# COMMISSION DIRECTIVE 96/12/EC

## of 8 March 1996

## amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market

**(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market [1], as last amended by Commission Directive 95/36/EC [2], and in particular Article 18 (2) thereof,

Whereas Annexes II and III to Directive 91/414/EEC set out the requirements for the dossier to be submitted by applicants respectively for the inclusion of an active substance in Annex I of that Directive and for the authorization of a plant protection product;

Whereas it is necessary to indicate, in Annexes II and III to Directive 91/414/EEC, to the applicants, as precisely as possible, any details on the required information, such as the circumstances, conditions and technical protocols under which certain data have to be generated; whereas these provisions should be introduced as soon as available in order to permit applicants to use them in the preparation of their files;

Whereas it is now possible to introduce more precision with regard to the data requirements concerning ecotoxicological studies on the active substance provided for in Part A, point 8, of Annex II to Directive 91/414/EEC;

Whereas it is also now possible to introduce more precision with regard to the data requirements concerning ecotoxicological studies on the plant protection product provided for in Part A, point 10, of Annex III to Directive 91/414/EEC;

Whereas the measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Plant Health,

HAS ADOPTED THIS DIRECTIVE:

*Article 1*

Directive 91/414/EEC is amended as follows:

1. In Part A of Annex II, point 8 'Ecotoxicological studies on the active substance' is replaced by Annex I hereto;
2. in Part A of Annex III, points 10 'Ecotoxicological studies' and 11 'Summary and evaluation of points 9 and 10' are replaced by Annex II hereto.

*Article 2*

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 March 1997. They shall immediately inform the Commission thereof.

When Member States adopt these measures, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by the Member States.

*Article 3*

This Directive shall enter into force on 1 April 1996.

*Article 4*

This Directive is addressed to the Member States.

Done at Brussels, 8 March 1996.

*For the Commission*

Ritt BJERREGAARD

*Member of the Commission*

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[1] OJ No L 230, 19. 8. 1991, p. 1.
[2] OJ No L 172, 22. 7. 1995, p. 8.

*ANNEX I*

'8. **ECOTOXICOLOGICAL STUDIES**

**Introduction**

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

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

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

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

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

— classify the active substance as to hazard,

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

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

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

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

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

**Test substance**

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

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

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

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

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

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

**Test organisms**

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

## 8.1. Effects on birds

### 8.1.1. Acute oral toxicity

*Aim of the test*

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

*Circumstances in which required*

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

*Test conditions*

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

*Test guideline*

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

### 8.1.2. Short-term dietary toxicity

*Aim of the test*

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

*Circumstances in which required*

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

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

*Circumstances in which required*

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

*Test guideline*

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

8.2. **Effects on aquatic organisms**

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

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

8.2.1. Acute toxicity to fish

*Aim of the test*

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

*Circumstances in which required*

The test must always be carried out.

*Test conditions*

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

*Test guideline*

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

8.2.2. Chronic toxicity to fish

*Circumstances in which required*

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

Expert judgment is required to decide which test has to be performed. In particular for active substance for which there are indications of particular concerns (related to the toxicity of the active substance for fish or the potential exposure) the applicant shall seek the agreement of the competent authorities on the type of test to be performed.

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

A fish life cycle test might be appropriate in cases where

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

or

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

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

8.2.2.1. Chronic toxicity test on juvenile fish

*Aim of the test*

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

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

*Test conditions*

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

8.2.2.2. Fish early life stage toxicity test

*Aim of the test*

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

*Test guideline*

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

8.2.2.3. Fish life cycle test

*Aim of the test*

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

*Test conditions*

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

8.2.3. Bioconcentration in fish

*Aim of the test*

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

*Circumstances in which required*

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

*Test guideline*

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

8.2.4. Acute toxicity to aquatic invertebrates

*Aim of the test*

The test should provide the 24 and 48-hour acute toxicity of the active substance, expressed as the median effective concentration ($EC_{50}$) for immobilization, and where possible the highest concentration causing no immobilization.

*Circumstances in which required*

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

*Test guideline*

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

8.2.5. Chronic toxicity to aquatic invertebrates

*Aim of the test*

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

*Circumstances in which required*

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

*Test conditions*

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

*Test guideline*

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

8.2.6. Effects on algal growth

*Aim of the test*

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

*Circumstances in which required*

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

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

*Test guideline*

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

8.2.7. Effects on sediment dwelling organisms

*Aim of test*

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

*Circumstances in which required*

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

*Test conditions*

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

8.2.8. Aquatic plants

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

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

8.3. **Effect on arthropods**

8.3.1. Bees

8.3.1.1. Acute toxicity

*Aim of the test*

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

*Circumstances in which required*

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

— food storage in enclosed spaces,

— non-systemic seed dressings,

— non-systemic preparations for application to soil,

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

— wound sealing and healing treatments,

— rodenticidal baits,

— use in glasshouses without pollinators.

*Test guideline*

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

8.3.1.2. Bee brood feeding test

*Aim of the test*

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

*Circumstances in which required*

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

*Test guideline*

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

8.3.2. Other arethropods

*Aim of the test*

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

*Circumstances in which required*

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

— food storage in enclosed spaces,

— wound sealing and healing treatments,

— rodenticidal baits.

*Test conditions*

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

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

*Test guideline*

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

8.4. **Effects on earthworms**

8.4.1. Acute toxicity

*Aim of the test*

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

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

*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 [1] adapting to technical progress for the ninth time Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, Part C, Toxicity for earthworms: Artificial soil test.

8.4.2. Sublethal effects

*Aim of the test*

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

*Circumstances in which required*

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

*Test conditions*

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

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

*Aim of the test*

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

*Circumstances in which required*

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

*Test conditions*

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

*Test guideline*

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

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

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

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

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

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

*ANNEX II*

'10. ECOTOXICOLOGICAL STUDIES

**Introduction**

(i) The information provided, taken together with that for the active substance(s), must be sufficient to permit an assessment of the impact on non-target species (flora and fauna), of the plant protection product, when used as proposed. Impact can result from single, prolonged or repeated exposure, and can be reversible, or irreversible.

(ii) In particular, the information provided for the plant protection product, together with other relevant information, and that provided for the active substance, should be sufficient to:

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

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

— permit an evaluation of whether special precautions are necessary for the protection of non-target species.

(iii) There is a need to report all potentially adverse effects found during routine ecotoxicological investigations and to undertake and report such additional studies which may be necessary to investigate the mechanisms involved and assess the significance of these effects.

(iv) In general, much of the data relating to impact on non-target species, required for authorization of plant protection products, will have been submitted and evaluated for the inclusion of the active substance(s) in Annex I. The information on fate and behaviour in the environment, generated and submitted in accordance with points 9.1 to 9.3, and on residue levels in plants generated and submitted in accordance with point 8 is central to the assessment of impact on non-target species, in that it provides information on the nature and extent of potential or actual exposure. The final PEC estimations are to be adapted according to the different groups of organisms taking in particular into consideration the biology of the most sensitive species.

The toxicological studies and information submitted in accordance with point 7.1 provide essential information as to toxicity to vertebrate species.

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

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

(vii) Where exposure data are necessary to decide whether a study has to be performed, the data obtained in accordance with the provisions of Annex III, point 9 should be used.

For the estimation of exposure of organisms all relevant information on the plant protection product and on the active substance must be taken into account. A useful approach for these estimations is provided in the EPPO/Council of Europe schemes for environmental risk assessment (1). Where relevant the parameters provided for in this section should be used. Where it appears from available data that the plant protection product is more toxic as the active substance, the toxicity data of the plant protection product have to be used for the calculation of relevant toxicity/exposure ratios.

(viii) In the context of the influence that impurities can have on ecotoxicological behaviour, it is essential that for each study submitted, a detailed description (specification) of the material used as provided for under point 1.4, be provided.

(ix) In order to facilitate the assessment of the significance of test results obtained the same strain of each relevant species should where possible be used in the various toxicity tests specified.

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

10.1. **Effects on birds**

Possible effects on birds must be investigated except where the possibility that birds will be exposed, directly or indirectly, can be ruled out such as for use in enclosed spaces or wound healing treatments.

The acute toxicity/exposure ratio ($TER_a$), the short term dietary toxicity/exposure ratio ($TER_{st}$) and the long term dietary toxicity/exposure ratio ($TER_{lt}$) must be reported, where:

$TER_a$ = $LD_{50}$ (mg a.s./kg body weight) / ETE (mg a.s./kg body weight)
$TER_{st}$ = $LC_{50}$ (mg a.s./kg food) / ETE (mg a.s./kg food)
$TER_{lt}$ = NOEC (mg a.s./kg food) / ETE (mg a.s./kg food)

where ETE = estimated theoretical exposure.

In the case of pellets, granules or treated seeds the amount of a.s. in each pellet, granule or seed must be reported as well as the proportion of the $LD_{50}$ for the a.s. in 100 particles and per gram of particles. The size and shape of pellets or granules must be reported.

In the case of baits the concentration of a.s. in the bait (mg/kg) must be reported.

10.1.1. Acute oral toxicity

*Aim of the test*

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

*Circumstances in which required*

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

*Test conditions*

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

10.1.2. Supervised cage or field trials

*Aim of the test*

The test will provide sufficient data to evaluate the nature and the extent of the risk in practical conditions of use.

*Circumstances in which required*

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

Where $TER_a$ and $TER_{st} \leq 10$ or $TER_{lt} \leq 5$, cage or field trials must be conducted and reported unless a final assessment is possible on the basis of studies according to point 10.1.3.

*Test conditions*

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

10.1.3. Acceptance of bait, granules or treated seeds by birds

*Aim of the test*

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

*Circumstances in which required*

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

10.1.4. Effects of secondary poisoning

Expert judgment is required to decide whether the effects of secondary poisoning should be investigated.

10.2. **Effects on aquatic organisms**

Possible effects on aquatic species must be investigated except where the possibility that aquatic species will be exposed can be ruled out.

$TER_a$ and $TER_{lt}$ must be reported, where:

$TER_a$ = acute $LC_{50}$ (mg a.s./l)/realistic worst case $PEC_{sw}$ (initial or short-term, in mg a.s./l)

$TER_{lt}$ = chronic NOEC (mg a.s./l)/long term $PEC_{sw}$ (mg a.s./l)

10.2.1. Acute toxicity to fish, aquatic invertebrates or effects on algal growth

*Circumstances in which required*

In principle tests should be carried out on one species from each of the three groups of aquatic organisms as referred to in Annex II, point 8.2 (fish, aquatic invertebrates and algae) in case the plant protection product itself can contaminate water. However where the available information permits to conclude that one of these groups is clearly more sensitive, tests on only the most sensitive species of the relevant group have to be performed.

The test must be performed where:

— the acute toxicity of the plant protection product can not be predicted on the basis of the data for the active substance which is especially the case if the formulation contains two or more active substances or formulants such as solvents, emulgators, surfactants, dispersants, fertilizers which are able to increase the toxicity in comparison with the active substance, or

— the intended use includes direct application on water

unless suitable studies referred to under point 10.2.4 are available.

*Test conditions and test guidelines*

The relevant provisions as under the corresponding paragraphs of Annex II, points 8.2.1, 8.2.4 and 8.2.6 apply.

10.2.2. Microcosm or mesocom study

*Aim of the test*

The tests must provide sufficient data to evaluate the essential impact on aquatic organisms under field conditions.

*Circumstances in which required*

Where $TER_a \leq 100$ or where $TER_{lt} \leq 10$, expert judgment must be used to decide whether a microcosm or mesocom study is appropriate. This judgment will take into account the results of any additional data over and above those required by the provisions of Annex II, point 8.2 and of point 10.2.1.

*Test conditions*

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

The study should include at least the highest likely exposure rate, whether from direct applicaiton, drift, drainage or run-off. The duration of the study must be sufficient to permit evaluation of all effects.

*Test guideline*

Appropriate guidelines are included in:

Setac — Guidance document on testing procedures for pesticides in freshwater mesocosms/Workshop Huntingdon, 3 and 4 July 1991

or

Freshwater field tests for hazard assessment of chemicals — European Workshop on Freshwater Field Tests (EWOFFT).

10.2.3. Residue data in fish

*Aim of the test*

The test will provide sufficient data to evaluate the potential for occurrence of residues in fish.

*Circumstances in which required*

In general data are available from bioconcentration studies in fish.

Where bioconcentration has been observed in the study performed in accordance with Annex II, point 8.2.3 expert judgement is required to decide whether a long-term microcosm or mesocosm study has to be carried out in order to establish the maximum residues likely to be encountered.

*Test guideline*

Setac — Guidance document on testing procedures for pesticides in freshwater mesocosms/Workshop Huntingdon, 3 and 4 July 1991.

10.2.4. Additional studies

The studies referred to in Annex II, points 8.2.2 and 8.2.5 may be required for particular plant protection products where it is not possible to extrapolate from data obtained in the corresponding studies on the active substance.

10.3. **Effects on terrestrial vertebrates other than birds**

Possible effects on wild vertebrate species must be investigated except where it can be justified that it is not likely that terrestrial vertebrates other than birds are exposed, directly or indirectly. $TER_a$, $TER_{st}$ and $TER_{lt}$ must be reported, where:

$TER_a$ = $LD_{50}$ (mg a.s./kg body weight) / ETE (mg a.s./kg body weight)

$TER_{st}$ = subchronic NOEL (mg a.s./kg food) / ETE (mg a.s./kg food)

$TER_{lt}$ = chronic NOEL (mg a.s./kg food) / ETE (mg a.s./kg food)

where ETE = estimated theoretical exposure.

In principle the evaluation sequence for the assessment of risks to such species is similar to that for birds. In practice it is not often necessary to perform further testing as the studies conducted in accordance with the requirements of Annex II, point 5 and Annex III, point 7 would provide the required information.

*Aim of the test*

The test will provide sufficient information to evaluate the nature and the extent of risks for terrestrial vertebrates other than birds in practical conditions of use.

*Circumstances in which required*

Where $TER_a$ and $TER_{st} > 100$ and where there is no evidence of risk from any further study no further testing is required. In the other cases, expert judgment is necessary to decide whether there is a need to carry out further studies. This expert judgment will take into account, where relevant, foraging behaviour, repellency, alternative food, actual residue content in the food, persistence of the compound in the vegetation, degradation of the formulated product or treated produce, the amount of predation of the food, acceptance of bait, granules or treated seed and the possibility for bioconcentration.

Where $TER_a$ and $TER_{st} \leq 10$ or $TER_{lt} \leq 5$ cage or field trials or other appropriate studies must be reported.

*Test conditions*

Before performing these studies the applicant shall seek the agreement of the competent authorities on the type and conditions of the study to be performed and whether the effects of secondary poisoning should be investigated.

10.4. **Effects on bees**

The possible effects on bees must be investigated except where the product is for exclusive use in situations where bees are not likely to be exposed such as:

— food storage in enclosed spaces,
— non-systemic seed dressings,
— non-systemic preparations for application to soil,
— non-systemic dipping treatments for transplanted crops and bulbs,
— wound sealing and healing treatments,
— rodenticidal baits,
— use in glasshouses without pollinators.

The hazard quotients for oral and contact exposure ($Q_{HO}$ and $Q_{HC}$), must be reported:

$Q_{HO}$ = dose/oral $LD_{50}$ (µg a.s. per bee)

$Q_{HC}$ = dose/contact $LD_{50}$ (µg a.s. per bee)

where

dose = the maximum application rate, for which authorization is sought, in g of active substance per hectare.

10.4.1. Acute oral and contact toxicity

*Aim of the test*

The test should provide the $LD_{50}$ values (by oral and contact exposure).

*Circumstances in which required*

Testing is required if:

— the product contains more than one active substance;

— the toxicity of a new formulation cannot be reliably predicted to be either the same or lower than a formulation tested according to the provisions of Annex II, point 8.3.1.1 or of this point.

*Test guideline*

The test must be carried out according to EPPO Guideline 170.

10.4.2. Residue test

*Aim of the test*

The test should provide sufficient information to evaluate possible risks to foraging bees from residual traces of plant protection products remaining on crops.

*Circumstances in which required*

Where $Q_{HC} \geq 50$, expert judgment is required to decide whether the effect of residues must be determined unless there is evidence that there are no significant residual traces remaining on crops which could affect foraging bees or unless sufficient information is available from cage, tunnel or field tests.

*Test conditions*

The median lethal time ($LT_{50}$) (in hours) following 24-hour exposure to residues on leaves aged during eight hours must be determined, and reported. Where $LT_{50}$ is more than eight hours, no further testing is required.

10.4.3. Cage tests

*Aim of the test*

The test should provide sufficient information to evaluate possible risks from the plant protection product for bee survival and behaviour.

*Circumstances in which required*

Where $Q_{HO}$ and $Q_{HC}$ are $< 50$, further testing is not required except if significant effects are observed in the bee brood feeding test or if there are indications for indirect effects such as delayed action or modification of bee behaviour; in those cases cage and/or field tests shall be carried out.

Where $Q_{HO}$ and $Q_{HC}$ are $> 50$, cage and/or field testing is required.

Where field testing is conducted and reported in accordance with point 10.4.4, it is not necessary to conduct cage tests. However, cage tests where conducted, must be reported.

*Test conditions*

The test should be carried out using healthy bees. If bees have been treated, e.g. with a varroacide, it is necessary to wait for four weeks before using the colony.

*Test guideline*

The tests must be conducted in accordance with EPPO Guideline 170.

10.4.4. Field tests

*Aim of the test*

The test should provide sufficient information to evaluate possible risks from the plant protection product on bee behaviour, colony survival and development.

*Circumstances in which required*

Field tests must be conducted where on the basis of expert judgement, taking into account the proposed manner of use and the fate and behaviour of the active substance, significant effects are observed in cage testing.

*Test conditions*

The test should be carried out using healthy honeybee colonies of similar natural strength. If bees have been treated, e.g. with a varroacide, it is necessary to wait for four weeks before using the colony. The tests shall be conducted under conditions reasonably representative of the proposed use.

Special effects (larval toxicity, long residual effect, disorienting effects on bees) identified by the field tests may require further investigation using specific methods.

*Test guideline*

The tests must be conducted in accordance with EPPO Guideline 170.

10.4.5. Tunnel tests

*Aim of the test*

The test should provide sufficient information to evaluate the impact on bees resulting from feeding on contaminated honey dew or flowers.

*Circumstances in which required*

Where it is not possible to investigate certain effects in cage or field trials, a tunnel test should be carried out, e.g. in the case of plant protection products intended for control of aphids and other sucking insects.

*Test conditions*

The test should be carried out using healthy bees. If bees have been treated, e.g. with a varroacide, it is necessary to wait for four weeks before using the colony.

*Test guideline*

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

10.5. **Effects on arthropods other than bees**

The effects of plant protection products on non-target terrestrial arthropods (e.g. predators or parasitoids of harmful organisms) must be investigated. The information obtained for these species can also be used to indicate the potential for toxicity to non-target species inhabiting the same environment.

10.5.1. Laboratory, extended laboratory and semi-field tests

*Aim of the test*

The test should provide sufficient information to evaluate the toxicity of the plant protection product for selected arthropod species that are relevant to the intended use of the product.

*Circumstances in which required*

Testing is not required where severe toxicity (> 99 % effect on the organisms compared to control) can be predicted from relevant available data or where the plant protection product is for exclusive use in situations where non-target arthropods are not exposed such as:

— food storage in enclosed spaces,

— wound sealing and healing treatments,

— rodenticidal baits.

Testing is required when significant effects on the organisms in comparison with the control are reported in the laboratory tests at the maximum recommended dose, conducted in accordance with the requirements of Annex II, point 8.3.2. Effects on a particular test species are considered to be significant when they exceed the threshold values as defined in the EPPO schemes for the environmental risk assessment unless species-specific threshold values are defined in the respective test guidelines.

Testing is also required if:

— the product contains more than one active substance,

— the toxicity of a new formulation cannot be reliably predicted to be either the same or lower than a formulation tested according to the provisions of Annex II, point 8.3.2 or of this point,

— on the basis of the proposed manner of use or on the basis of the fate and behaviour continued or repeated exposure can be anticipated,

— there is a significant change in the proposed use, e.g. from arable crops to orchards, and species relevant to the new use have not previously been tested,

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

*Test conditions*

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

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

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

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

Where on the basis of the proposed manner of use or on the basis of the fate and behaviour continued or repeated exposure can be anticipated (such as the product is to be applied more than three times per season with a re-application of 14 days or less), expert judgment is required to examine whether further testing is required, beyond initial laboratory testing, which will reflect the proposed use pattern. These tests may be performed in the laboratory or under semi-field conditions. When the test is done in the laboratory a realistic substrate such as plant material or a natural soil should be used. However it may be more appropriate to carry out field tests.

*Test guideline*

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

10.5.2. Field tests

*Aim of the test*

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

*Circumstances in which required*

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

*Test conditions*

The tests must be conducted under representative agricultural conditions and in accordance with the proposed recommendations for use, resulting in a realistic worst case study.

A toxic standard should be included in all tests.

*Test guideline*

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

10.6. **Effects on earthworms and other soil non-target macro-organisms, believed to be at risk**

10.6.1. Effects on earthworms

The possible impact on earthworms must be reported except where it can be justified that it is not likely that earthworms are exposed, directly or indirectly.

$TER_a$ and $TER_{lt}$ must be reported where:

$TER_a$ = $LC_{50}$ (mg a.s./kg)/realistic worst case $PEC_s$ (initial or short-term, in mg a.s./kg)

$TER_{lt}$ = NOEC (mg a.s./kg)/long term $PEC_s$ (mg a.s./kg).

10.6.1.1. Acute toxicity tests

*Aim of the test*

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

*Circumstances in which required*

These studies are only required where

— the product contains more than one active substance,

— the toxicity of a new formulation cannot be reliably predicted from the formulation tested according to the provisions of Annex II, point 8.4 or of this point.

*Test guideline*

The tests must be conducted in accordance to OECD Method 207.

10.6.1.2. Tests for sublethal effects

*Aim of the test*

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

*Circumstances in which required*

These studies are only required where

— the product contains more than one active substance,

— the toxicity of a new formulation cannot be reliably predicted from the formulation tested according to the provisions of Annex II, point 8.4 or of this point,

— there is an increase in the recommended application rate, above that previously tested.

*Test conditions*

The same provisions as under the corresponding paragraphs of Annex II, point 8.4.2 apply.

10.6.1.3. Field studies

*Aim of the test*

The test should provide sufficient data to evaluate the effects on earthworms in field conditions.

*Circumstances in which required*

Where $TER_{lt} < 5$ a field study to determine effects under practical field conditions must be conducted and reported.

Expert judgment is required to decide whether residue contents of earthworms should be investigated.

*Test conditions*

Fields selected shall have a reasonable earthworm population.

The test must be carried out at the maximum proposed application rate. A toxic reference product must be included in the test.

10.6.2. Effects on other soil non-target macro-organisms

*Aim of the test*

The test should provide sufficient data to evaluate the impact of the plant protection product on macro-organisms that contribute to the breakdown of dead plant and animal organic matter.

*Circumstances in which required*

Testing is not required where in accordance with Annex III, point 9.1, it is evident that $DT_{90}$ values are less than 100 days, or the nature and manner of use of the plant protection product are such that exposure does not occur or when data from studies on the active substance performed in accordance with the provisions of Annex II, points 8.3.2, 8.4 and 8.5 indicate that there is no risk for soil macrofauna, earthworms or soil microflora.

Impact on organic matter breakdown must be investigated and reported, where the $DT_{90f}$ values determined in field dissipation studies (point 9.1) are > 365 days.

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

10.7.1. Laboratory testing

*Aim of the test*

The test should provide sufficient data to evaluate the impact of the plant protection product on soil microbial activity in terms of nitrogen transformation and carbon mineralization.

*Circumstances in which required*

Where the $DT_{90f}$ values determined in field dissipation studies (point 9.1) are > 100 days, impact on soil non-target micro-organisms must be investigated through laboratory testing. Testing is, however, not required if in the studies performed in accordance with the provisions of Annex II, point 8.5 deviations from control values in terms of metabolic activity of the microbial biomass after 100 days is < 25 %, and such data are relevant to the uses, nature, and properties of the particular preparation to be authorized.

*Test guideline*

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

10.7.2. Additional testing

*Aim of the test*

The test should provide sufficient data to evaluate the impact of the plant protection product under field conditions on microbial activitiy.

*Circumstances in which required*

Where at the end of 100 days, measured activity deviates by more than 25 % from the control, in the laboratory testing further testing in the laboratory, under glass and/or in the field may be necessary.

10.8. **Available data from biological primary screening in summary form**

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

11. **SUMMARY AND EVALUATION OF POINTS 9 AND 10**

A summary and evaluation of all data presented in points 9 and 10 should be carried out according to the guidance given by the competent authorities of the Member States concerning the format of such summaries and evaluations. It should include a detailed and critical assessment of those data in the context of relevant evaluative and decision making criteria and guidelines, with particular reference to the risks for the environment and non-target species that may or do arise, and the extent, quality and reliability of the data base. In particular the following issues should be addressed:

— predicting distribution and fate in the environment, and the time courses involved,

— identifying non-target species and populations at risk, and predicting the extent of potential exposure,

— evaluation as to the short- and long-term risks for non-target species — populations, communities, and processes — as appropriate,

— evaluation as to the risk of fish kills, and fatalities in large vertebrates, or terrestrial predators, regardless of effects at population or community level, and

— identification of precautions necessary to avoid or minimize contamination of the environment, and for the protection of non-target species.'