate and behaviour in the environment, generated and submitted in accordance with points 7.1 to 7.4, and on residue levels in plants generated and submitted in accordance with point 6 is central to the assessment of impact on non-target species, in that together with information on the nature of the preparation and its manner of use, it defines the nature and extent of potential exposure. The toxicokinetic and toxicological studies and information submitted in accordance with points 5.1 to 5.8 provide essential information as to toxicity to vertebrate species and the mechanisms involved.
(v) Where relevant, tests should be designed and data analyzed using appropriate statistical methods. Full details of the statistical analysis should be reported (e.g. all points estimates should be given with confidence intervals, exact p-values should be given rather than stalling significant/non significant).
Test substance
(vi) A detailed description (specification) of the material used, as provided for under point 1.11 must be provided. Where testing is done using active substance the material used should be of that specification that will be used in the manufacture of preparations to be authorised except where radiolabelled material is used.
(vii) Where studies are conducted using active substance produced in the laboratory or in a pilot plant production system, the studies must be repeated using active substance as manufactured, unless it can be justified that the test material used is essentially the same, for the purposes of ecotoxicological testing and assessment. In cases of uncertainty, appropriate bridging studies must be submitted

to serve as a basis for a decision as to the possible need for repetition of the studies.
(viii) In the case of studies in which dosing extends over a period, dosing should preferably be done using a single batch of active substance if stability permits.
Whenever a study implies the use of different doses, the relationship between dose and adverse effect must be reported.
(ix) For all feeding studies, average achieved dose must be reported, including where possible the dose in mg/kg body weight. Where dosing via the diet is utilized the test compound must be distributed uniformly in the diet.
(x) It may be necessary to conduct separate studies for metabolites, degradation or reaction products, where there products can constitute a relevant risk to non-target organisms and where their effects cannot be evaluated by the available results relating to the active substance. Before such studies are performed the information from points 5, 6 and 7 has to be taken into account.
Test organisms
(xi) In order to facilitate the assessment of the significance of tests results obtained, including the estimation of intrinsic toxicity and the factors affecting toxicity, the same strain (or recorded origin) of each relevant species should, where possible, be used in the various toxicity tests specified.
8.1 Effects on birds
8.1.1. Acute oral toxicity
Aim of the test
The test should provide, where possible, LD50 values, the lethal threshold dose, time courses of response and recovery and the NOEL, and must include relevant gross pathological findings.
Circumstances in which required
The possible effects of the active substance on birds must be investigated except where the active substance is intended solely to be included in preparations for exclusive use in enclosed spaces (e.g. in glasshouses or in food storage practice).
Test conditions
The acute oral toxicity of active substance to a quail species (Japanese quail (Coturnix coturnix japonica) or Bobwhite quail (Colinus virginianus) or to mallard duck (Anas platyrhynchos)) must be determined. The highest dose used in tests need not exceed 2,000 mg/kg body weight.
Test guideline
SETAC - Procedures for assessing the environmental fate and ecotoxicity of pesticides.
8.1.2 Short-term dietary toxicity
Aim of the test
The test should provide the short term dietary toxicity (LC50 values, lowest lethal concentration (LLC), where possible no observed effect concentrations (NOEC). time courses of response and recovery) and include relevant gross pathological findings.
Circumstances in which required

The dietary (five-day) toxicity of the active substance to birds must always be investigated on one species except where a study in accordance with the provisions of point 8.1.3 is reported. Where its acute oral NOEL is £ 500 mg/kg body weight or where the short-term NOEC < 500 mg/kg food the test must be performed on a second species.

Test conditions

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

Test guideline

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

8.1.3 Subchronic toxicity and reproduction

Aim of the test

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

Circumstances in which required

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

Test guideline

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

8.2 Effects on aquatic organisms

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

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

8.2.1 Acute toxicity to fish

Aim of the test

The test should provide the acute toxicity (LC50), and details of observed effects.

Circumstances in which required

The test must always be carried out.

Test conditions

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

Test guideline

The test must be carried out in accordance with EEC Method C 1.

8.2.2 Chronic toxicity to fish

Circumstances in which required

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

Expert judgment is required to decide which test has to be performed. In particular for active substance for which there are indications of particular concerns (related to the toxicity of the active substance for fish or the potential exposure) the applicant shall seek the agreement of the competent authorities on the type of test to be performed.
A fish early life stage toxicity test might be appropriate where bioconcentration factors (BCF) are between 100 and 1,000 or where EC50 of the active substance < 0.1 mg/l.
A fish life cycle test might be appropriate in cases where
· the bioconcentration factor is greater than 1,000 and the elimination of the active substance during a depuration phase of 14 days is lower than 95%, or
· the substance is stable in water or sediment (DT50 > 100 days).
It is not necessary to perform a chronic toxicity test on juvenile fish when a fish early life stage toxicity test or a fish life cycle test has been performed; it is likewise not necessary to perform a fish early life stage toxicity test when a fish life cycle test has been performed.
8.2.2.1 Chronic toxicity test on juvenile fish
Aim of the test
The test should provide effects on growth, the threshold level for lethal effects and for observed effects, the NOEC and details of observed effects.
Test conditions
The test must be conducted on juvenile rainbow trout, following exposure of 28 days to the active substance. Data on the effects on growth and behaviour must be generated.
8.2.2.2. Fish early life stage toxicity test
Aim of the test
The test should provide effects on development, growth and behaviour, the NOEC and details of observed effects on fish early life stages.
Test guideline
The test must be carried out in accordance with OECD Method 210.
8.2.2.3. Fish life cycle test
Aim of the test
The test will provide effects on reproduction of the parental and the viability of the filial generation.
Test conditions
Before performing these studies the applicant shall seek the agreement of the competent authorities on the type and conditions of the study to be performed.
8.2.3. Bioconcentration in fish
Aim of the test
The test should provide the steady-state bioconcentration factors, uptake rate constants and depuration rate constants, calculated for each test compound, as well as relevant confidence limits.
Circumstances in which required
The bioconcentration potential of active substances, of metabolites and of degradation and reaction products, likely to partition into

fatty tissues (such as log Pow ³ 3 - see point 2.8 or other relevant indications of bioconcentration), must be investigated and be reported, unless it can be justified that exposure leading to bio-concentration is not likely to occur.

Test guideline

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

8.2.4. Acute toxicity to aquatic invertebrates

Aim of the test

The test should provide the 24 and 48 hour acute toxicity of the active substance, expressed as the median effective concentration (EC50) for immobilization, and where possible the highest concentration causing no immobilization.

Circumstances in which required

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

Test guideline

The test must be carried out in accordance with EEC Method C 2.

8.2.5. Chronic toxicity to aquatic invertebrates

Aim of the test

The test should provide where possible EC50 values for effects such as immobilization and reproduction and the highest concentration at which no effect such as on mortality or reproduction occurs (NOEC) and details of observed effects.

Circumstances in which required

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

Test conditions

The test with Daphnia must be continued for 21 days.

Test guideline

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

8.2.6. Effects on algal growth

Aim of the test

The test should provide EC50 values for growth and growth rate, NOEC values, and details of observed effects.

Circumstances in which required

Possible effects on algal growth of active substances must always be reported. For herbicides a test on a second species from a different taxonomic group has to be performed.

Test guideline

The test must be carried out in accordance with EEC Method C 3.

8.2.7. Effects on sediment dwelling organisms

Aim of test

The test will measure effects on survival and development (including effects on emergence of adults for Chironomus), the relevant EC50 values and the NOEC values.
Circumstances in which required
Where environmental fate and behaviour data required in point 7 supports the conclusion that an active substance is likely to partition to and persist in aquatic sediments, expert judgement should be used to decide whether an acute or a chronic sediment toxicity test is required. Such expert judgement should take into account whether effects on sediment dwelling invertebrates are likely by comparing the aquatic invertebrate toxicity EC50 data from points 8.2.4 and 8.2.5 with the predicted levels of the active substance in sediment from data in Annex III, point 9.
Test conditions
Before performing these studies the applicant shall seek the agreement of the competent authorities on the type and conditions of the study to be performed.
8.2.8. Aquatic plants
A test on aquatic plants has to be performed for herbicides.
Before performing these studies the applicant shall seek the agreement of the competent authorities on the type and conditions of the study to be performed.
8.3 Effect on arthropods
8.3.1 Bees
8.3.1.1 Acute toxicity
Aim of the test
The test should provide the acute oral and contact LC50 value of the active substance.
Circumstances in which required
Potential impact on bees must be investigated, except where preparations containing the active substance are for exclusive use in situations where bees are not likely to be exposed such as:
· food storage in enclosed spaces,
· non-systemic seed dressings,
· non-systemic preparations for application to soil,
· non-systemic dipping treatments for transplanted crops and bulbs, wound sealing and healing treatments,
· rodenticidal baits,
· use in glasshouses without pollinators.
Test guideline
The test must be carried out in accordance with EPPO Guideline 170.
8.3.1.2. Bee brood feeding test
Aim of the test
The test should provide sufficient information to evaluate possible risks from the plant protection product on honeybee larvae.
Circumstances in which required
The test must be carried out when the active substance may act as an insect growth regulator unless it can be justified that it is not likely that bee brood would be exposed to it.
Test guideline

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

8.3.2 Other arthropods

Aim of the test

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

Circumstances in which required

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

· food storage in enclosed spaces,
· wound sealing and healing treatments,
· rodenticidal baits.

Test conditions

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

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

Test guideline

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

"From the Workshop European Standard Characteristics of beneficials Regulatory Testing (Escort), 28 to 30 March 1994, ISBN 0-95-22535-2-6

8.4 Effects on earthworms

8.4.1 Acute toxicity

Aim of the test
The test should provide the LC50 value of the active substance to earthworms, where possible the highest concentration causing no mortality and the lowest concentration causing 100% mortality, and must include observed morphological and behavioural effects.
Circumstances in which required
Effects on earthworms must be investigated, where preparations containing the active substance are applied to soil, or can contaminate soil.
Test guideline
The test must be carried out in accordance with Commission Directive 88/302/EEC, Part C, Toxicity for earthworms: Artificial soil test.
8.4.2 Sublethal effects
Aim of the test
The test should provide the NOEC and the effects on growth, reproduction and behaviour.
Circumstances in which required
Where on the basis of the proposed manner of use of preparations containing the active substance or on the basis of its fate and behaviour in soil (DT90 > 100 days), continued or repeated exposure of earthworms to the active substance, or to significant quantities of metabolites, degradation or reaction products, can be anticipated expert judgement is required to decide whether a sublethal test can be useful.
Test conditions
The test must be carried out on Eisenia foetida.
8.5 Effects on soil non-target micro-organisms
Aim of the test
The test should provide sufficient data to evaluate the impact of the active substance on soil microbial activity, in terms of nitrogen transformation and carbon mineralization.
Circumstances in which required
The test must be carried out where preparations containing the active substance are applied to soil or can contaminate soil under practical conditions of use. In the case of active substances intended for use in preparations for soil sterilization, the studies must be designed to measure rates of recovery following treatment.
Test conditions
Soils used must be freshly sampled agricultural soils. The sites from which soil is taken must not have been treated during the previous two years with any substance that could substantially alter the diversity and levels of microbial populations present, other than in a transitory manner.
Test guideline
SETAC - Procedures for assessing the environmental fate and ecotoxicity of pesticides.
8.6 Effects on other non-target organisms (flora and fauna) believed to be at risk
A summary of available data from preliminary tests used to assess the biological activity and dose range finding, whether positive or

negative, which may provide information with respect to possible impact on other non-target species, both flora and fauna, must be provided, together with a critical assessment as to its relevance to potential impact on non-target species.
8.7 Effects on biological methods for sewage treatment
Effects on biological methods for sewage treatment must be reported where the use of plant protection products containing the active substance can give rise to adverse effects on sewage treatment plants."

REG 11

11. Point 10 and point 11 of Part A of Annex III, as set out m Part 2 of the First Schedule of the Principal Regulations are hereby revoked and replaced by the following:
" 10. ECOTOXICOLOGICAL STUDIES
Introduction
(i) The information provided, taken together with that for the active substance(s), must be sufficient to permit an assessment of the impact on non-target species (flora and fauna), of the plant protection product, when used as proposed. Impact can result from single, prolonged or repeated exposure, and can be reversible, or irreversible.
(ii) In particular, the information provided for the plant protection product, together with other relevant information, and that provided for the active substance, should be sufficient to:
· specify the hazard symbols, the indications of danger, and relevant risk and safety phrases for the protection of the environment, to be mentioned on packaging (containers),
· permit an evaluation of the short and long-term risks for non-target species-populations, communities, and processes as appropriate,
· permit an evaluation of whether special-precautions are necessary for the protection of non-target species.
(iii) There is a need to report all potentially adverse effects found during routine ecotoxicological investigations and to undertake and report such additional studies which may be necessary to investigate the mechanisms involved and assess the significance of these effects.
(iv) In general, much of the data relating to impact on non-target species, required for authorization of plant protection products, will have been submitted and evaluated for the inclusion of the active substance(s) in Annex I. The information on fate and behaviour in the environment, generated and submitted in accordance with points 9.1 to 9.3, and on residue levels in plants generated and submitted in accordance with point 8 is central to the assessment of impact on non-target species, in that it provides information on the nature and extent of potential or actual exposure. The final PEC estimations are to be adapted according to the different groups of

organisms taking in particular into consideration the biology of the most sensitive species.
The toxicological studies and information submitted in accordance with point 7.1 provide essential information as to toxicity to vertebrate species.
(v) Where relevant, tests should be designed and data analysed using appropriate statistical methods. Full details of statistical analyses should be reported (e.g. all point estimates should be given with confidence intervals, exact p-values should be given rather than stating significant/non- significant).
(vi) Whenever a study implies the use of different doses, the relationship between dose and adverse effect must be reported.
(vii) Where exposure data are necessary to decide whether a study has to be performed, the data obtained in accordance with the provisions of Annex III, point 9 should be used.
For the estimation of exposure of organisms all relevant information on the plant protection product and on the active substance must be taken into account. A useful approach for these estimations is provided in the EPPO/ Council of Europe schemes for environmental risk assessment. Where relevant the parameters provided for in this section should be used. Where it appears from available data that the plant protection product is more toxic than the active substance, the toxicity data of the plant protection product must be used for the calculation of relevant toxicity/exposure ratios.
(viii) In the context of the influence that impurities can have on ecotoxicological behaviour, it is essential that for each study submitted, a detailed description (specification) of the material used as provided for under point 1.4, be provided.
(ix) In order to facilitate the assessment of the significance of test results obtained the same strain of each relevant species should, where possible, be used in the various toxicity tests specified.
10.1 Effects on birds
Possible effects on birds must be investigated except where the possibility that birds will be exposed, directly or indirectly, can be ruled out such as for use in enclosed spaces or wound healing treatments.
The acute toxicity/exposure ratio (TERa), the short term dietary toxicity/exposure ratio (TERst) and the long term dietary toxicity/exposure ratio (TERit) must be reported, where:
TERa = LD50 (mg as/kg body weight) / ETE (mg as/kg body weight)
TERst = LC50 (mg as/kg food) / ETE (mg as/kg food)
TERit = NOEC (mg as/kg food) / ETE (mg as/kg food)
where ETE = estimated theoretical exposure.
In the case of pellets, granules or treated seeds the amount of a.s. in each pellet, granule or seed must be reported as well as the proportion of the LD50 for the a.s. in 100 particles and per gram of particles. The size and shape of pellets or granules must be reported.
In the case of baits the concentration of a.s. in the bait (mg/kg)

must be reported.

10.1.1 Acute oral toxicity

Aim of the test

The test should provide, where possible, LD50 values, the lethal threshold dose, time courses of response and recovery, the NOEL, and must include relevant gross pathological findings.

Circumstances in which required

The acute oral toxicity of preparations must be reported, where TERa or TERst for the active substance(s) in birds are between 10 and 100 or where results from mammal testing provide evidence of a significantly higher toxicity of the preparation compared to the active substance unless it can be justified that it is not likely that birds are exposed to the plant protection product itself.

Test conditions

The study must be conducted on the most sensitive species identified in the studies provided for in Annex II, point 8.1.1 or 8.1.2.

10.1.2 Supervised cage or field trials

Aim of the test

The test must provide sufficient data to permit evaluation of the nature and the extent of the risk under practical conditions of use.

Circumstances in which required

Where the TERa and TERst are > 100 and when there is no evidence of risk from any further study on the active substance (e.g. reproduction study) no further testing is required. In other cases, expert judgement is necessary to decide whether there is a need to carry out further studies. This expert judgement will take into account, where relevant, foraging behaviour, repellency, alternative food, actual residue content in the food, persistence of the compound in the vegetation, degradation of the formulated product or treated produce, the amount of predation of the food, acceptance of bait, granules or treated seed and the possibility for bioconcentration.

Where TERa and TERst < 10 or TERlt < 5, cage or field trials must be conducted and reported unless a final assessment is possible on the basis of studies according to point 10.1.3.

Test conditions

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

10.1.3 Acceptance of bait, granules or treated seeds by birds

Aim of the test

The test will provide sufficient data to evaluate the possibility of consumption of the protection product or plant products treated with it.

Circumstances in which required

In the case of seed dressings, pellets, baits and preparations which are granules and where TERa £ 10, acceptability (palatability) tests must be conducted.

10.1.4 Effects of secondary poisoning

Expert judgement is required to decide whether the effects of

secondary poisoning should be investigated.
10.2. Effects on aquatic organisms
Possible effects on aquatic species must be investigated except where the possibility that aquatic species will be exposed can be ruled out.
TERa and TERit must be reported, where:
TERa = acute LC50 mg as/l) / realistic worst case PECsw (initial or short-term, in mg as/l)
TERit = chronic NOEC (mg as/l) / long term PECsw (mg as/l)
10.2.1 Acute toxicity to fish, aquatic invertebrates or effects on algal growth
Circumstances in which required
In principle tests should be carried out on one species from each of the three groups of aquatic organisms as referred to in Annex II, point 8.2 (fish, aquatic invertebrates and algae) in cases where the plant protection product itself can contaminate water. However where the available information permits the conclusion that one of these groups is clearly more sensitive, tests on only the most sensitive species of the relevant group have to be performed.
The test must be performed where:
· the acute toxicity of the plant protection product cannot be predicted on the basis of the data for the active substance which is especially the case if the formulation contains two or more active substances or formulants such as solvents, emulgators surfactants, dispersants, fertilizers which are able to increase the toxicity in comparison with the active substance, or
· the intended use includes direct application on water,
unless suitable studies referred to under point 10.2.4 are available.
Test conditions and test guidelines
The relevant provisions of the corresponding paragraphs of Annex II, points 8.2.1, 8.2.4 and 8.2.6 apply.
10.2.2. Microcosm or mesocosm study
Aim of the test
The tests must provide sufficient data to evaluate the essential impact on aquatic organisms under field conditions.
Circumstances in which required
Where TERa £ 100 or where TERlt £ 10, expert judgement must be used to decide whether a microcosm or mesocosm study is appropriate. This judgement will take into account the results of any additional data over and above those required by the provisions of Annex II, point 8.2 and of point 10.2.1.
Test conditions
Before performing these studies the applicant shall seek the agreement of the competent authorities on the specific aims of the study to be performed and consequently on the type and conditions of the study to be performed.
The study should include at least the highest likely exposure rate, whether from direct application, drift, drainage or run-off. The duration of the study must be sufficient to permit evaluation of all effects.

Test guideline
Appropriate guidelines are included in:
SETAC - Guidance document on testing procedures for pesticides in freshwater mesocosms/Workshop Huntingdon, 3 and 4 July 1991, or Freshwater field tests for hazard assessment of chemicals-European Workshop on Freshwater Field Tests (EWOFFT).
10.2.3. Residue data in fish
Aim of the test
The test will provide sufficient data to evaluate the potential for occurrence of residues in fish.
Circumstances in which required
In general data are available from bioconcentration studies in fish. Where bioconcentration has been observed in the study performed in accordance with Annex II, point 8.2.3 expert judgement is required to decide whether a long-term microcosm or mesocosm study has to be carried out in order to establish the maximum residues likely to be encountered.
Test guideline
SETAC - Guidance document on testing procedures for pesticides in freshwater mesocosms/Workshop Huntingdon. 3 and 4 July 1991.
10.2.4 Additional studies
The studies referred to in Annex II, points 8.2.2. and 8.2.5. may be required for particular plant protection products where it is not possible to extrapolate from data obtained in the corresponding studies on the active substance.
10.3. Effects on terrestrial vertebrates other than birds
Possible effects on wild vertebrate species must be investigated except where it can be justified that it is not likely that terrestrial vertebrates other than birds are exposed, directly or indirectly. TERa, TERst and TERit must be reported, where:
TERa = LD50 (mg as/kg body weight) / ETE (mg as/kg body weight
TERst = subchronic NOEL (mg as/kg food) / ETE mg as/kg food)
TERit = chronic NOEL mg as/kg food) / ETE (mg as/kg food)
where ETE = estimated theoretical exposure.
In principle the evaluation sequence for the assessment of risks to such species is similar to that for birds. In practice it is not often necessary to perform further testing as the studies conducted in accordance with the requirements of Annex II, point 5 and Annex III, point 7 would provide the required information.
Aim of the test
The test will provide sufficient information to evaluate the nature and the extent of risks for terrestrial vertebrates other than birds under practical conditions of use.
Circumstances in which required
Where TERa and TERst > 100 and where there is no evidence of risk from any further study no further testing is required. In other cases, expert judgement is necessary to decide whether or not there is a need to carry out further studies. This expert judgement must take into account, where relevant, foraging behaviour, repellency, alternative food, actual residue content in the food, persistence of

the compound in the vegetation, degradation of the formulated product or treated produce, the amount of predation of the food, acceptance of bait, granules or treated seed and the possibility for bioconcentration.
Where TERa and TERst £ 10 or TERit £ 5 cage or field trials or other appropriate studies must be reported.
Test conditions
Before performing these studies the applicant shall seek the agreement of the competent authorities on the type and conditions of the study to be performed and whether the effects of secondary poisoning should be investigated.
10.4 Effects on bees
The possible effects on bees must be investigated except where the product is for exclusive use in situations where bees are not likely to be exposed such as:
· food storage in enclosed spaces,
· non-systemic seed dressing,
· non-systemic preparations for application to soil,
· non-systemic dipping treatments for transplanted crops and bulbs,
· wound sealing and healing treatments,
· rodenticidal baits,
· use in glasshouses without pollinators.
The hazard quotients for oral and contact exposure (QHO and QHC), must be reported:

QHO =dose/oral LD50 (µg a.s per bee)QHC =dose/contact LD50 (µg a.s per bee)wheredose =the maximum application rate, for which authorization is sought, in g of active substance per hectare.
10.4.1 Acute oral and contact toxicity
Aim of the test
The test should provide the LD50 values (by oral and contact exposure).
Circumstances in which required
Testing is required if:
· the product contains more than one active substance;
· the toxicity of a new formulation cannot be reliably predicted to be either the same or lower than a formulation tested according to the provisions of Annex II, point 8.3.1.1 or of this point.
Test guideline
The test must be carried out according to EPPO Guideline 170.
10.4.2 Residue test
Aim of the test
The test should provide sufficient information to evaluate possible risks to foraging bees from residual traces of plant protection products remaining on crops.
Circumstances in which required
Where QHC ³ 50, expert judgement is required to decide whether the effect of residues must be determined unless there is evidence that there are no significant residual traces remaining on crops which could affect foraging bees or unless sufficient information is

available from cage, tunnel or field tests.
Test conditions
The median lethal time (LT50) (in hours) following 24 hour exposure to residues on leaves aged during eight hours must be determined, and reported. Where LT50 is more than eight hours, no further testing is required.
10.4.3 Cage tests
Aim of the test
The test should provide sufficient information to evaluate possible risks from the plant protection product for bee survival and behaviour.
Circumstances in which required
Where QHOand QHC are < 50, further testing is not required except if significant effects are observed in the bee brood feeding test or if there are indications of indirect effects such as delayed action or modification of bee behaviour. In such cases cage and/or field tests shall be carried out.
Where QHOand QHC > 50, cage and/or field testing is required.
Where field testing is conducted and reported in accordance with point 10.4.4, it is not necessary to conduct cage tests. However, cage tests where conducted, must be reported.
Test conditions
The test should be carried out using healthy bees. If bees have been treated, e.g. with a varroacide, it is necessary to wait for four weeks before using the colony.
Test guideline
The tests must be conducted in accordance with EPPO Guideline 170.
10.4.4 Field tests
Aim of the test
The test should provide sufficient information to evaluate possible risks from the plant protection product on bee behaviour, colony survival and development.
Circumstances in which required
Field tests must be conducted where on the basis of expert judgement, taking into account the proposed manner of use and the fate and behaviour of the active substance, significant effects are observed in cage testing.
Test conditions
The test should be carried out using healthy honeybee colonies of similar natural strength. If bees have been treated, e.g. with a varroacide, it is necessary to wait for four weeks before using the colony. The tests shall be conducted under conditions reasonably representative of the proposed use.
Special effects (larval toxicity, long residual effect, disorienting effects on bees) identified by the field tests may require further investigation using specific methods.
Test guideline
The tests must be conducted in accordance with EPPO Guideline 170.
10.4.5 Tunnel tests
Aim of the test
The test should provide sufficient information to evaluate the impact

on bees resulting from feeding on contaminated honey dew or flowers.
Circumstances in which required
Where it is not possible to investigate certain effects in cage or field trials, a tunnel test should be carried out, e.g. in the case of plant protection products intended for control of aphids and other sucking insects.
Test conditions
The test should be carried out using healthy bees. If bees have been treated, e.g. with a varroacide, it is necessary to wait for four weeks before using the colony.
Test guideline
The test must be carried out in accordance with EPPO Guideline 170.
10.5 Effects on arthropods other than bees
The effects of plant protection products on non-target terrestrial arthropods (e.g. predators or parasitoids of harmful organisms) must be investigated. The information obtained for these species can also be used to indicate the potential for toxicity to non-target species inhabiting the same environment.
10.5.1 Laboratory, extended laboratory and semi-field tests
Aim of the test
The test should provide sufficient information to evaluate the toxicity of the plant protection product for selected arthropod species that are relevant to the intended use of the product.
Circumstances in which required
Testing is not required where severe toxicity (> 99% effect on the organisms compared to control) can be predicted from relevant available data or where the plant protection product is for exclusive use in situations where non-target arthropods are not exposed such as:
· food storage in enclosed spaces,
· wound sealing and healing treatments,
· rodenticidal baits.
Testing is required when significant effects on the organisms in comparison with the control are reported in the laboratory tests at the maximum recommended dose, conducted in accordance with the requirements of Annex II, point 8.3.2. Effects on a particular test species are considered to be significant when they exceed the threshold values specified in the EPPO schemes for environmental risk assessment unless species-specific threshold values are defined in the respective test guidelines.
Testing is also required if:
· the product contains more than one active substance,
· the toxicity of a new formulation cannot be reliably predicted to be either the same or lower than a formulation tested according to the provisions of Annex II, point 8.3.2 or of this point,
· on the basis of the proposed manner of use or on the basis of fate and behaviour continued or repeated exposure can be anticipated,
· there is a significant change in the proposed use, e.g. from arable crops to orchards and species relevant to the new use have not previously been tested,

· there is an increase in the recommended application rate, above that previously tested under Annex II.

Test conditions

Where significant effects were observed in the studies performed in accordance with the requirements of Annex II, point 8.3.2, or in the case of change of use such as from arable crops to orchards, the toxicity of two additional relevant species must be investigated and reported. These must be different to the relevant species already tested under Annex II, point 8.3.2.

For a new mixture or formulation, the toxicity should initially be assessed using the two most sensitive species as identified in studies already performed for which the threshold values were exceeded but effects still remain below 99%. This will enable a comparison to be made; if it is significantly more toxic two species relevant to its proposed use must be tested.

Testing must be conducted at a rate equivalent to the maximum rate of application for which authorization is sought. A sequential testing approach should be adopted, i.e. laboratory, and if necessary extended laboratory and/or semi-field.

Where there will be more than one application per season, the product should be applied at twice the recommended application rate unless this information is already available from studies performed in accordance with Annex II, point 8.3.2.

Where on the basis of the proposed manner of use or on the basis of fate and behaviour continued or repeated exposure can be anticipated (such as the product is to be applied more than three times per season with a re-application interval of 14 days or less), expert judgement is required to determine whether or not further testing is required, beyond initial laboratory testing, and which will reflect the proposed use pattern. These tests may be performed in the laboratory or under semi-field conditions. When the test is done in the laboratory a realistic substrate such as plant material or a natural soil should be used. However it may be more appropriate to carry out field tests.

Test guideline

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

10.5.2 Field tests

Aim of the test

The tests should provide sufficient information to evaluate the risk of the plant protection product for arthropods under field conditions.

Circumstances in which required

Where significant effects are seen following laboratory and semi-field exposure, or where on the basis of the proposed manner of use or on the basis of fate and behaviour continued or repeated exposure can be anticipated expert judgement is required to determine whether more extensive testing is necessary to permit an accurate risk

assessment.
Test conditions
The tests must be conducted under representative agricultural conditions and in accordance with the proposed recommendations for use, resulting in a realistic worst case study.
A toxic standard should be included in all tests.
Test guideline
Where relevant testing should be done according to appropriate guidelines which satisfy at least the requirements for testing as included in SETAC - Guidance document on regulatory testing procedures for pesticides with non-target arthropods.
10.6 Effects on earthworms and other soil non-target macro-organisms, believed to be at risk
10.6.1 Effects on earthworms
The possible impact on earthworms must be reported except where it can be justified that it is not likely that earthworms are exposed, directly or indirectly.
TERa and TERit must be reported where:
TERa = LC50 (mg as/kg)/realistic worst case PECs, (initial or short term, in mg a.s./kg)
TERit = NOEC (mg as/kg)/long term PECs, (mg a.s./kg).
10.6.1.1 Acute toxicity tests
Aim of the test
The test should provide the LC50, where possible the highest concentration causing no mortality and the lowest concentration causing 100% mortality and must include observed morphological and behaviourial effects.
Circumstances in which required
These studies are only required where:
· the product contains more than one active substance,
· the toxicity of a new formulation cannot be reliably predicted from the formulation tested according to the provisions of Annex II, point 8.4 or of this point.
Test guideline
The tests must be conducted in accordance to OECD Method 207.
10.6.1.2 Tests for sublethal effects
Aim of the test
The test should provide the NOEC and the effects on growth, reproduction and behaviour.
Circumstances in which required
These studies are only required where:
· the product contains more than one active substance,
· the toxicity of a new formulation cannot be reliably predicted from the formulation tested according to the provisions of Annex II, point 8.4 or of this point,
· there is an increase in the recommended application rate, above that previously tested.
Test conditions
The same provisions as under the corresponding paragraphs of Annex II, point 8.4.2 apply.

10.6.1.3 Field studies
Aim of the test
The test should provide sufficient data to evaluate the effects on earthworms under field conditions.
Circumstances in which required
Where TERit < 5 a field study to determine effects under practical field conditions must be conducted and reported.
Expert judgement is required to decide whether the residue content of earthworms should be investigated.
Test conditions
Fields selected shall have a reasonable earthworm population.
The test must be carried out at the maximum proposed application rate. A toxic reference product must be included in the test.
10.6.2. Effects on other soil non-target macro-organisms
Aim of the test
The test should provide sufficient data to evaluate the impact of the plant protection product on macro-organisms that contribute to the breakdown of dead plant and animal organic matter.
Circumstances in which required
Testing is not required where in accordance with Annex III, point 9.1, it is evident that DT90 values are less than 100 days, or the nature and manner of use of the plant protection product are such that exposure does not occur or when data from studies on the active substance performed in accordance with the provisions of Annex II, points 8.3.2, 8.4 and 8.5 indicate that there is no risk for soil macrofauna, earthworms or soil microflora.
Impact on organic matter breakdown must be investigated and reported, where the DT90f, values determined in field dissipation studies (point 9.1) are > 365 days.
10.7. Effects on soil non-target micro-organisms
10.7.1. Laboratory testing
Aim of the test
The test should provide sufficient data to evaluate the impact of the plant protection product on soil microbial activity in terms of nitrogen transformation and carbon mineralization.
Circumstances in which required
Where the DT90f values determined in field dissipation studies (point 9.1) are >> 100 days, impact on soil non-target micro-organisms must be investigated through laboratory testing. Testing is, however, not required if in the studies performed in accordance with the provisions of Annex II, point 8.5, deviations from control values in terms of metabolic activity of the microbial biomass after 100 days is < 25%, and such data are relevant to the uses, nature and properties of the particular preparation to be authorized.
Test guideline
SETAC - Procedures for assessing the environmental fate and ecotoxicity of pesticides.
10.7.2. Additional testing Aim of the test
The test should provide sufficient data to evaluate the impact of the plant protection product under field conditions on microbial

activity.
Circumstances in which required
Where at the end of 100 days, measured activity deviates by more than 25% from the control, in laboratory tests, further testing in the laboratory, under glass and/or in the field may be necessary.
10.8 Available data from biological primary screening in summary form
A summary of available data from preliminary tests used to assess the biological activity and dose range finding whether positive or negative, which provides information with respect to possible impact on non-target species, both flora and fauna, must be provided, together with a critical assessment as to its relevance to potential impact on non-target species.
11 SUMMARY AND EVALUATION OF POINTS 9 AND 10
A summary and evaluation of all data presented in points 9 and 10, prepared in accordance with the relevant guidelines - 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), Commission Document 1663/VI/94 rev 7 - must be provided. It should include a detailed and critical assessment of those data in the context of relevant evaluative and decision making criteria and guidelines, with particular reference to the risks for the environment and non-target species that may or do arise, and the extent, quality and reliability of the data base. In particular the following issues should be addressed:
· predicting distribution and fate in the environment, and the time courses involved,
· identification of non-target species and populations at risk, and prediction of the extent of potential exposure,
· evaluation as to the short- and long-term risks for non target species - populations, communities, and processes - as appropriate,
· evaluation as to the risk of fish kills, and fatalities in large vertebrates, or terrestrial predators, regardless of effects at population or community level, and
· identification of precautions necessary to avoid or minimize contamination of the environment, and for the protection of non-target species."

Given under my Official Seal, this thirtieth day of May, 1996
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 and 1995 (S.I. No. 139 of 1994 and S.I. No. 200 of 1995). The amendments, inter alia, specify the detailed requirements relating to fate and behaviour in the environment and impact on non-target species, to be submitted in support of applications for authorization for marketing and use of plant protection products.