COMMISSION DIRECTIVE 95/36/EC

of 14 July 1995

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 95/35/EC [2], and in particular Article 18 (2) thereof,

Whereas Annexes II and III to Directive 91/414/EEC provide the requirements for the dossier to be submitted by applicants respectively for the inclusion of an active substance in Annex I 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 possible to introduce now more precision with regard to the data requirements concerning fate and behaviour in the environment of the active substance provided for in Annex II, Part A, Section 7;

Whereas it is also possible to introduce now more precision with regard to the data requirements concerning fate and behaviour in the environment of the plant protection product provided for in Section 9 of Part A of Annex III, Part A, Section 9;

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, the section headed '7. Fate and behaviour in the environment' is replaced by Annex I hereto;
2. in Part A of Annex III, the section headed '9. Fate and behaviour in the environment' is replaced by Annex II hereto.

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply, not later than 30 April 1996, with the provisions of this Directive. 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 July 1995.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 14 July 1995.

For the Commission

Ritt BJERREGAARD

Member of the Commission

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[1] OJ No L 230, 19. 8. 1991, p. 1.

[2] See page 6 of this Official Journal.

ANNEX I

'7. **FATE AND BEHAVIOUR IN THE ENVIRONMENT**

Introduction

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

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

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

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

— classify the active substance as to hazard ;

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

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

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

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

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

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

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

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

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

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

7.1. **Fate and behaviour in soil**

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

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

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

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

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

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

  — 4,5 to 5,5

  — 6 to 7, and

  — 8 (approximately).

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

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

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

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

7.1.1. *Route and rate of degradation*

7.1.1.1. Route of degradation

Aim of the tests

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

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

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

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

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

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

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

7.1.1.1.1. Aerobic degradation

Circumstances in which required

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

Test conditions

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

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

— active substance,

— CO_2,

— volatile compounds other than CO_2,

— individual identified transformation products,

— extractable substances not identified, and

— non-extractable residues in soil.

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

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

Test guideline

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

7.1.1.1.2. Supplementary studies

— Anaerobic degradation

Circumstances in which required

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

Test conditions and test guideline

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

— Soil photolysis

Circumstances in which required

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

Test guideline

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

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

7.1.1.2. Rate of degradation

7.1.1.2.1. Laboratory studies

Aim of the tests

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

— Aerobic degradation

Circumstances in which required

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

Test conditions

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

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

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

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

Test guideline

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

— Anaerobic degradation

Circumstances in which required

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

Test conditions

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

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

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

Test guideline

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

7.1.1.2.2. Field studies

— Soil dissipation studies

Aim of the test

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

Circumstances in which required

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