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## ANNEX

### PART A

## CHEMICAL ACTIVE SUBSTANCES

### SECTION 7

#### *Fate and behaviour in the environment*

##### 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, particle size distribution and water holding capacity shall be reported.

The microbial biomass of soils used for laboratory degradation studies shall be determined immediately before the commencement and at the end of the study.

The soils used for degradation, adsorption and desorption or mobility studies shall be representative of the range of agricultural soils typical of the various regions of the Union where use exists or is anticipated.

The soils shall fulfil the following conditions:

- they shall cover a range of organic carbon content, particle size distribution and pH<sub>(preferably CaCl<sub>2</sub>)</sub> values, and
- where on the basis of other information, degradation or mobility are expected to be pH dependent, for example solubility and hydrolysis rate (see points 2.7 and 2.8), they shall cover approximately the following pH<sub>(preferably CaCl<sub>2</sub>)</sub> ranges: 5 to 6, 6 to 7 and 7 to 8.

Soils used shall, wherever possible, be freshly sampled. If use of stored soils is unavoidable, storage shall be carried out for a limited time (at the most three months) under defined and reported conditions, which are adequate to maintain soil microbial viability. Soils stored for longer periods of time may only be used for adsorption/desorption studies.

A soil having extreme characteristics with respect to parameters such as particle size distribution, organic carbon content and pH shall not be used.

Field studies shall be carried out in conditions as close to normal agricultural practice as possible on a range of soils and climatic conditions representative of the areas of use. Weather conditions shall be reported in cases where field studies are conducted.

##### 7.1.1. *Route of degradation in soil*

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

- (a) identify, if possible, the relative importance of the types of processes involved (balance between chemical and biological degradation);
- (b) identify the individual components present which at any time account for more than 10 % of the amount of active substance added, including, if possible, non-extractable residues;

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- (c) identify, if possible, the individual components which in at least two sequential measurements, account for more than 5 % of the amount of active substance added;
- (d) identify, if possible, the individual components (> 5 %) for which at the end of the study the maximum of formation is not yet reached;
- (e) identify or characterise, if possible, other individual components present;
- (f) establish the relative proportions of the components present (mass balance); and
- (g) permit the soil residue of concern to which non-target species are or may be exposed, to be defined.

For the purposes of this Section non-extractable residues means chemical species originating from active substances contained in plant protection products used in accordance with good agricultural practice that cannot be extracted by methods which do not significantly change the chemical nature of these residues or the nature of the soil matrix. These non-extractable residues are not considered to include fragments through metabolic pathways leading to natural products.

#### 7.1.1.1. *Aerobic degradation*

##### *Circumstances in which required*

The pathway or pathways of aerobic degradation shall be reported except where the nature and manner of use of plant protection products containing the active substance precludes soil contamination, such as indoor uses on stored products or brush applied wound healing treatments for trees.

##### *Test conditions*

Studies on the degradation pathway or pathways shall be reported for at least one soil. Oxygen levels shall be maintained at levels that do not restrict micro-organisms ability to metabolise aerobically. If there is reason to believe that the route of degradation is dependent on one or more properties of the soil, such as pH or clay content, the route of degradation shall be reported for at least one additional soil for which dependent properties are different.

Results obtained shall 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:

- (a) active substance;
- (b) CO<sub>2</sub>;
- (c) volatile compounds other than CO<sub>2</sub>;
- (d) individual identified transformation products referred to in point 7.1.1;
- (e) extractable substances not identified; and
- (f) non-extractable residues in soil.

The investigation of degradation pathways shall include all possible 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 shall be selected on a case-by-case basis. A justification shall be provided where the compounds involved are not characterised.

The duration of the study shall be at least 120 days, except where after a shorter period the levels of non-extractable residues and CO<sub>2</sub> are such that they can be extrapolated in a reliable way to

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100 days. It shall be longer where this is necessary to establish the degradation pathway of the active substance and its metabolites, breakdown or reaction products.

#### 7.1.1.2. *Anaerobic degradation*

##### *Circumstances in which required*

An anaerobic degradation study shall be submitted unless the applicant shows that exposure of the plant protection products containing the active substance to anaerobic conditions is unlikely to occur for the intended uses.

##### *Test conditions*

Point 7.1.1.1 shall apply as regards test conditions except oxygen levels which shall be minimised as to ensure that micro-organisms metabolise anaerobically.

#### 7.1.1.3. *Soil photolysis*

##### *Circumstances in which required*

A soil photolysis study shall be submitted unless the applicant shows that deposition of the active substance on the soil surface is unlikely to occur or that photolysis is not expected to contribute significantly to the degradation of the active substance in soil for example due to low light absorbance of the active substance.

#### 7.1.2. *Rate of degradation in soil*

##### 7.1.2.1. *Laboratory studies*

Laboratory studies on soil degradation shall provide best possible estimates of the time required for degradation of 50 % and 90 % (DegT50<sub>lab</sub> and DegT90<sub>lab</sub>) of the active substance, its metabolites, breakdown and reaction products under laboratory conditions.

##### 7.1.2.1.1. *Aerobic degradation of the active substance*

###### *Circumstances in which required*

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

###### *Test conditions*

Studies on the rate of aerobic degradation of the active substance shall be reported for three soils in addition to the one required under point 7.1.1.1. Reliable DegT50 and 90 values shall be available for a minimum of four different soils.

The duration of the study shall be at least 120 days. It shall be longer where this is necessary to establish the kinetic formation fractions of the metabolites, breakdown or reaction products. If more than 90 % of the active substance is degraded before the period of 120 days expires, the test duration may be shorter.

In order to assess the influence of temperature on degradation, a calculation with an adequate Q10 factor or an adequate number of additional studies at a range of temperatures shall be performed.

##### 7.1.2.1.2. *Aerobic degradation of metabolites, breakdown and reaction products*

###### *Circumstances in which required*

Aerobic degradation (DegT50 and 90 values) from a minimum of three different soils shall be provided for metabolites, breakdown and reaction products which occur in soil if one of the following conditions is fulfilled:

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- (a) they account for more than 10 % of the amount of active substance added at any time during the studies;
- (b) they account for more than 5 % of the amount of active substance added in at least two sequential measurements;
- (c) the maximum of formation is not reached at the end of the study but accounts for at least 5 % of the active substance at the final measurement;
- (d) all metabolites found in lysimeter studies at annual average concentrations exceed 0.1 µg/L in the leachate.

Studies shall not be required where three DegT50 and 90 values can be reliably determined from the results of the degradation studies where the active substance is applied as test substance.

Test conditions

Test conditions shall be those indicated in Section 7.1.2.1.1 except the test substance applied will be the metabolite, breakdown or reaction product. Studies on metabolites, breakdown and reaction products shall be provided where these are necessary to obtain reliable DegT50 and 90 values for at least three different soils.

#### *7.1.2.1.3. Anaerobic degradation of the active substance*

Circumstances in which required

The rate of anaerobic degradation of the active substance shall be reported where an anaerobic study has to be performed in accordance with point 7.1.1.2.

Test conditions

Anaerobic DegT50 and 90 values for the active substance are needed for the test conditions outlined in point 7.1.1.2.

#### *7.1.2.1.4. Anaerobic degradation of metabolites, breakdown and reaction products*

Circumstances in which required

Anaerobic degradation studies shall be provided for metabolites, breakdown and reaction products which occur in soil if they fulfil one of the following conditions:

- (a) at any time during the studies account for more than 10 % of the amount of active substance added;
- (b) in at least two sequential measurements account for more than 5 % of the amount of active substance added, if feasible;
- (c) at the end of the study the maximum of formation is not yet reached but accounts for at least 5 % of the active substance at the final measurement, if feasible.

The applicant may deviate from such requirement by showing that DegT50 values for metabolites, breakdown and reaction products can be reliably determined from the results of the anaerobic degradation studies with the active substance.

Test conditions

Studies on metabolites, breakdown and reaction products shall be provided for one soil for the test conditions outlined at point 7.1.1.2.

#### *7.1.2.2. Field studies*

##### *7.1.2.2.1. Soil dissipation studies*

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The soil dissipation studies shall provide estimates of the time required for dissipation of 50 % and 90 % ( $DisT50_{field}$  and  $DisT90_{field}$ ) and, if possible, of the time required for degradation of 50 % and 90 % ( $DegT50_{field}$  and  $DegT90_{field}$ ), of the active substance under field conditions. Where relevant, information on metabolites, breakdown and reaction products shall be provided. Circumstances in which required

Such studies shall be conducted for the active substance, its metabolites, breakdown and reaction products if one of the following conditions is fulfilled:

- (a)  $DegT50_{lab}$  for active substance,  $DegT50_{lab}$  or  $DisT50_{lab}$  for metabolites, breakdown and reaction products, in one or more soils determined at 20 °C and at a moisture content of the soil related to a pF value of 2 (suction pressure) is greater than 60 days; or
- (b)  $DegT90_{lab}$  for active substance,  $DegT90_{lab}$  or  $DisT90_{lab}$  for metabolites, breakdown and reaction products, in one or more soils determined at 20 °C and at a moisture content of the soil related to a pF value of 2 (suction pressure) is greater than 200 days.

However, where plant protection products containing the active substance are intended for use in cold climatic conditions, the studies shall be conducted if one of the following conditions is fulfilled:

- (a)  $DegT50_{lab}$  for active substance,  $DegT50_{lab}$  or  $DisT50_{lab}$  for metabolites, breakdown and reaction products, determined at 10 °C and at a moisture content of the soil related to a pF value of 2 (suction pressure) is greater than 90 days; or
- (b)  $DegT90_{lab}$  for active substance,  $DegT90_{lab}$  or  $DisT90_{lab}$  for metabolites, breakdown and reaction products, in one or more soils, determined at 10 °C and at a moisture content of the soil related to a pF value of 2 (suction pressure) is greater than 300 days.

If during field studies metabolites, breakdown and reaction products which are present in laboratory studies are below the lowest technically feasible LOQ, which shall not exceed an equivalent of 5 % (molar basis) of the nominal concentration of active ingredient applied, no additional information on the fate and behaviour of these compounds shall be provided. In those cases, a scientifically valid justification for any discrepancy between laboratory and field appearance of metabolites shall be provided.

Test conditions

Individual studies on a range of representative soils (normally at least four different types at different geographical locations) shall be continued until at least 90% of the amount applied has dissipated from the soil or been transformed to substances that are not the subject of the investigation.

#### 7.1.2.2.2. Soil accumulation studies

Soil accumulation studies shall provide sufficient information to evaluate the possibility of accumulation of residues of the active substance and of metabolites, breakdown and reaction products. The soil accumulation studies shall provide estimates of the time required for dissipation of 50 % and 90 % ( $DisT50_{field}$  and  $DisT90_{field}$ ) and, if possible, shall provide estimates of the time required for degradation of 50 % and 90 % ( $DegT50_{field}$  and  $DegT90_{field}$ ), of the active substance under field conditions.

Circumstances in which required

Where on the basis of soil dissipation studies it is established that  $DisT90_{field}$ , in one or more soils, is greater than 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

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the level at which a plateau concentration is achieved shall be investigated except where reliable information can be provided by a model calculation or another appropriate assessment.

Test conditions

Long-term field studies shall be performed on at least two relevant soils at different geographical locations and involve multiple applications.

In absence of guidance being included in the list referred to under point 6 of the introduction, the type and conditions of the study to be performed shall be discussed with the national competent authorities.

### 7.1.3. *Adsorption and desorption in soil*

#### 7.1.3.1. *Adsorption and desorption*

The information provided, together with other relevant data, shall be sufficient to establish the adsorption coefficient of the active substance and of its metabolites, breakdown and reaction products.

##### 7.1.3.1.1. *Adsorption and desorption of the active substance*

Circumstances in which required

Studies on adsorption and desorption of the active substance shall be provided, except where the nature and manner of use of plant protection products containing the active substance preclude soil contamination such as indoor uses on stored products or brush applied wound healing treatments for trees.

Test conditions

Studies on the active substance shall be reported for at least four soils.

Where the batch equilibrium method cannot be applied due to fast degradation, methods such as studies with short equilibration times, QSPR (Quantitative Structure Property Relationship) or the HPLC (High-Performance Liquid Chromatography) method shall be considered as possible alternatives. Where the batch equilibrium method cannot be applied due to weak adsorption, column leaching studies (see point 7.1.4.1) shall be considered as an alternative.

##### 7.1.3.1.2. *Adsorption and desorption of metabolites, breakdown and reaction products*

Circumstances in which required

Studies on adsorption and desorption shall be provided for all metabolites, breakdown and reaction products, for which in soil degradation studies one of the following conditions is fulfilled:

- (a) they account for more than 10 % of the amount of active substance added, at any time during the studies;
- (b) they account for more than 5 % of the amount of active substance added in at least two sequential measurements;
- (c) the maximum of formation is not reached at the end of the study but accounts for at least 5 % of the active substance at the final measurement;
- (d) all metabolites found in lysimeter studies at annual average concentrations exceeding 0,1 µg/L in the leachate.

Test conditions

Studies on metabolites, breakdown and reaction products shall be provided for at least three soils.

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Where the batch equilibrium method cannot be applied due to fast degradation, methods such as studies with short equilibration times, QSPR or the HPLC method shall be considered as an alternative. Where the batch equilibrium method cannot be applied due to weak adsorption, column leaching studies (see point 7.1.4.1) shall be considered as an alternative.

#### 7.1.3.2. *Aged sorption*

As a higher tier option, information on aged sorption may be provided.

##### *Circumstances in which required*

The need to carry out a study on aged sorption shall be discussed with the national competent authorities.

##### *Test conditions*

In absence of guidance being included in the list referred to under point 6 of the introduction, the type and conditions of the study to be performed shall be discussed with the national competent authorities. The influence on the rate of degradation shall also be considered. Aged sorption data shall be compatible with the model in which those values will be used.

#### 7.1.4. *Mobility in soil*

##### 7.1.4.1. *Column leaching studies*

###### 7.1.4.1.1. *Column leaching of the active substance*

Column leaching studies shall provide sufficient data to evaluate the mobility and leaching potential of the active substance.

##### *Circumstances in which required*

Studies in at least four soils shall be carried out where in the adsorption and desorption studies provided for under point 7.1.2 it is not possible to obtain reliable adsorption coefficient values due to weak adsorption (such as  $K_{oc} < 25$  L/Kg).

###### 7.1.4.1.2. *Column leaching of metabolites, breakdown and reaction products*

The test shall provide sufficient data to evaluate the mobility and leaching potential of metabolites, breakdown and reaction products.

##### *Circumstances in which required*

Studies in at least three soils shall be carried out where in the adsorption and desorption studies provided for under point 7.1.2 it is not possible to obtain reliable adsorption coefficient values due to weak adsorption (such as  $K_{oc} < 25$  L/Kg).

#### 7.1.4.2. *Lysimeter studies*

Lysimeter studies shall be performed, where necessary, to provide information on:

- the mobility in soil,
- the potential for leaching to ground water,
- the potential distribution in soil.

##### *Circumstances in which required*

The decision whether lysimeter studies are to be carried out, as an experimental outdoor study in the framework of a tiered leaching assessment scheme shall take 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 Section 9 of Part A of the Annex to Regulation (EU) No 284/2013. The type and conditions of the study to be performed shall be discussed with the national competent authorities.

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### *Test conditions*

Studies shall cover the realistic worst case situation, and the duration necessary for observation of potential leaching, taking into account the soil type, climatic conditions, the application rate and the frequency and period of application.

Water percolating from soil columns shall be analysed at suitable intervals, while residues in plant material shall be determined at harvest. Residues in the soil profile in at least five layers shall be determined on termination of experimental work. Intermediate sampling shall be avoided, since removal of plants (except for harvesting in accordance with normal agricultural practice) and soil influence the leaching process.

Precipitation, soil and air temperatures shall be recorded at regular intervals, at least on a weekly base.

The depth of the lysimeters shall be at least 100 cm. The soil cores shall be undisturbed. Soil temperatures shall be similar to those pertaining in the field. Where necessary, supplementary irrigation shall be provided to ensure optimal plant growth and to ensure that the quantity of percolation water is similar to that in the regions for which authorisation is sought. When during the study the soil has to be disturbed for agricultural reasons it shall not be disturbed deeper than 25 cm.

#### *7.1.4.3. Field leaching studies*

Field leaching studies shall be performed, where necessary, to provide information on:

- the mobility in soil,
- the potential for leaching to ground water,
- the potential distribution in soil.

#### *Circumstances in which required*

The decision whether field leaching studies are to be carried out, as an experimental outdoor study in the framework of a tiered leaching assessment scheme shall take into account the results of degradation and other mobility studies and the predicted environmental concentrations in groundwater (PEC<sub>GW</sub>), calculated in accordance with the provisions of Section 9 of Part A of the Annex to Regulation (EU) No 284/2013. The type and conditions of the study to be performed shall be discussed with the national competent authorities.

### *Test conditions*

Studies shall 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 shall be analysed at suitable intervals. Residues in the soil profile in at least five layers shall be determined on termination of experimental work. Intermediate sampling of plant and soil material shall be avoided (except for harvesting in accordance with normal agricultural practice), since removal of plants and soil influence the leaching process.

Precipitation, soil and air temperatures shall be recorded at regular intervals (at least on a weekly base).

Information on the groundwater table in the experimental fields shall be submitted. Depending on the experimental design, a detailed hydrological characterisation of the test field shall be carried out. If soil cracking is observed during the study this shall be fully described.

Attention shall be given to the number and the location of water collection devices. The placement of these devices in the soil shall not result in preferential flow paths.



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**Changes and effects yet to be applied to the whole legislation item and associated provisions**

- Signature words omitted by [S.I. 2019/556 reg. 21\(4\)](#)
- Annex Pt. A s. 8 word omitted by [S.I. 2019/556 reg. 21\(5\)\(b\)\(xiv\)](#)
- Annex Pt. A s. 1 point 1.4 word substituted in earlier amending provision S.I. 2019/720, Sch. 2 para. 176(2)(a)(i) by [S.I. 2020/1567 Sch. 2 para. 61](#)
- Annex Pt. A s. 1 point 1.4.1 word substituted in earlier amending provision S.I. 2019/720, Sch. 2 para. 176(2)(b) by [S.I. 2020/1567 Sch. 2 para. 61](#)
- Annex Pt. B s. 9 words omitted by [S.I. 2019/556 reg. 21\(5\)\(c\)\(vi\)](#)
- Art. 1(1) Art. 1 renumbered as Art. 1(1) by [S.I. 2019/556 reg. 21\(2\)\(a\)](#)
- Art. 1(2) inserted by [S.I. 2019/556 reg. 21\(2\)\(b\)](#)