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.