

Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (Text with EEA relevance)

Article 1	Data requirements for active substances
Article 2	Repeal
Article 3	Transitional measures as regards procedures concerning active substances
Article 4	Transitional measures as regards procedures concerning plant protection products
Article 5	Entry into force and date of application
	Signature

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## ANNEX

INTRODUCTION

Information to be submitted, its generation and its presentation

1. The information submitted shall meet the following requirements.
  - 1.1. The information shall be sufficient to evaluate the foreseeable risks,...
  - 1.2. Any information on potentially harmful effects of the active substance,...
  - 1.3. Any information on potentially unacceptable effects of the active substance,...
  - 1.4. The information shall include all relevant data from the scientific...
  - 1.5. The information shall include a full and unbiased report of...
  - 1.6. The simultaneous use of the active substance as a biocide...
  - 1.7. Where relevant, the information shall be generated using test methods,...
  - 1.8. The information shall include a full description of the test...
  - 1.9. The information shall include a list of endpoints for the...
  - 1.10. Where relevant, the information shall be generated in accordance with...
  - 1.11. The information on the active substance, taken together with the...
  - 1.12. Where relevant, tests shall be designed and data analysed using...
  - 1.13. Exposure calculations shall refer to scientific methods accepted by the...
  - 1.14. For each section of the data requirements, a summary of...
2. The requirements set out in this Regulation shall represent the...
3. Good laboratory practice (GLP)
  - 3.1. Tests and analyses shall be conducted in accordance with the...
  - 3.2. By way of derogation from point 3.1:
4. Test material
  - 4.1. A detailed description (specification) of the material used shall be...
  - 4.2. Where studies are conducted using an active substance produced in...
  - 4.3. Where studies are conducted using an active substance of different...
  - 4.4. In the case of studies in which dosing extends over...

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- 4.5. When tests shall be conducted using purified active substance ( $\geq$ ...
- 4.6. Where radio-labelled test material is used, radio-labels shall be positioned...
5. Tests on vertebrate animals
  - 5.1. Tests on vertebrate animals shall be undertaken only where no...
  - 5.2. The principles of replacement, reduction and refinement of the use...
  - 5.3. Tests involving the deliberate administration of the active substance or...
  - 5.4. For ethical reasons, study designs shall be carefully considered, taking...
6. For purposes of information and of harmonisation the list of...

## PART A

### CHEMICAL ACTIVE SUBSTANCES

#### SECTION 1

##### Identity of the active substance

- 1.1. Applicant
- 1.2. Producer
- 1.3. Common name proposed or ISO-accepted, and synonyms
- 1.4. Chemical name (IUPAC and CA nomenclature)
- 1.5. Producer's development code numbers
- 1.6. CAS, EC and CIPAC numbers
- 1.7. Molecular and structural formula, molar mass
- 1.8. Method of manufacture (synthesis pathway) of the active substance
- 1.9. Specification of purity of the active substance in g/kg
- 1.10. Identity and content of additives (such as stabilisers) and impurities...
  - 1.10.1. Additives
  - 1.10.2. Significant impurities
  - 1.10.3. Relevant impurities
- 1.11. Analytical profile of batches

#### SECTION 2

##### Physical and chemical properties of the active substance

- 2.1. Melting point and boiling point
- 2.2. Vapour pressure, volatility

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- 2.3. Appearance (physical state, colour)
- 2.4. Spectra (UV/VIS, IR, NMR, MS), molar extinction at relevant wavelengths,...
- 2.5. Solubility in water
- 2.6. Solubility in organic solvents
- 2.7. Partition coefficient n-octanol/water
- 2.8. Dissociation in water
- 2.9. Flammability and self-heating
- 2.10. Flash point
- 2.11. Explosive properties
- 2.12. Surface tension
- 2.13. Oxidising properties
- 2.14. Other studies

### SECTION 3

#### Further information on the active substance

- 3.1. Use of the active substance
- 3.2. Function
- 3.3. Effects on harmful organisms
- 3.4. Field of use envisaged
- 3.5. Harmful organisms controlled and crops or products protected or treated...
- 3.6. Mode of action
- 3.7. Information on the occurrence or possible occurrence of the development...
- 3.8. Methods and precautions concerning handling, storage, transport or fire
- 3.9. Procedures for destruction or decontamination
- 3.10. Emergency measures in case of an accident

### SECTION 4

#### Analytical methods

##### Introduction

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- 4.1. Methods used for the generation of pre-approval data
  - 4.1.1. Methods for the analysis of the active substance as manufactured...
  - 4.1.2. Methods for risk assessment
- 4.2. Methods for post-approval control and monitoring purposes

## SECTION 5

### Toxicological and metabolism studies

#### Introduction

- 1. The relevance of generating toxicity data in animal models with...
  - 2. All potentially adverse effects found during toxicological investigations (including effects...
  - 3. Where available, historical control data shall be provided routinely. The...
  - 4. When preparing a study plan, available data on the test...
  - 5. For all studies actual achieved dose in mg/kg body weight,...
  - 6. The analytical methods to be used in toxicity studies shall...
  - 7. Where, as a result of metabolism or other processes in...
  - 8. The oral route shall always be used if it is...
  - 9. For dose selection, toxicokinetic data such as saturation of absorption...
- 5.1. Studies on absorption, distribution, metabolism and excretion in mammals
    - 5.1.1. Absorption, distribution, metabolism and excretion after exposure by oral route...
    - 5.1.2. Absorption, distribution, metabolism and excretion after exposure by other routes...
  - 5.2. Acute toxicity
    - 5.2.1. Oral
      - Circumstances in which required
    - 5.2.2. Dermal
      - Circumstances in which required
    - 5.2.3. Inhalation
      - Circumstances in which required
    - 5.2.4. Skin irritation
      - Circumstances in which required
    - 5.2.5. Eye irritation
      - Circumstances in which required
    - 5.2.6. Skin sensitisation
      - Circumstances in which required
    - 5.2.7. Phototoxicity
      - Circumstances in which required
  - 5.3. Short-term toxicity
    - 5.3.1. Oral 28-day study
      - Circumstances in which required
    - 5.3.2. Oral 90-day study
      - Circumstances in which required
    - 5.3.3. Other routes
      - Circumstances in which required
  - 5.4. Genotoxicity testing

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- 5.4.1. In vitro studies
  - Circumstances in which required
- 5.4.2. In vivo studies in somatic cells
  - Circumstances in which required
- 5.4.3. In vivo studies in germ cells
  - Circumstances in which required
- 5.5. Long-term toxicity and carcinogenicity
  - Circumstances in which required
  - Test conditions
- 5.6. Reproductive toxicity
  - 5.6.1. Generational studies
    - Circumstances in which required
  - 5.6.2. Developmental toxicity studies
    - Circumstances in which required
    - Test conditions
- 5.7. Neurotoxicity studies
  - 5.7.1. Neurotoxicity studies in rodents
    - Circumstances in which required
  - 5.7.2. Delayed polyneuropathy studies
    - Circumstances in which required
- 5.8. Other toxicological studies
  - 5.8.1. Toxicity studies of metabolites
  - 5.8.2. Supplementary studies on the active substance
  - 5.8.3. Endocrine disrupting properties
- 5.9. Medical data
  - 5.9.1. Medical surveillance on manufacturing plant personnel and monitoring studies
  - 5.9.2. Data collected on humans
  - 5.9.3. Direct observations
  - 5.9.4. Epidemiological studies
  - 5.9.5. Diagnosis of poisoning (determination of active substance, metabolites), specific signs...
  - 5.9.6. Proposed treatment: first aid measures, antidotes, medical treatment
  - 5.9.7. Expected effects of poisoning

## SECTION 6

### Residues in or on treated products, food and feed

- 6.1. Storage stability of residues
  - Circumstances in which required
  - Test conditions
- 6.2. Metabolism, distribution and expression of residues
  - 6.2.1. Plants
    - Circumstances in which required
    - Test conditions
  - 6.2.2. Poultry
    - Circumstances in which required

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- 6.2.3. Lactating ruminants
  - Test conditions
  - Circumstances in which required
  - Test conditions
- 6.2.4. Pigs
  - Circumstances in which required
  - Test conditions
- 6.2.5. Fish
  - Circumstances in which required
- 6.3. Magnitude of residue trials in plants
  - Circumstances in which required
  - Test conditions
- 6.4. Feeding studies
  - Circumstances in which required
  - 6.4.1. Poultry
  - 6.4.2. Ruminants
  - 6.4.3. Pigs
  - 6.4.4. Fish
- 6.5. Effects of processing
  - 6.5.1. Nature of the residue
    - Circumstances in which required
    - Test conditions
  - 6.5.2. Distribution of the residue in inedible peel and pulp
    - Circumstances in which required
    - Test conditions
  - 6.5.3. Magnitude of residues in processed commodities
    - Circumstances in which required
    - Industrial processing
    - Domestic processing
    - Test conditions
- 6.6. Residues in rotational crops
  - 6.6.1. Metabolism in rotational crops
    - Circumstances in which required
    - Test conditions
  - 6.6.2. Magnitude of residues in rotational crops
    - Circumstances in which required
    - Test conditions
- 6.7. Proposed residue definitions and maximum residue levels
  - 6.7.1. Proposed residue definitions
  - 6.7.2. Proposed maximum residue levels (MRLs) and justification of the acceptability...
  - 6.7.3. Proposed maximum residue levels (MRLs) and justification of the acceptability...
- 6.8. Proposed safety intervals
- 6.9. Estimation of the potential and actual exposure through diet and...

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- 6.10. Other studies
  - 6.10.1. Residue level in pollen and bee products

## SECTION 7

### Fate and behaviour in the environment

- 7.1. Fate and behaviour in soil
  - 7.1.1. Route of degradation in soil
    - 7.1.1.1. Aerobic degradation
      - Circumstances in which required
      - Test conditions
    - 7.1.1.2. Anaerobic degradation
      - Circumstances in which required
      - Test conditions
    - 7.1.1.3. Soil photolysis
      - Circumstances in which required
  - 7.1.2. Rate of degradation in soil
    - 7.1.2.1. Laboratory studies
      - 7.1.2.1.1 Aerobic degradation of the active substance
        - Circumstances in which required
        - Test conditions
      - 7.1.2.1.2 Aerobic degradation of metabolites, breakdown and reaction products
        - Circumstances in which required
        - Test conditions
      - 7.1.2.1.3 Anaerobic degradation of the active substance
        - Circumstances in which required
        - Test conditions
      - 7.1.2.1.4 Anaerobic degradation of metabolites, breakdown and reaction products
        - Circumstances in which required
        - Test conditions
    - 7.1.2.2. Field studies
      - 7.1.2.2.1 Soil dissipation studies
        - Circumstances in which required
        - Test conditions
      - 7.1.2.2.2 Soil accumulation studies
        - Circumstances in which required
        - Test conditions
  - 7.1.3. Adsorption and desorption in soil
    - 7.1.3.1. Adsorption and desorption
      - 7.1.3.1.1 Adsorption and desorption of the active substance
        - Circumstances in which required
        - Test conditions
      - 7.1.3.1.2 Adsorption and desorption of metabolites, breakdown and reaction products
        - Circumstances in which required
        - Test conditions
    - 7.1.3.2. Aged sorption
      - Circumstances in which required
      - Test conditions
  - 7.1.4. Mobility in soil

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- 7.1.4.1. Column leaching studies
  - 7.1.4.1.1. Column leaching of the active substance
    - Circumstances in which required
  - 7.1.4.1.2. Column leaching of metabolites, breakdown and reaction products
    - Circumstances in which required
- 7.1.4.2. Lysimeter studies
  - Circumstances in which required
  - Test conditions
- 7.1.4.3. Field leaching studies
  - Circumstances in which required
  - Test conditions
- 7.2. Fate and behaviour in water and sediment
  - 7.2.1. Route and rate of degradation in aquatic systems (chemical and...
    - 7.2.1.1. Hydrolytic degradation
      - Circumstances in which required
      - Test conditions
    - 7.2.1.2. Direct photochemical degradation
      - Circumstances in which required
      - Test conditions
    - 7.2.1.3. Indirect photochemical degradation
      - Circumstances in which required
      - Test conditions
  - 7.2.2. Route and rate of biological degradation in aquatic systems
    - 7.2.2.1. 'Ready biodegradability'
      - Circumstances in which required
    - 7.2.2.2. Aerobic mineralisation in surface water
      - Circumstances in which required
      - Test conditions
    - 7.2.2.3. Water/sediment study
      - Circumstances in which required
      - Test conditions
    - 7.2.2.4. Irradiated water/sediment study
      - Circumstances in which required
      - Test conditions
  - 7.2.3. Degradation in the saturated zone
- 7.3. Fate and behaviour in air
  - 7.3.1. Route and rate of degradation in air
  - 7.3.2. Transport via air
    - Circumstances in which required
  - 7.3.3. Local and global effects
- 7.4. Definition of the residue
  - 7.4.1. Definition of the residue for risk assessment
  - 7.4.2. Definition of the residue for monitoring
- 7.5. Monitoring data



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## SECTION 8

### Ecotoxicological studies

#### Introduction

1. All available biological data and information which is relevant to...
  2. The ecotoxicological assessment shall be based on the risk that...
  3. It may be necessary to conduct separate studies for metabolites,...
  4. In the case of certain study types, the use of...
  5. The potential impact of the active substance on biodiversity and...
  6. For those guidelines which allow for the study to be...
  7. All of the aquatic toxicity data shall be used when...
  8. In order to facilitate the assessment of the significance of...
  9. Higher tier studies shall be designed and data analysed using...
  10. Pending the validation and adoption of new studies and of...
- 
- 8.1. Effects on birds and other terrestrial vertebrates
    - 8.1.1. Effects on birds
      - 8.1.1.1. Acute oral toxicity to birds  
Circumstances in which required  
Test conditions
      - 8.1.1.2. Short-term dietary toxicity to birds  
Circumstances in which required  
Test conditions
      - 8.1.1.3. Sub-chronic and reproductive toxicity to birds  
Circumstances in which required  
Test conditions
    - 8.1.2. Effects on terrestrial vertebrates other than birds
      - 8.1.2.1. Acute oral toxicity to mammals  
Circumstances in which required
      - 8.1.2.2. Long-term and reproductive toxicity to mammals  
Circumstances in which required
    - 8.1.3. Active substance bioconcentration in prey of birds and mammals
    - 8.1.4. Effects on terrestrial vertebrate wildlife (birds, mammals, reptiles and amphibians)...
    - 8.1.5. Endocrine disrupting properties
  - 8.2. Effects on aquatic organisms
    - 8.2.1. Acute toxicity to fish  
Circumstances in which required  
Test conditions
    - 8.2.2. Long-term and chronic toxicity to fish  
Circumstances in which required
      - 8.2.2.1. Fish early life stage toxicity test
      - 8.2.2.2. Fish full life cycle test  
Test conditions
      - 8.2.2.3. Bioconcentration in fish  
Circumstances in which required
    - 8.2.3. Endocrine disrupting properties
    - 8.2.4. Acute toxicity to aquatic invertebrates  
Circumstances in which required
      - 8.2.4.1. Acute toxicity to *Daphnia magna*  
Test conditions

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- 8.2.4.2. Acute toxicity to an additional aquatic invertebrate species
  - Test conditions
- 8.2.5. Long-term and chronic toxicity to aquatic invertebrates
  - Circumstances in which required
  - 8.2.5.1. Reproductive and development toxicity to *Daphnia magna*
  - 8.2.5.2. Reproductive and development toxicity to an additional aquatic invertebrate species...
  - 8.2.5.3. Development and emergence in *Chironomus riparius*
    - Test conditions
  - 8.2.5.4. Sediment dwelling organisms
    - Test conditions
- 8.2.6. Effects on algal growth
  - Circumstances in which required
  - 8.2.6.1. Effects on growth of green algae
    - Test conditions
  - 8.2.6.2. Effects on growth of an additional algal species
    - Test conditions
- 8.2.7. Effects on aquatic macrophytes
  - Circumstances in which required
  - Test conditions
- 8.2.8. Further testing on aquatic organisms
  - Circumstances in which required
  - Test conditions
- 8.3. Effect on arthropods
  - 8.3.1. Effects on bees
    - 8.3.1.1. Acute toxicity to bees
      - 8.3.1.1.1Acute oral toxicity
        - Test conditions
      - 8.3.1.1.2Acute contact toxicity
        - Test conditions
    - 8.3.1.2. Chronic toxicity to bees
      - Circumstances in which required
      - Test conditions
    - 8.3.1.3. Effects on honeybee development and other honeybee life stages
      - Circumstances in which required
    - 8.3.1.4. Sub-lethal effects
  - 8.3.2. Effects on non-target arthropods other than bees
    - Circumstances in which required
    - 8.3.2.1. Effects on *Aphidius rhopalosiphii*
      - Test conditions
    - 8.3.2.2. Effects on *Typhlodromus pyri*
      - Test conditions
- 8.4. Effects on non-target soil meso- and macrofauna
  - 8.4.1. Earthworm — sub-lethal effects
    - Circumstances in which required
    - Test conditions
  - 8.4.2. Effects on non-target soil meso- and macrofauna (other than earthworms)...
    - Circumstances in which required
    - 8.4.2.1. Species level testing
      - Test conditions

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- 8.5. Effects on soil nitrogen transformation
  - Circumstances in which required
  - Test conditions
- 8.6. Effects on terrestrial non-target higher plants
  - 8.6.1. Summary of screening data
    - Circumstances in which required
    - Test conditions
  - 8.6.2. Testing on non-target plants
    - Circumstances in which required
    - Test conditions
- 8.7. Effects on other terrestrial organisms (flora and fauna)
- 8.8. Effects on biological methods for sewage treatment
  - Circumstances in which required
- 8.9. Monitoring data

## SECTION 9

Literature data

## SECTION 10

Classification and labelling

## PART B

### MICRO-ORGANISMS INCLUDING VIRUSES

#### Introduction

- (i) Active substances are defined in Article 2(2) of Regulation (EC)...
- (ii) For all micro-organisms that are subject to application all available...
- (iii) Pending the acceptance of specific guidelines at international level, the...
- (iv) Where testing is done, a detailed description (specification) of the...
- (v) Where the micro-organism has been genetically modified, a copy of...
- (vi) Where relevant, data shall be analysed using appropriate statistical methods....
- (vii) In the case of studies in which dosing extends over...
- (viii) If the plant protection action is known to be due...

#### 1. IDENTITY OF THE MICRO-ORGANISM

- 1.1. Applicant
- 1.2. Producer
- 1.3. Name and species description, strain characterisation
  - (i) The micro-organism should be deposited at an internationally recognised culture...
  - (ii) Each micro-organism that is subject to the application shall be...
  - (iii) Best available technology should be used to identify and characterise...
  - (iv) Common name or alternative and superseded names and code names...
  - (v) Relationships to known pathogens shall be indicated.
- 1.4. Specification of the material used for manufacturing of formulated products...

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- 1.4.1. Content of the micro-organism
    - 1.4.2. Identity and content of impurities, additives, contaminating micro-organisms
    - 1.4.3. Analytical profile of batches
2. **BIOLOGICAL PROPERTIES OF THE MICRO-ORGANISM**
  - 2.1. History of the micro-organism and its uses. Natural occurrence and...
    - 2.1.1. Historical background
    - 2.1.2. Origin and natural occurrence
  - 2.2. Information on target organism(s)
    - 2.2.1. Description of the target organism(s)
    - 2.2.2. Mode of action
  - 2.3. Host specificity range and effects on species other than the...
  - 2.4. Development stages/life cycle of the micro-organism
  - 2.5. Infectiveness, dispersal and colonisation ability
  - 2.6. Relationships to known plant or animal or human pathogens
  - 2.7. Genetic stability and factors affecting it
  - 2.8. Information on the production of metabolites (especially toxins)
  - 2.9. Antibiotics and other anti-microbial agents
3. **FURTHER INFORMATION ON THE MICRO-ORGANISM**

Introduction

  - (i) The information provided must describe the intended purposes for which...
  - (ii) The information provided must specify the normal methods and precautions...
  - (iii) The studies, data and information submitted, must demonstrate the suitability...
  - (iv) The information and data referred to are required for each...
  - 3.1. Function
  - 3.2. Field of use envisaged
  - 3.3. Crops or products protected or treated
  - 3.4. Method of production and quality control
  - 3.5. Information on the occurrence or possible occurrence of the development...
  - 3.6. Methods to prevent loss of virulence of seed stock of...
  - 3.7. Recommended methods and precautions concerning handling, storage, transport or fire...
  - 3.8. Procedures for destruction or decontamination
  - 3.9. Measures in case of an accident
4. **ANALYTICAL METHODS**

Introduction

  - 4.1. Methods for the analysis of the micro-organism as manufactured
  - 4.2. Methods to determine and quantify residues (viable or non-viable)
5. **EFFECTS ON HUMAN HEALTH**

Introduction

  - (i) Available information based on the properties of the micro-organism and...
  - (ii) The information provided, taken together with that provided for one...
  - (iii) All effects found during investigations shall be reported. Investigations which...
  - (iv) For all studies actual achieved dose in colony forming units...

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- (v) Evaluation of the micro-organism shall be carried out in a...
    - TIER I
      - 5.1. Basic information
        - 5.1.1. Medical data
        - 5.1.2. Medical surveillance on manufacturing plant personnel
        - 5.1.3. Sensitisation/allergenicity observations, if appropriate
        - 5.1.4. Direct observation, e.g. clinical cases
      - 5.2. Basic studies
        - 5.2.1. Sensitisation
          - Aim of the test
          - Circumstances in which required
        - 5.2.2. Acute toxicity, pathogenicity and infectiveness
          - 5.2.2.1. Acute oral toxicity, pathogenicity and infectiveness
            - Circumstances in which required
          - 5.2.2.2. Acute inhalation toxicity, pathogenicity and infectiveness
            - Circumstances in which required
          - 5.2.2.3. Intraperitoneal/subcutaneous single dose
            - Circumstances in which required
        - 5.2.3. Genotoxicity testing
          - Circumstances in which required
          - Aim of the test
          - Test conditions
          - 5.2.3.1. In vitro studies
            - Circumstances in which required
        - 5.2.4. Cell culture study
        - 5.2.5. Information on short-term toxicity and pathogenicity
          - Aim of the test
          - Circumstances in which required
          - 5.2.5.1. Health effects after repeated inhalatory exposure
            - Circumstances in which required
        - 5.2.6. Proposed treatment: first aid measures, medical treatment
    - TIER II
      - 5.3. Specific toxicity, pathogenicity and infectiveness studies
      - 5.4. In vivo studies in somatic cells
        - Circumstances in which required
      - 5.5. Genotoxicity — In vivo studies in germ cells
        - Aim of the test and test conditions
        - Circumstances in which required
  - 5.6. Summary of mammalian toxicity, pathogenicity and infectiveness and overall evaluation...
6. RESIDUES IN OR ON TREATED PRODUCTS, FOOD AND FEED
  - Introduction
    - (i) The information provided, taken together with that for one or...
    - (ii) In addition, the information provided must be sufficient to:
    - (iii) For the evaluation of risk arising from residues, experimental data...
  - 6.1. Persistence and likelihood of multiplication in or on crops, feedingstuffs...
  - 6.2. Further information required
    - 6.2.1. Non-viable residues
    - 6.2.2. Viable residues
  - 6.3. Summary and evaluation of residue behaviour resulting from data submitted...

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## 7. FATE AND BEHAVIOUR IN THE ENVIRONMENT

### Introduction

- (i) Information on the origin, the properties, and the survival of...
- (ii) The information provided, taken together with other relevant information, and...
- (iii) In particular, the information provided shall be sufficient to:
- (iv) Any relevant metabolites (i.e. of concern for human health and/or...
- (v) Available information on the relationship with naturally occurring wild type...
- (vi) Before performing studies as referred to below, the applicant shall...

### 7.1. Persistence and multiplication

- 7.1.1. Soil
- 7.1.2. Water
- 7.1.3. Air

### 7.2. Mobility

## 8. EFFECTS ON NON-TARGET ORGANISMS

### Introduction

- (i) The information on identity, biological properties and further information in...
- (ii) The choice of the appropriate non-target organisms for testing of...
- (iii) The information provided, taken together with that for one or...
- (iv) In particular, the information provided for the micro-organism, together with...
- (v) There is a need to report all potentially adverse effects...
- (vi) For all studies, average achieved dose in cfu/kg body weight...
- (vii) It may be necessary to conduct separate studies for relevant...
- (viii) In order to facilitate the assessment of the significance of...
- (ix) Tests must be performed unless it can be justified that...

### 8.1. Effects on birds

#### Aim of the test

### 8.2. Effects on aquatic organisms

#### Aim of the test

#### 8.2.1. Effects on fish

##### Aim of the test

#### 8.2.2. Effects on freshwater invertebrates

##### Aim of the test

#### 8.2.3. Effects on algae growth

##### Aim of the test

#### 8.2.4. Effects on plants other than algae

##### Aim of the test

### 8.3. Effects on bees

#### Aim of the test

### 8.4. Effects on arthropods other than bees

#### Aim of the test

### 8.5. Effects on earthworms

#### Aim of the test

### 8.6. Effects on non-target soil micro-organisms

### 8.7. Additional studies

## 9. SUMMARY AND EVALUATION OF ENVIRONMENTAL IMPACT

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**Changes to legislation:** *There are outstanding changes not yet made to Commission Regulation (EU) No 283/2013. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) [View outstanding changes](#)*

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- (1) OJ L 309, 24.11.2009, p. 1.
- (2) OJ L 155, 11.6.2011, p. 1.
- (3) OJ L 230, 19.8.1991, p. 1.

**Changes to legislation:**

There are outstanding changes not yet made to Commission Regulation (EU) No 283/2013. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.

[View outstanding changes](#)

**Changes and effects yet to be applied to :**

- Annex Pt. A Section 1 point 1.4.1 inserted by [S.I. 2019/720 Sch. 2 para. 176\(2\)\(b\)](#)
- Annex word omitted by [S.I. 2019/556 reg. 21\(5\)\(a\)\(i\)](#)
- Annex Pt. A point 6.10.1 word omitted by [S.I. 2019/556 reg. 21\(5\)\(b\)\(x\)](#)
- Annex Pt. A point 7.1.4.3 word omitted by [S.I. 2019/556 reg. 21\(5\)\(b\)\(xiii\)](#)
- Annex Pt. A point 7.2.2.4 word omitted by [S.I. 2019/556 reg. 21\(5\)\(b\)\(xiii\)](#)
- Annex Pt. A point 7.2.3 word omitted by [S.I. 2019/556 reg. 21\(5\)\(b\)\(xiii\)](#)
- Annex Pt. A point 7.3.2 word omitted by [S.I. 2019/556 reg. 21\(5\)\(b\)\(xiii\)](#)
- Annex Pt. A point 8.1.5 word omitted by [S.I. 2019/556 reg. 21\(5\)\(b\)\(xv\)\(bb\)](#)
- Annex Pt. A point 8.2 word omitted by [S.I. 2019/556 reg. 21\(5\)\(b\)\(xvi\)](#)
- Annex Pt. A point 8.2.2.2 word omitted by [S.I. 2019/556 reg. 21\(5\)\(b\)\(xvi\)](#)
- Annex Pt. A point 8.2.3 word omitted by [S.I. 2019/556 reg. 21\(5\)\(b\)\(xvii\)\(bb\)](#)
- Annex Pt. A point 8.2.7 word omitted by [S.I. 2019/556 reg. 21\(5\)\(b\)\(xviii\)](#)
- Annex Pt. A point 8.2.8 word omitted by [S.I. 2019/556 reg. 21\(5\)\(b\)\(xviii\)](#)
- Annex Pt. A point 8.3.2 word omitted by [S.I. 2019/556 reg. 21\(5\)\(b\)\(xviii\)](#)
- Annex Pt. A point 8.4.2 word omitted by [S.I. 2019/556 reg. 21\(5\)\(b\)\(xviii\)](#)
- Annex Pt. A point 5.8.3 word substituted by [S.I. 2019/556 reg. 21\(5\)\(b\)\(v\)](#)
- Annex Pt. A point 6.5.3 word substituted by [S.I. 2019/556 reg. 21\(5\)\(b\)\(viii\)](#)
- Annex Pt. A point 8.1.5 word substituted by [S.I. 2019/556 reg. 21\(5\)\(b\)\(xv\)\(aa\)](#)
- Annex Pt. A point 8.2.3 word substituted by [S.I. 2019/556 reg. 21\(5\)\(b\)\(xvii\)\(aa\)](#)
- Annex Pt. A Section 1 point 1.4 word substituted by [S.I. 2019/720 Sch. 2 para. 176\(2\)\(a\)\(ii\)](#)
- Annex words inserted by [S.I. 2019/556 reg. 21\(5\)\(a\)\(v\)](#)
- Annex Pt. A point 5.9 words inserted by [S.I. 2019/556 reg. 21\(5\)\(b\)\(vi\)](#)
- Annex Pt. B point 5.1.1 words inserted by [S.I. 2019/556 reg. 21\(5\)\(c\)\(iii\)](#)
- Annex words omitted by [S.I. 2019/556 reg. 21\(5\)\(a\)\(iv\)](#)
- Annex words omitted by [S.I. 2019/556 reg. 21\(5\)\(a\)\(vii\)](#)
- Annex Pt. A point 1.5 words omitted by [S.I. 2019/556 reg. 21\(5\)\(b\)\(ii\)](#)
- Annex Pt. A point 6.3 words omitted by [S.I. 2019/556 reg. 21\(5\)\(b\)\(vii\)\(bb\)](#)
- Annex Pt. A point 6.3 words omitted by [S.I. 2019/556 reg. 21\(5\)\(b\)\(vii\)\(cc\)](#)
- Annex Pt. A point 6.3 words omitted by [S.I. 2019/556 reg. 21\(5\)\(b\)\(vii\)\(dd\)](#)
- Annex Pt. A point 6.3 words omitted by [S.I. 2019/556 reg. 21\(5\)\(b\)\(vii\)\(ff\)](#)
- Annex Pt. A point 7.1.2.2.2 words omitted by [S.I. 2019/556 reg. 21\(5\)\(b\)\(xii\)\(aa\)](#)
- Annex Pt. A point 7.1.3.2 words omitted by [S.I. 2019/556 reg. 21\(5\)\(b\)\(xii\)\(aa\)](#)
- Annex Pt. A point 7.1.2.2.2 words omitted by [S.I. 2019/556 reg. 21\(5\)\(b\)\(xii\)\(bb\)](#)
- Annex Pt. A point 7.1.3.2 words omitted by [S.I. 2019/556 reg. 21\(5\)\(b\)\(xii\)\(bb\)](#)
- Annex Pt. B point 7.1.1 words omitted by [S.I. 2019/556 reg. 21\(5\)\(c\)\(iv\)](#)
- Annex words substituted by [S.I. 2019/556 reg. 21\(5\)\(a\)\(ii\)](#)
- Annex words substituted by [S.I. 2019/556 reg. 21\(5\)\(a\)\(iii\)](#)
- Annex words substituted by [S.I. 2019/556 reg. 21\(5\)\(a\)\(vi\)](#)
- Annex Pt. A point 1.2 words substituted by [S.I. 2019/556 reg. 21\(5\)\(b\)\(i\)](#)
- Annex Pt. A point 3.9 words substituted by [S.I. 2019/556 reg. 21\(5\)\(b\)\(iii\)](#)
- Annex Pt. A point 4.2 words substituted by [S.I. 2019/556 reg. 21\(5\)\(b\)\(iv\)](#)
- Annex Pt. A point 6.6.2 words substituted by [S.I. 2019/556 reg. 21\(5\)\(b\)\(ix\)\(aa\)](#)
- Annex Pt. A point 6.6.2 words substituted by [S.I. 2019/556 reg. 21\(5\)\(b\)\(ix\)\(bb\)](#)
- Annex Pt. A point 6.6.2 words substituted by [S.I. 2019/556 reg. 21\(5\)\(b\)\(ix\)\(cc\)](#)
- Annex Pt. A point 6.3 words substituted by [S.I. 2019/556 reg. 21\(5\)\(b\)\(vii\)\(aa\)](#)
- Annex Pt. A point 6.3 words substituted by [S.I. 2019/556 reg. 21\(5\)\(b\)\(vii\)\(ee\)](#)
- Annex Pt. A point 7.1 words substituted by [S.I. 2019/556 reg. 21\(5\)\(b\)\(xi\)](#)



- Annex Pt. B point 1.1 words substituted by [S.I. 2019/556 reg. 21\(5\)\(c\)\(i\)](#) (This amendment not applied to legislation.gov.uk. Reg. 21(5)(c)(i) substituted immediately before IP completion day by [S.I. 2020/1376, regs. 1\(4\), 3\(17\)\(b\)](#))
- Annex Pt. B point 1.2 words substituted by [S.I. 2019/556 reg. 21\(5\)\(c\)\(ii\)](#)
- Annex Pt. B point 1.4.1 words substituted by [S.I. 2019/556 reg. 21\(5\)\(c\)\(ii\)](#)
- Annex Pt. B point 8.6 words substituted by [S.I. 2019/556 reg. 21\(5\)\(c\)\(v\)](#)
- Annex Pt. A Section 1 point 1.4 words substituted by [S.I. 2019/720 Sch. 2 para. 176\(2\)\(a\)\(i\)](#)
- Annex Pt. B point 1.1 words substituted by [S.I. 2019/556, reg. 21\(5\)\(c\)\(i\)](#) (as substituted) by [S.I. 2020/1376 reg. 3\(17\)\(b\)](#)
- Annex Pt. A point 6.6.2 words substituted in earlier amending provision [S.I. 2019/556, reg. 21\(5\)\(b\)\(ix\)\(aa\)](#) by [S.I. 2020/1376 reg. 3\(17\)\(a\)\(ii\)](#)
- Annex Pt. A point 6.6.2 words substituted in earlier amending provision [S.I. 2019/556, reg. 21\(5\)\(b\)\(ix\)\(bb\)](#) by [S.I. 2020/1376 reg. 3\(17\)\(a\)\(ii\)](#)
- Annex Pt. A point 6.3 words substituted in earlier amending provision [S.I. 2019/556, reg. 21\(5\)\(b\)\(vii\)\(ee\)](#) by [S.I. 2020/1376 reg. 3\(17\)\(a\)\(i\)](#)
- Annex Pt. A point 7.1 words substituted in earlier amending provision [S.I. 2019/556, reg. 21\(5\)\(b\)\(xi\)](#) by [S.I. 2020/1376 reg. 3\(17\)\(a\)\(iii\)\(aa\)](#)
- Annex Pt. A point 7.1 words substituted in earlier amending provision [S.I. 2019/556, reg. 21\(5\)\(b\)\(xi\)](#) by [S.I. 2020/1376 reg. 3\(17\)\(a\)\(iii\)\(bb\)](#)
- Art. 2-5 omitted by [S.I. 2019/556 reg. 21\(3\)](#)

**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\(2\)\(b\)](#)