ANNEX II U.K.

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

PART A U.K.

Chemical substances[(1)]

[F1 7. Fate and behaviour in the environment U.K.

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 U.K.

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 U.K.

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[(2)].

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.

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 ^{o}C has to be performed on one of the soils used for the investigation of degradation at 20 ^{o}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 ^{o}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.

Where plant protection products containing the active substance are intended to be used in cold climatic conditions, the tests have to be conducted where DT_{50lab}, determined at 10 ^{o}C and at a moisture content of the soil related to a pF value of 2 to 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 have 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 cowing or planting succeeding crops.

Circumstances in which required

Soil residue studies must be reported where DT_{50lab} is greater than one-third of the period between the 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 have 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 DT_{90f}> 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 U.K.

Aim of the test

The data and information provided, together with other relevant data and information, should be sufficient to establish the absorption 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 trees.

Testo 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 U.K.

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 metabolities, 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 to 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:

— the mobility in soil,

— the potential for leaching to ground water,

— The potential distribution in soil.

Circumstances in which requried

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 groundwater (PEC_{GW}), 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 have to 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 deeper than 25 cm.

— *Field leaching studies*

  Test conditions

  Information on the groundwater 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 should 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 U.K.

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 groundwater.

7.2.1. Route and rate of degradation in aquatic systemes (as far as not covered by point 2.9) U.K.

Aim of the tests

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

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

— 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 groundwater.

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) U.K.

Guidance under development.

7.3. Definition of the residue U.K.

In the light of the chemical composition of residues occurring in soil, water or air, resulting from use, or proposed use, of a plant protection product 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 U.K.

Available monitoring data concerning fate and behaviour of the active substance and relevant metabolites, degradation and reaction products must be reported.]

Textual Amendments

F1 Substituted by 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).

(**1**) Substance within the meaning of the definition of Article 2, point 3.

(**2**) **[**[F1]Society of Environmental Toxicology and Chemistry (SETAC), 1995. Procedures for assessing the environmental fate and ecotoxicity of pesticides, ISBN 90-5607-002-9.**]**

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