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ANNEX

PART A

CHEMICAL PLANT PROTECTION PRODUCTS

SECTION 9

Fate and behaviour in the environment

Introduction

1. Predicted environmental concentrations (PEC).
 - 1.1. A realistic worst-case estimation shall be made of the expected concentrations of the active substance and metabolites, breakdown and reaction products:
 - which account for more than 10 % of the amount of active substance added,
 - which account for more than 5 % of the amount of active substance added, in at least two sequential measurements,
 - for whose individual components (> 5 %) the maximum of formation is not yet reached at the end of the study, in soil, surface in soil, groundwater, surface water, sediment and air, following use as proposed or already occurring.
 - 1.2. For the purposes of the estimation of such concentrations the following definitions apply:
 - (a) Predicted environmental concentration in soil (PEC_S) : the level of residues in the top layer of the soil and to which non-target soil organisms may be exposed (acute and chronic exposure).
 - (b) Predicted environmental concentration in surface water (PEC_{SW}) : the level of residues, in surface water to which non-target organisms may be exposed (acute and chronic exposure).
 - (c) Predicted environmental concentration in sediment (PEC_{SED}) : the level of residues, in sediment to which non-target benthic organisms may be exposed (acute and chronic exposure).
 - (d) Predicted environmental concentration in groundwater (PEC_{GW}) : the level of residues in groundwater.
 - (e) Predicted environmental concentration in air (PEC_A) : the level of residues in air, to which man, animals and other non-target organisms may be exposed (acute and chronic exposure).
 - 1.3. For the estimation of these concentrations all relevant information on the plant protection product and on the active substance shall be taken into account. Where

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relevant the parameters set out in Section 7 of Part A of the Annex to Regulation (EU) No 283/2013 shall be used.

- 1.4. When models are used for estimation of predicted environmental concentrations they shall:
- make a best-possible estimation of all relevant processes involved taking into account realistic parameters and assumptions,
 - where possible be reliably validated with measurements carried out under circumstances relevant for the use of the model,
 - be relevant to the conditions in the area of use.
- 1.5. The information provided shall, where relevant, include that referred to in Section 7 of Part A of the Annex to Regulation (EU) No 283/2013.
2. For solid plant protection products, treated and coated seeds there shall be an assessment of the risk from dust drift on to non-target species during application or sowing. Until agreed dust dissipation rates are available, then likely exposure levels shall be determined using a range of application techniques, suitable dust measurement methodology and, where appropriate, mitigation measures.

9.1. **Fate and behaviour in soil**

9.1.1. *Rate of degradation in soil*

9.1.1.1. *Laboratory studies*

Laboratory studies on soil degradation shall provide best possible estimates of the time required for degradation of 50 % and 90 % (DegT50_{lab} and DegT90_{lab}) of the active substance under laboratory conditions.

Circumstances in which required

The persistence and behaviour of plant protection products in soil shall be investigated unless it is possible to extrapolate from data obtained on the active substance and metabolites, breakdown and reaction products in accordance with the requirements set out in point 7.1.2.1 of Part A of the Annex to Regulation (EU) No 283/2013.

Where it is not possible to extrapolate from anaerobic incubation data obtained on the active substance and metabolites, breakdown and reaction products in accordance with the requirements set out in point 7.1.2.1 of Part A of the Annex to Regulation (EU) No 283/2013, an anaerobic degradation study shall be submitted unless the applicant shows that exposure of the plant protection product containing the active substance to anaerobic conditions is unlikely to occur for the intended uses.

Test conditions

Studies on the rate of aerobic degradation of the active substance shall be reported for at least four soils. Soil properties shall be comparable to those used for the aerobic studies performed in accordance with point 7.1.1 and 7.1.2.1 of Part A of the Annex to Regulation (EU) No 283/2013. Reliable DegT50 and 90 values shall be available for a minimum of four different soils.

Studies on the rate of anaerobic degradation of the active substance shall be carried out using the same procedure and comparable soil as for the anaerobic study performed in accordance with point 7.1.1.2 of Part A of the Annex to Regulation (EU) No 283/2013.

The kinetic formation fraction and degradation rates of potentially relevant metabolites shall be established, in the studies under both aerobic and anaerobic conditions by extension of the

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study for the active substance, where it is not possible to extrapolate from points 7.1.2.1.2 and 7.1.2.1.4 of Part A of the Annex to Regulation (EU) No 283/2013.

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.

Reliable DegT50 and 90 values for metabolites, breakdown and reaction products shall be provided for at least three soils from the studies under aerobic conditions.

9.1.1.2. *Field studies*

9.1.1.2.1. *Soil dissipation studies*

The soil dissipation studies shall provide best-possible estimates of the time taken for dissipation of 50 % and 90 % (DisT50_{field} and DisT90_{field}) and if possible the time taken 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 reported. Circumstances in which required

The dissipation and behaviour of plant protection products in soil shall be investigated unless it is possible to extrapolate from data obtained on the active substance and metabolites, breakdown and reaction products in accordance with the requirements set out in point 7.1.2.2.1 of Part A of the Annex to Regulation (EU) No 283/2013.

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.

9.1.1.2.2. *Soil accumulation studies*

The tests shall provide sufficient data to evaluate the possibility of accumulation of residues of the active substance and of metabolites, breakdown and reaction products.

Circumstances in which required

Soil accumulation studies shall be reported unless it is possible to extrapolate from data obtained on the active substance and metabolites, breakdown and reaction products in accordance with the requirements set out in point 7.1.2.2.2 of Part A of the Annex to Regulation (EU) No 283/2013.

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.

9.1.2. *Mobility in soil*

The information made available shall provide sufficient data to evaluate the mobility and leaching potential of the active substance and metabolites, breakdown and reaction products.

9.1.2.1. *Laboratory studies*

Circumstances in which required

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The mobility of plant protection products in soil shall be investigated unless it is possible to extrapolate from data obtained in accordance with the requirements set out in points 7.1.2 and 7.1.3.1 of Part A of the Annex to Regulation (EU) No 283/2013.

Test conditions

The same provisions as provided under points 7.1.2 and 7.1.3.1 of Part A of the Annex to Regulation (EU) No 283/2013 apply.

9.1.2.2. *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 mobility studies and the calculated PEC_{GW} . The type of study to be conducted shall be discussed with the national competent authorities.

These studies shall be performed unless it is possible to extrapolate from data obtained on the active substance and metabolites, breakdown and reaction products in accordance with the requirements set out in point 7.1.4.2 of Part A of the Annex to Regulation (EU) No 283/2013.

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.

9.1.2.3. *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

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calculated PEC_{GW} and the results of degradation and mobility studies. The type of study to be conducted shall be discussed with the national competent authorities. These studies shall be performed unless it is possible to extrapolate from data obtained on the active substance and metabolites, breakdown and reaction products in accordance with the requirements set out in point 7.1.4.3 of Part A of the Annex to Regulation (EU) No 283/2013.

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.

9.1.3. *Estimation of concentrations in soil*

PEC_S estimations shall relate both to a single application at the highest rate of application for which authorisation is sought, and to the maximum number at the shortest interval and highest rates of application for which authorisation is sought, and shall be expressed in terms of mg of active substance per kg of dry soil.

The factors which shall be considered in making PEC_S estimations relate to direct and indirect application to soil, drift, run off, and leaching and include processes such as volatilisation, adsorption, hydrolysis, photolysis, aerobic and anaerobic degradation. Appropriate soil layer depths shall be used depending on the application method and soil cultivation. Where ground cover is present at time of application, the impact of crop interception in reducing soil exposure may be included in estimations.

Initial PEC_S , immediately after application, shall be provided for the active substance, metabolites, breakdown and reaction products. Appropriate short-term and long-term PEC_S calculations (time weighted averages) shall be provided for the active substance, metabolites, breakdown and reaction products with respect to data from ecotoxicological studies.

Calculation of plateau concentrations in soil shall be provided where on the basis of soil dissipation studies it is established that $DisT90 > one$ year, and where repeated application is envisaged, whether in the same growing season or in succeeding years.

9.2. **Fate and behaviour in water and sediment**

9.2.1. *Aerobic mineralisation in surface water* *Circumstances in which required*

The persistence and behaviour of plant protection products in open water (freshwater, estuarine and marine) shall be investigated unless it is possible to extrapolate from data obtained on the active substance and metabolites, breakdown and reaction products in accordance with the requirements set out in point 7.2.2.2 of Part A of the Annex to Regulation (EU) No 283/2013.

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The test shall be reported unless the applicant shows that contamination of open water will not occur.

Test conditions

The rate of degradation and the pathway or pathways shall be reported either for a 'pelagic' test system or for a 'suspended sediment' system. Where relevant, additional test systems, which differ with respect to organic carbon content, texture or pH shall be used.

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 in water and, where relevant, sediment as a function of time, as between:

- (a) active substance;
- (b) CO₂;
- (c) volatile compounds other than CO₂;
- (d) individual identified transformation products;
- (e) extractable substances not identified; and
- (f) non-extractable residues in sediment.

The duration of the study shall not exceed 60 days unless the semi-continuous procedure with periodical renewal of the test suspension is applied. However, the period for the batch test may be extended to a maximum of 90 days, if the degradation of the test substance has started within the first 60 days.

9.2.2. *Water/sediment study*

Circumstances in which required

The persistence and behaviour of plant protection products in aquatic systems shall be investigated unless it is possible to extrapolate from data obtained on the active substance and metabolites, breakdown and reaction products in accordance with the requirements set out in point 7.2.2.3 of Part A of the Annex to Regulation (EU) No 283/2013.

The test shall be reported unless the applicant shows that contamination of surface water will not occur.

Test conditions

The degradation pathway or pathways shall be reported for two water/sediment systems. The two sediments selected shall differ with respect to organic carbon content and texture, and where relevant, with respect to pH.

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 in water and sediment as a function of time, as between:

- (a) active substance;
- (b) CO₂;
- (c) volatile compounds other than CO₂;
- (d) individual identified transformation products;
- (e) extractable substances not identified; and

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(f) non-extractable residues in sediment.

The duration of the study shall be at least 100 days. It shall be longer where this is necessary to establish the degradation pathway and water/sediment distribution pattern of the active substance and its metabolites, breakdown and reaction products. If more than 90% of the active substance is degraded before the period of 100 days expires, the test duration may be shorter.

The degradation pattern of potentially relevant metabolites occurring within the water/sediment study shall be established by extension of the study for the active substance, when it is not possible to extrapolate from point 7.2.2.3 of Part A of the Annex to Regulation (EU) No 283/2013.

9.2.3. *Irradiated water/sediment study*

If photochemical degradation is of importance, a water/sediment study under influence of a light/dark regime may additionally be reported.

Test conditions

The type and conditions of the study to be performed shall be discussed with the national competent authorities.

9.2.4. *Estimation of concentrations in groundwater*

The groundwater contamination routes shall be defined taking into account relevant agricultural, plant health, and environmental (including climatic) conditions.

9.2.4.1. *Calculation of concentrations in groundwater*

PEC_{GW} estimations shall relate to the maximum number and highest rates of application, at the shortest interval, and to the time of application for which authorisation is sought.

Relevant EU groundwater models shall be run. Where specific crops and circumstances are relevant, specific scenarios for typical use situations for the regions of use, for the respective crop or other situation of use shall be used. In case the behaviour in soil is dependent on soil parameters, respective parameters on degradation and adsorption in soil (DegT₅₀ and Koc values) reflecting this dependency shall be used. If identified metabolites, breakdown or reaction products are found to occur in concentrations above 0,1 µg/L in the leachate, an assessment of their relevance shall be required.

Suitable estimations (calculations) of predicted environmental concentration in groundwater PEC_{GW}, of active substance shall be submitted, unless it is clearly evident from the data on degradation or adsorption, taking worst case values, that leaching would be negligible under the intended areas of use.

For all metabolites, breakdown or reaction products identified as a part of the residue definition for risk assessment with respect to groundwater (see point 7.4.1 of Part A of the Annex to Regulation (EU) No 283/2013) a PEC_{GW} calculation shall be required for assessing their relevance.

Where identified metabolites, breakdown or reaction products are found to occur in concentrations above 0,1 µg/L in the leachate, an assessment of their relevance shall be required.

9.2.4.2. *Additional field tests*

The need to perform additional field tests and the type and conditions of the tests to be performed shall be discussed with the national competent authorities.

9.2.5. *Estimation of concentrations in surface water and sediment*

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The surface water and sediment contamination routes shall be defined taking into account relevant agricultural, plant health, and environmental (including climatic) conditions. Suitable estimations (calculations) of predicted environmental concentration in surface water PEC_{SW} and sediment PEC_{SED} of active substance shall be submitted, unless the applicant shows that contamination will not occur. PEC_{SW} and PEC_{SED} estimations shall relate to the maximum number and highest rates of application, at the shortest interval, for which authorisation is sought, and be relevant to ditches, ponds, and streams.

Relevant EU surface water modelling tools shall be run. The factors which shall be considered in making PEC_{SW} and PEC_{SED} estimations relate to direct application to water, drift, run-off, discharge via drains and atmospheric deposition, and include processes such as volatilisation, adsorption, advection, hydrolysis, photolysis, biodegradation, sedimentation and re-suspension, and transfer between water and sediment. Initial maximum concentration following an application (global maximum), short-term and long-term PEC_{SW} calculations for relevant water bodies (time weighted averages) shall be provided. Corresponding initial maximum concentration following an application (global maximum), short-term and long-term PEC_{SED} calculations for relevant water bodies (time weighted averages) shall also be provided. These PEC values shall be provided for the active substance and all metabolites, breakdown and reaction products identified as a part of the residue definition for the risk assessment with respect to surface water and sediment. They shall be used to complete risk assessments, through a comparison with the endpoints derived from data from ecotoxicological studies.

Short-term and long-term PEC_{SW} and corresponding short-term and long-term PEC_{SED} calculations for relevant static water bodies (ponds; time weighted averages) and for relevant slow moving water bodies (ditches and streams; time weighted averages), shall be calculated with the aid of a moving time-window. Appropriate time windows with respect to data from ecotoxicological studies shall be applied.

The need to perform additional higher tier tests and the type and conditions of the tests to be performed shall be discussed with the national competent authorities.

9.3. Fate and behaviour in air

9.3.1. Route and rate of degradation in air and transport via air

If the trigger for volatilisation, $V_p = 10^{-5}$ Pa (for volatilisation from plant) or 10^{-4} Pa (for volatilisation from soil) at a temperature of 20 °C is exceeded and (drift) mitigation measures are required to reduce exposure to non-target organisms, model calculations of off-site deposition (PEC) originating from volatilisation shall be provided. The volatilisation term (PEC) shall be added into the relevant risk assessment procedures for PEC_S and PEC_{SW} . The calculation may be refined using data from confined experiments. Where relevant, laboratory, wind-tunnel or field experiments to determine PEC_S from deposition following volatilisation and mitigation measures shall be provided.

9.4. Estimation of concentrations for other routes of exposure

Suitable estimations (calculations) of predicted environmental concentration, of active substance and metabolites, breakdown and reaction products shall be submitted unless the applicant shows that contamination will not occur in case of exposure by other routes, such as:

- deposition of dust containing plant protection products by drift during sowing,
- indirect exposure of surface water via a sewage treatment plant (STP) after application of a plant protection product in storage rooms, and
- amenity use.

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PEC estimations shall relate to the maximum number and highest rates of application, at the shortest interval, for which authorisation is sought, and be relevant to the relevant environmental compartments.

The type of information to be provided shall be discussed with the national competent authorities.

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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. 22\(4\)](#)
- Annex Pt. B s. 11 words omitted by [S.I. 2019/556 reg. 22\(5\)\(c\)\(v\)](#)
- Art. 1(1) Art. 1 renumbered as Art. 1(1) by [S.I. 2019/556 reg. 22\(2\)\(a\)](#)
- Art. 1(2) inserted by [S.I. 2019/556 reg. 22\(2\)\(b\)](#)