Commission Regulation (EU) No 545/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for plant protection products (Text with EEA relevance) (repealed)

COMMISSION REGULATION (EU) No 545/2011

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implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for plant protection products

(Text with EEA relevance) (repealed)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC[(1)], and in particular the first sentence of Article 8(4) thereof,

After consulting the Standing Committee on the Food Chain and Animal Health,

Whereas:

(1) In accordance with Regulation (EC) No 1107/2009 the dossier to be submitted for the approval of an active substance or for the authorisation of a plant protection product is to fulfil the same requirements in respect of the data requirements for the plant protection product as under the previously applicable rules which are set out in Annexes II and III to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market[(2)].

(2) It is therefore necessary for the implementation of Regulation (EC) No 1107/2009 to adopt a regulation containing those data requirements for the plant protection product. Such a regulation is not to include any substantial modification,

HAS ADOPTED THIS REGULATION:

Article 1

The data requirements for the plant protection product provided for in Article 8(1)(c) of Regulation (EC) No 1107/2009 shall be as set out in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

It shall apply from 14 June 2011.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 10 June 2011.

For the Commission

The President

José Manuel BARROSO

ANNEX

DATA REQUIREMENTS FOR PLANT PROTECTION PRODUCTS, AS PROVIDED FOR IN ARTICLE 8(1)(c) OF REGULATION (EC) No 1107/2009

INTRODUCTION

1. The information required shall:

1.1. include a technical dossier supplying the information necessary for evaluating efficacy and the foreseeable risks, whether immediate or delayed, which the plant protection product may entail for humans, animals and the environment and containing at least the information and results of the studies referred to below;

1.2. where relevant, be generated using test guidelines, in accordance with the latest adopted version, referred to or described in this Annex; in the case of studies initiated before the entry into force of the modification of this Annex, the information shall be generated using suitable internationally or nationally validated test guidelines or, in the absence thereof, test guidelines accepted by the competent authority;

1.3. in the event of a test guideline being inappropriate or not described, or where another one than those referred to in this Annex has been used, include a justification, which is acceptable to the competent authority for the guidelines used. In particular, when reference is made in this Annex to a method laid down in Commission Regulation (EC) No 440/2008[(3)] which consists in the transposal of a method developed by an international organisation (e.g. OECD), Member States may accept that the required information is generated in accordance with the latest version of that method if at the initiation of the studies the method under Regulation (EC) No 440/2008 has not yet been updated;

1.4. include when required by the competent authority, a full description of test guidelines used, except if they are referred to or described in this Annex, and a full description of any deviations from them including a justification, which is acceptable to the competent authority, for these deviations;

1.5. include a full and unbiased report of the studies conducted as well as a full description of them or a justification, which is acceptable to the competent authority where:
- — particular data and information which would not be necessary owing to the nature of the product or its proposed uses, are not provided, or
- — it is not scientifically necessary, or technically possible to supply information and data;

1.6. where relevant, have been generated in accordance with the requirements of Council Directive 86/609/EEC[(4)].

2. **Tests and analyses**

2.1. Tests and analyses must be conducted in accordance with the principles laid down in Directive 2004/10/EC of the European Parliament and of the Council[(5)] where testing is done to obtain data on the properties and/or safety with respect to human or animal health or the environment.

2.2. Tests and analyses, required under points 6.2 to 6.7 of this Annex, shall be conducted by official or officially recognised testing facilities or organisations which satisfy at least the following requirements:

— have at their disposal sufficient scientific and technical staff, having the necessary education, training, technical knowledge and experience for their assigned functions,

— have at their disposal suitable items of equipment required for correct performance of the tests and measurements which it claims to be competent to carry out. This equipment shall be properly maintained and calibrated where appropriate before being put into service and thereafter in accordance with an established programme,

— have at their disposal appropriate experimental fields and, where necessary glasshouses, growth cabinets or storage rooms. The environment in which the tests are undertaken shall not invalidate its results or adversely effect the required accuracy of measurement,

— make available to all relevant personnel operating procedures and protocols used for the trials,

— make available, where requested by the competent authority, prior to the commencement of a test, detailed information on it, containing at least its location and the plant protection products included in it,

— ensure that the quality of the work performed is appropriate to its type, range, volume and intended purpose,

— maintain records of all original observations, calculations and derived data, calibration records and the final test report as long as the product concerned is authorised in the Union.

2.3. Officially recognised testing facilities and organisations, and, where requested, official facilities and organisations shall:

— report to the relevant national authority all detailed information necessary to demonstrate that they can satisfy the requirements provided for in point 2.2,

— accept at any time the inspections, which each Member State shall regularly organise on its territory in order to verify the compliance with the requirement as laid down in point 2.2.

2.4. By way of derogation from point 2.1, Member States may apply points 2.2 and 2.3, by extension, to tests and analyses performed on their territory in order to obtain data on the properties and/or safety of the preparations with respect to honey-bees and beneficial arthropods other than bees and actually started on or before 31 December 1999.

2.5. By way of derogation from point 2.1, Member States may apply points 2.2 and 2.3, by extension, to supervised residue trials performed on their territory in accordance with Section 8 ‘Residues in or on treated products, food and feed’ with plant protection products containing active substances already on the market on the 26 July 1993 and actually started on or before 31 December 1997.

2.6. By way of derogation from point 2.1, for active substances consisting of micro-organisms or viruses, tests and analyses done to obtain data on the properties and/or safety with respect to other aspects than human health, may have been conducted by official or officially recognised testing facilities or organisations which satisfy at least the requirements under points 2.2 and 2.3 of the introduction to this Annex.

3. The information required shall include the proposed classification and labelling of the plant protection product in accordance with Directive 1999/45/EC of the European Parliament and of the Council[6] or with Regulation (EC) No 1272/2008 of the European Parliament and of the Council[7].

4. In individual cases it may be necessary to require certain information as provided for in the Annex to Commission Regulation (EU) No 544/2011[8], Part A, for co-formulants. Before such information will be required and before possible new studies have to be performed, all information on the co-formulant, made available to the competent authority, will be considered, in particular when:

— the use of the co-formulant is permitted in food, animal feeding stuffs, medicines or cosmetics in accordance with EU legislation, or

— a safety data sheet is provided for the co-formulant in accordance with Article 31 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council[9].

PART A

CHEMICAL PREPARATIONS

1. Identity of the plant protection product

The information provided, taken together with that provided for the active substance(s), must be sufficient to precisely identify preparations and define them in terms of their specification and nature. The information and data referred to, unless otherwise specified, are required for all plant protection products.

1.1. *Applicant (name and address, etc.)*

The name and address of the applicant must be provided as must the name, position, telephone and telefax number of the appropriate person to contact.

Where in addition, the applicant has an office, agent or representative in the Member State in which the authorisation is being sought, the name and address of the local office, agent or representative shall be provided, as shall the name, position, telephone and telefax number of the appropriate person to contact.

1.2. *Manufacturer of the preparation and the active substance(s) (names and addresses etc. including location of plants)*

The name and address of the manufacturer of the preparation and of each active substance in the preparation must be provided as must the name and address of each manufacturing plant in which the preparation and active substance are manufactured.

A contact point (preferable a central contact point, to include name, telephone and telefax numbers) must be provided for each.

If the active substance originates from a manufacturer from which data in accordance with the Annex to Regulation (EU) 544/2011 had not been submitted previously, a statement of purity and detailed information on the impurities referred to in the Annex to Regulation 544/2011 have to be provided.

1.3. *Trade name or proposed trade name, and manufacturer's development code number of the preparation if appropriate*

All former and current trade names and proposed trade names and development code numbers of the preparation as well as the current names and numbers must be provided. Where trade names and code numbers referred to, relate to similar but different preparations (possibly obsolete), full details of the differences, must be provided. (The proposed trade name may not give rise to confusion with the trade name of already registered plant protection products.)

1.4. *Detailed quantitative and qualitative information on the composition of the preparation (active substance(s), and co-formulants)*

1.4.1. For preparations the following information must be reported:

— the content of both technical active substance(s) and pure active substance(s),

— the content of co-formulants.

The concentrations shall be expressed in terms as provided for in Directive 1999/45/EC.

1.4.2. For active substances their ISO common names or proposed ISO common names and their CIPAC[(10)] numbers, and, where available, the EC (Einecs or ELINCS) numbers must be provided. Where relevant it must be stated which salt, ester, anion or cation is present.

1.4.3. Co-formulants must where possible, be identified by their International Chemical Identification as given in Annex VI to Regulation (EC) No 1272/2008, or, if not included in that Regulation, in accordance with both IUPAC and CA nomenclature. Their structure or structural formula must be provided. For each component of the co-formulants the relevant EC (Einecs or ELINCS) number and CAS number where they exist, must be provided. Where the information provided does not fully identify a co-formulant, an appropriate specification must be provided. The trade name of co-formulants, where they exist, must also be provided.

1.4.4. For co-formulants the function must be given:

— adhesive (sticker),
— antifoaming agent,
— antifreeze,
— binder,
— buffer,
— carrier,
— deodorant,
— dispersing agent,
— dye,
— emetic,
— emulsifier,
— fertiliser,
— preservative,
— odorant,
— perfume,
— propellant,
— repellent,
— safener,
— solvent,
— stabiliser,
— synergist,
— thickener,
— wetting agent,
— miscellaneous (specify).

1.5. *Physical state and nature of the preparation (emulsifiable concentrate, wettable powder, solution, etc.)*

1.5.1. The type and code of preparation must be designated in accordance with the 'Catalogue of pesticide formulation types and international coding system (GIFAP[11] Technical Monograph No 2. 1989)'.

Where a particular preparation is not defined precisely in that publication a full description of the physical nature and state of the preparation must be provided, together with a proposal for a suitable description of the type of preparation and a proposal for its definition.

1.6. *Function (herbicide, insecticide, etc.)*

The function must be specified from among the following:
— acaricide,
— bactericide,
— fungicide,
— herbicide,
— insecticide,
— molluscicide,
— nematicide,
— plant growth regulator,
— repellent,
— rodenticide,
— semio-chemicals,
— talpicide,
— viricide,
— other (must be specified).

2. Physical, chemical and technical properties of the plant protection product

The extent to which plant protection products for which authorisation is sought, comply with relevant FAO specifications as agreed by the Group of Experts on Pesticide Specifications, of the FAO Panel of Experts on Pesticide Specifications, Registration Requirements and Application Standards, must be stated. Divergences from FAO specifications must be described in detail, and justified.

2.1. *Appearance (colour and odour)*

A description of both the colour and odour, if any, and the physical state of the preparation, must be provided.

2.2. *Explosivity and oxidising properties*

2.2.1. The explosive properties of preparations must be reported in accordance with method A 14 of Regulation (EC) No 440/2008. Where available thermodynamic information establishes beyond reasonable doubt that the preparation is incapable of exothermic reaction, it is sufficient to provide that information as a justification for not determining the explosive properties of the preparation.

2.2.2. Oxidising properties of preparations which are solids must be determined and reported in accordance with method A 17 of Regulation (EC) No 440/2008. For other preparations the method used must be justified. The oxidising properties do

not have to be determined if it can be shown without reasonable doubt on the basis of thermodynamic information, that the preparation is incapable of reacting exothermically with combustible materials.

2.3. *Flash point and other indications of flammability or spontaneous ignition*

The flash point of liquids which contain flammable solvents, must be determined and reported in accordance with method A 9 of Regulation (EC) No 440/2008. The flammability of solid preparations and gases must be determined and reported in accordance with methods A 10, A 11 and A 12 of Regulation (EC) No 440/2008 as appropriate. The auto-flammability of preparations must be determined and reported in accordance with method A 15 or A 16 of Regulation (EC) No 440/2008 as appropriate, and or, where necessary, in accordance with the UN-Bowes-Cameron-Cage-Test (UN-Recommendations on the Transport of Dangerous Goods, Chapter 14, No 14.3.4).

2.4. *Acidity/alkalinity and if necessary pH value*

2.4.1. In the case of preparations which are acidic (pH < 4) or alkaline (pH > 10) the acidity or alkalinity and the pH value must be determined and reported in accordance with CIPAC Methods MT 31 and MT 75 respectively.

2.4.2. Where relevant (if to be applied as aqueous dilution) the pH of a 1 % aqueous dilution, emulsion or dispersion of the preparation, must be determined and reported in accordance with CIPAC Method MT 75.

2.5. *Viscosity and surface tension*

2.5.1. In the case of liquid preparations for Ultra Low Volume use (ULV) the kinematic viscosity must be determined and reported in accordance with OECD Test Guideline 114.

2.5.2. For non-newtonian liquids the viscosity must be determined and reported together with the test conditions.

2.5.3. In the case of liquid preparations the surface tension has to be determined and reported in accordance with method A 5 of Regulation (EC) No 440/2008.

2.6. *Relative density and bulk density*

2.6.1. The relative density of liquid preparations must be determined and reported in accordance with method A 3 of Regulation (EC) No 440/2008.

2.6.2. The bulk (tap) density of preparations which are powders or granules, must be determined and reported in accordance with CIPAC Methods MT 33, MT 159 or MT 169 as appropriate.

2.7. *Storage — stability and shelf-life: Effects of light, temperature and humidity on technical characteristics of the plant protection product*

2.7.1. The stability of the preparation after storage for 14 days at 54 °C must be determined and reported in accordance with CIPAC Method MT 46.

Other times and/or temperatures may be needed (e.g. 8 weeks at 40 °C or 12 weeks at 35 °C or 18 weeks at 30 °C) if the preparation is heat sensitive.

If the active substance content after the heat stability test has decreased by more than 5 % of the initially found content, the minimum content shall be declared and information on the degradation products shall be supplied.

2.7.2. Additionally in the case of liquid preparations, the effect of low temperatures on stability, must be determined and reported in accordance with CIPAC Methods MT 39, MT 48, MT 51 or MT 54 as appropriate.

2.7.3. The shelf life of the preparation at ambient temperature must be reported. Where shelf life is less than 2 years, the shelf life in months, with appropriate temperature specifications, must be reported. Useful information is given in GIFAP Monograph No 17.

2.8. *Technical characteristics of the plant protection product*

The technical characteristics of the preparation must be determined to permit a decision to be made as to its acceptability.

2.8.1. *Wettability*

The wettability of solid preparations which are diluted for use (e.g. wettable powders, water soluble powders, water soluble granules and water dispersible granules), must be determined and reported in accordance with CIPAC Method MT 53.3.

2.8.2. *Persistent foaming*

The persistence of foaming of preparations to be diluted with water, must be determined and reported in accordance with CIPAC Method MT 47.

2.8.3. *Suspensibility and suspension stability*

— The suspensibility of water dispersible products (e.g. wettable powders, water dispersible granules, suspension concentrates) must be determined and reported in accordance with CIPAC Method MT 15, MT 161 or MT 168 as appropriate.

— The spontaneity of dispersion of water dispersible products (e.g. suspension concentrates and water dispersible granules) must be determined and reported in accordance with CIPAC Method MT 160 or MT 174 as appropriate.

2.8.4. *Dilution stability*

The dilution stability of water soluble products must be determined and reported in accordance with CIPAC Method MT 41.

2.8.5. *Dry sieve test and wet sieve test*

In order to ensure that dustable powders have a suitable particle size distribution for ease of application, a dry sieve test must be conducted and reported in accordance with CIPAC Method MT 59.1.

In the case of water dispersible products, a wet sieve test must be conducted and reported in accordance with CIPAC Method MT 59.3 or MT 167 as appropriate.

2.8.6. *Particle size distribution (dustable and wettable powders, granules), content of dust/fines (granules), attrition and friability (granules)*

2.8.6.1. The size distribution of particles in the case of powders, must be determined and reported in accordance with OECD Method 110.

The nominal size range of granules for direct application must be determined and reported in accordance with CIPAC MT 58.3, for water dispersible granules in accordance with CIPAC MT 170.

2.8.6.2. The dust content of granular preparations, must be determined and reported according CIPAC Method MT 171. If relevant for operator exposure the particle size of dust must be determined and reported in accordance with OECD Method 110.

2.8.6.3. The friability and attrition characteristics of granules, must be determined and reported once internationally agreed methods are available. Where already data are available they must be reported together with the method used.

2.8.7. *Emulsifiability, re-emulsifiability, emulsion stability*

2.8.7.1. The emulsifiability, emulsion stability and re-emulsifiability of preparations which form emulsions, must be determined and reported in accordance with CIPAC Method MT 36 or MT 173 as appropriate.

2.8.7.2. The stability of dilute emulsions and of preparations which are emulsions, must be determined and reported in accordance with CIPAC Method MT 20 or MT 173.

2.8.8. *Flowability, pourability (rinsability) and dustability*

2.8.8.1. The flowability of granular preparations must be determined and reported in accordance with CIPAC Method MT 172.

2.8.8.2. The pourability (including rinsed residue) of suspensions (e.g. suspension concentrates, suspo-emulsions), must be determined and reported in accordance with CIPAC Method MT 148.

2.8.8.3. The dustability of dustable powders following accelerated storage according 2.7.1 must be determined and reported in accordance with CIPAC Method MT 34 or another suitable method.

2.9. *Physical and chemical compatibility with other products including plant protection products with which its use is to be authorised*

2.9.1. The physical compatibility of tank mixes must be reported based on in-house test methods. A practical test would be an acceptable alternative.

2.9.2. The chemical compatibility of tank mixes must be determined and reported except where examination of the individual properties of the preparations would establish beyond reasonable doubt that there is no possibility of reaction taking place. In such cases it is sufficient to provide that information as justification for not practically determining the chemical compatibility.

2.10. *Adherence and distribution to seeds*

In the case of preparations for seed treatment, both distribution and adhesion must be investigated and reported; in the case of distribution in accordance with CIPAC Method MT 175.

3. Data on application

3.1. *Field of use envisaged, e.g. field, protected crops, storage of plant products, home gardening*

The field(s) of use, existing and proposed, for preparations containing the active substance must be specified from among the following:

— field use, such as agriculture, horticulture, forestry and viticulture,

— protected crops,

— amenity,

— weed control on non-cultivated areas,
— home gardening,
— house plants,
— plant products storage practice,
— other (specify).

3.2. *Effects on harmful organisms, e.g. contact, inhalation or stomach poison, fungitoxic or fungistatic, etc. systemic or not in plants*

The nature of the effects on harmful organisms must be stated:
— contact action,
— stomach action,
— inhalation action,
— fungitoxic action,
— fungistatic action,
— desiccant,
— reproduction inhibitor,
— other (must be specified).

It must be stated whether or not the product is translocated in plants.

3.3. *Details of intended use, e.g. types of harmful organisms controlled and/or plants or plant products to be protected*

Details of the intended use must be provided.

Where relevant, effects achieved, e.g. sprout suppression, retardation of ripening, reduction in stem length, enhanced fertilisation, etc. must be reported.

3.4. *Application rate*

For each method of application and each use, the rate of application per unit (ha, m^2, m^3) treated, in terms of g or kg of both preparation and active substance, must be provided.

Application rates shall normally be expressed in g or kg/ha or in kg/m^3 and where appropriate in g or kg/tonne; for protected crops and home gardening use rates shall be expressed in g or kg/100 m^2 or g or kg/m^3.

3.5. *Concentration of active substance in material used (e.g. in the diluted spray, baits or treated seed)*

The content of active substance shall be reported, as appropriate, in g/l, g/kg, mg/kg or in g/tonne.

3.6. *Method of application*

The method of application proposed must be described fully, indicating the type of equipment to be used, if any, as well as the type and volume of diluent to be used per unit of area or volume.

3.7. *Number and timing of applications and duration of protection*

The maximum number of applications to be used and their timing, must be reported. Where relevant the growth stages of the crop or plants to be protected and the development stages of the harmful organisms, must be indicated. Where possible the interval between applications, in days, must be stated.

The duration of protection afforded both by each application and by the maximum number of applications to be used, must be indicated.

3.8. *Necessary waiting periods or other precautions to avoid phytotoxic effects on succeeding crops*

Where relevant, minimum waiting periods between last application and sowing or planting of succeeding crops, which are necessary to avoid phytotoxic effects on succeeding crops, must be stated, and follow from the data provided under paragraph 6.6.

Limitations on choice of succeeding crops, if any, must be stated.

3.9. *Proposed instructions for use*

The proposed instructions for use of the preparation, to be printed on labels and leaflets, must be provided.

4. **Further information on the plant protection product**

4.1. *Packaging (type, materials, size, etc.), compatibility of the preparation with proposed packaging materials*

4.1.1. Packaging to be used must be fully described and specified in terms of the materials used, manner of construction (e.g. extruded, welded, etc.), size and capacity, size of opening, type of closure and seals. It must be designed in accordance with the criteria and guidelines specified in the FAO 'Guidelines for the Packaging of Pesticides'.

4.1.2. The suitability of the packaging, including closures, in terms of its strength, leakproofness and resistance to normal transport and handling, must be determined and reported in accordance with ADR Methods 3552, 3553, 3560, 3554, 3555, 3556; 3558, or appropriate ADR Methods for intermediate bulk containers, and, where for the preparation child-resistant closures are required, in accordance with ISO standard 8317.

4.1.3. The resistance of the packaging material to its contents must be reported in accordance with GIFAP Monograph No 17.

4.2. *Procedures for cleaning application equipment*

Cleaning procedures for both application equipment and protective clothing must be described in detail. The effectiveness of the cleaning procedure, must be fully investigated and reported.

4.3. *Re-entry periods, necessary waiting periods or other precautions to protect man, livestock and the environment*

The information provided must follow from and be supported by the data provided for the active substance(s) and that provided under Sections 7 and 8.

4.3.1. Where relevant pre-harvest intervals, re-entry periods or withholding periods necessary to minimise the presence of residues in or on crops, plants and plant products, or in treated areas or spaces, with a view to protecting man or livestock, must be specified, e.g.:

— pre-harvest interval (in days) for each relevant crop,
— re-entry period (in days) for livestock, to areas to be grazed,
— re-entry period (in hours or days) for man to crops, buildings or spaces treated,
— withholding period (in days) for animal feedingstuffs,
— waiting period (in days), between application and handling treated products, or

— waiting period (in days), between last application and sowing or planting succeeding crops.

4.3.2. Where necessary, in the light of the test results, information on any specific agricultural, plant health or environmental conditions under which the preparation may or may not be used must be provided.

4.4. *Recommended methods and precautions concerning: handling, storage, transport or fire*

The recommended methods and precautions concerning handling procedures (detailed) for the storage, at both warehouse and user level of plant protection products, for their transport and in the event of fire must be provided. Where available information on combustion products must be provided. The risks likely to arise and the methods and procedures to minimise the hazards arising, must be specified. Procedures to preclude or minimise the generation of waste or leftovers must be provided.

Where relevant, assessment has to be done in accordance with ISO — TR 9122.

Where appropriate the nature and characteristics of protective clothing and equipment proposed must be provided. The data provided must be sufficient to evaluate the suitability and effectiveness under realistic conditions of use (e.g. field or glasshouse circumstances).

4.5. *Emergency measures in the case of an accident*

Whether arising during transport, storage or use, detailed procedures to be followed in the event of an emergency, must be provided; and include:

— containment of spillages,
— decontamination of areas, vehicles and buildings,
— disposal of damaged packaging, adsorbents and other materials,
— protection of emergency workers and bystanders,
— first aid measures.

4.6. *Procedures for destruction or decontamination of the plant protection product and its packaging*

Procedures for destruction and decontamination must be developed for both small quantities (user level) and large quantities (warehouse level). The procedures must be consistent with provisions in place relating to the disposal of waste and of toxic waste. The means of disposal proposed shall be without unacceptable influence on the environment and be the most cost effective and practical means of disposal feasible.

4.6.1. *Possibility of neutralisation*

Neutralisation procedures (e.g. by reaction with alkali to form less toxic compounds) for use in the event of accidental spillages, must where they are feasible, be described. The products produced after neutralisation shall be practically or theoretically evaluated and reported.

4.6.2. *Controlled incineration*

In many cases the preferred or sole means to safely dispose of active substances as well as plant protection products containing them, contaminated materials, or contaminated packaging, is through controlled incineration in a licensed incinerator.

Where the content of halogens of the active substance(s) in the preparation is greater than 60 %, the pyrolytic behaviour of the active substance under controlled conditions (including where relevant supply of oxygen and defined residence time) at 800 °C and the content of

polyhalogenated dibenzo-p-dioxins and dibenzo-furans in the products of pyrolysis must be reported. The applicant must provide detailed instructions for safe disposal.

4.6.3. *Others*

Other methods to dispose of plant protection products, packaging and contaminated materials, where proposed, must be fully described. Data must be provided for such methods, to establish their effectiveness and safety.

5. Analytical methods

Introduction

This Section only covers analytical methods required for post-registration control and monitoring purposes.

For analytical methods used for generation of data as required in this Regulation or for other purposes the applicant has to provide a justification for the method used; where necessary separate guidance will be developed for such methods on the basis of the same requirements as defined for methods for post-registration control and monitoring purposes.

Descriptions of methods must be provided and include details of equipment, materials and conditions used.

As far as practicable these methods must employ the simplest approach, involve the minimum cost, and require commonly available equipment.

For this Section the following applies:

Impurities, metabolites, relevant metabolites	As defined in Article 3 of Regulation (EC) No 1107/2009
Relevant impurities	Impurities of toxicological and/or ecotoxicological or environmental concern

On request the following samples must be provided:

(i) samples of the preparation;

(ii) analytical standards of the pure active substance;

(iii) samples of the active substance as manufactured;

(iv) analytical standards of relevant metabolites and all other components included in the residue definition;

(v) if available, samples of reference substances for the relevant impurities.

For definitions see the Annex of Regulation (EU) No 544/2011, points 4.1 and 4.2 of Part A.

5.1. *Methods for the analysis of the preparation*

5.1.1. Methods, which must be described in full, must be provided for the determination of the active substance in the preparation. In the case of a preparation containing more than one active substance a method capable of determining each, in the presence of the other, shall be provided. If a combined method is not submitted, the technical reasons must be stated. The applicability of existing CIPAC methods must be reported.

5.1.2. Methods must also be provided for the determination in the preparation of relevant impurities, if the composition of the preparation is such that — on the basis of theoretical consideration — such impurities may be formed by its manufacturing process or from degradation during storage.

If required, methods for the determination of co-formulants or constituents of co-formulants in the preparation must be submitted.

5.1.3. *Specificity, linearity, accuracy and repeatability*

5.1.3.1. Specificity of methods submitted, must be demonstrated and reported. In addition the extent of interference by other substances present in the preparation must be determined.

While interferences due to other components may be identified as systematic errors in the assessment of the accuracy of methods proposed, an explanation must be provided for any interference occurring which contribute more than ± 3 % to the total quantity determined.

5.1.3.2. The linearity of proposed methods over an appropriate range, must be determined and reported. The calibration range must extend (by at least 20 %) the highest and lowest nominal content of the analyte in relevant analytical solutions of the preparation. Duplicate calibration determinations must be made at three or more concentrations. Alternatively, five concentrations, each as single measurements, are acceptable. Reports submitted must include the equation of the calibration line and the correlation coefficient and representative and properly labelled documentation from the analysis, e.g. chromatograms.

5.1.3.3. Accuracy will normally only be required for methods for the determination of pure active substance and relevant impurities in the preparation.

5.1.3.4. For the repeatability in principle a minimum of five determinations must be made. The relative standard deviation (% RSD) must be reported. Outliers identified through an appropriate method (e.g. Dixons or Grubbs test), may be discarded. Where outliers have been discarded, that fact must be clearly indicated. An explanation as to the reason for the occurrence of individual outliers, must be attempted.

5.2. *Analytical methods for the determination of residues*

Analytical methods for the determination of residues must be submitted unless it is justified that the methods already submitted in accordance with the requirements of the Annex to Regulation (EU) No 544/2011, Part A, point 4.2 can be applied.

The same provisions as provided in point 4.2, Part A of the Annex to Regulation (EU) No 544/2011 apply.

6. **Efficacy data**

General

The data supplied must be sufficient to permit an evaluation of the plant protection product to be made. In particular it must be possible to evaluate the nature and extent of benefits that accrue following use of the preparation, where they exist in comparison to suitable reference products and damage thresholds, and to define its conditions of use.

The number of trials to be conducted and reported depends mainly on factors such as the extent to which the properties of the active substance(s) it contains are known and on the range of conditions that arise, including variability in plant health conditions, climatic differences, the

range of agricultural practices, the uniformity of the crops, the mode of application, the type of harmful organism and the type of plant protection product.

Sufficient data must be generated and submitted to confirm that patterns determined hold for the regions and the range of conditions, likely to be encountered in the regions concerned, for which its use is to be recommended. Where an applicant claims that tests in one or more of the proposed regions of use are unnecessary because conditions are comparable with those in other regions where tests have been carried out, the applicant must substantiate the claim for comparability with documentary evidence.

In order to assess seasonal differences, if any, sufficient data must be generated and submitted to confirm the performance of the plant protection product in each agronomically and climatically different region for each particular crop (or commodity)/harmful organism combination. Normally trials on effectiveness or phytotoxicity, where relevant, in at least two growing seasons must be reported.

If to the opinion of the applicant the trials from the first season adequately confirm the validity of claims made on the basis of extrapolation of results from other crops, commodities or situations or from tests with closely similar preparations, a justification, which is acceptable to the competent authority for not carrying out a second season's work must be provided. Conversely, where, because of climatic or plant health conditions or other reasons the data obtained in any particular season are of limited value for the assessment of performance, trials in one or more further seasons must be conducted and reported.

6.1. *Preliminary tests*

Reports in summary form of preliminary tests, including glasshouse and field studies, used to assess the biological activity and dose range finding of the plant protection product and of the active substance(s) it contains, must be submitted when requested by the competent authority. These reports will provide additional information for the competent authority when it evaluates the plant production product. Where this information is not submitted a justification which is acceptable to the competent authority must be provided.

6.2. *Testing effectiveness*
Aim of the tests

The tests shall provide sufficient data to permit an evaluation of the level, duration and consistency of control or protection or other intended effects of the plant protection product in comparison to suitable reference products, where they exist.
Test conditions

Normally a trial consists of three components: test product, reference product and untreated control.

The performance of the plant protection product must be investigated in relation to suitable reference products, where they exist. A suitable reference product is defined as an authorised plant protection product which has proved a sufficient performance in practice under the agricultural, plant health and environmental (including climatic) conditions in the area of proposed use. In general, formulation type, effects on the harmful organisms, working spectrum and method of application shall be close to those of the tested plant protection product.

Plant protection products must be tested in circumstances where the target harmful organism has been shown to have been present at a level causing or known to cause adverse effects (yield, quality, operational benefit) on an unprotected crop or area or on plants or plant products which have not been treated or where the harmful organism is present at such a level that an evaluation of the plant protection product can be made.

Trials to provide data on plant protection products for control of harmful organisms must show the level of control of the species of harmful organisms concerned or of species representative of groups for which claims are made. Trials must include the different stages of growth of life cycle of the harmful species, where this is relevant and the different strains or races, where these are likely to show different degrees of susceptibility.

Similarly, trials to provide data on plant protection products which are plant growth regulators, must show the level of effects on the species to be treated, and include investigation of differences in the response of a representative sample of the range of cultivars on which its use is proposed.

In order to clarify the dose response, dose rates lower than the recommended one must be included in some trials in order to enable to assess whether the recommended rate is the minimum necessary to achieve the desired effect.

The duration of the effects of treatment must be investigated in relation to the control of the target organism or effect on the treated plants or plant products, as appropriate. When more than one application is recommended, trials must be reported which establish the duration of the effects of an application, the number of applications necessary and the desired intervals between them.

Evidence must be submitted to show that the dose, timing and method of application recommended give adequate control, protection or have the intended effect in the range of circumstances likely to be encountered in practical use.

Unless there are clear indications that the performance of the plant protection production is unlikely to be affected to a significant degree by environmental factors, such as temperature or rain, an investigation of the effects of such factors on performance must be carried out and reported, particularly where it is known that the performance of chemically related products is so affected.

Where proposed label claims include recommendations for the use of the plant protection product with other plant protection product(s) or adjuvant(s) information on the performance of the mixture must be provided.

Test guideline

Trials must be designed to investigate specified issues, to minimise the effects of random variation between different parts of each site and to enable statistical analysis to be applied to results amenable to such analysis. The design, analysis and reporting of trials must be in accordance with European and Mediterranean Plant Protection Organisation (EPPO) guidelines 152 and 181. The report shall include a detailed and critical assessment of the data.

The trials must be carried out in accordance with specific EPPO guidelines where available, or with guidelines satisfying at least the requirements of the corresponding EPPO guideline.

A statistical analysis of results amenable to such analysis must be carried out; where necessary the test guideline used must be adapted to enable such analysis.

6.3. *Information on the occurrence or possible occurrence of the development of resistance*

Laboratory data and where it exists, field information relating to the occurrence and development of resistance or cross-resistance in populations of harmful organisms to the active substance(s), or to related active substances, must be provided. Where such information is not directly relevant to the uses for which authorisation is sought or to be renewed (different species of harmful organism or different crops), it must, if available, nevertheless be provided, as it may provide an indication of the likelihood of resistance developing in the target population.

Where there is evidence or information to suggest that, in commercial use, the development of resistance is likely, evidence must be generated and submitted as to the sensitivity of the population of the harmful organism concerned to the plant protection product. In such cases a management strategy designed to minimise the likelihood of resistance or cross-resistance developing in target species must be provided.

6.4. *Effects on the yield of treated plants or plant products in terms of quantity and/or quality*

6.4.1. *Effects on the quality of plants or plant products*
Aim of the tests

The tests shall provide sufficient data to permit an evaluation of the possible occurrence of taint or odour or other quality aspects of plants or plant products after treatment with the plant protection product.
Circumstances in which required

The possibility of the occurrence of taint or odour in food crops must be investigated and be reported where:
— the nature of the products or its use is such that a risk of occurrence of taint or odour might be expected, or
— other products based on the same or a closely similar active ingredient have been shown to present a risk of occurrence of taint or odour.

The effects of plant protection products on other quality aspects of treated plants or plant products must be investigated and reported where:
— the nature of the plant protection product or it use could have an adverse influence on other quality aspects (for example in the case of use of plant growth regulators close to the harvest), or
— other products based on the same or a closely similar active ingredient have been shown to have an adverse influence on the quality.

Testing shall be conducted initially on the main crops on which the plant protection product is to be used, at twice the normal rates of application and using, where relevant, the main methods of processing. Where effects are observed it is necessary to perform testing at the normal rate of application.

The extent of investigation necessary on other crops will depend on their degree of similarity of the main crops already tested, the quantity and quality of data available on those main crops and how far the manner of use of the plant protection product and methods of processing the crops, are similar. It is generally sufficient to perform the test with the main formulation type to be authorised.

6.4.2. *Effects on transformation processes*
Aim of the tests

The tests shall provide sufficient data to permit an evaluation of the possible occurrence of adverse effects after treatment with the plant protection product on transformation processes or on the quality of their products.
Circumstances in which required

When the treated plants or plant products are normally intended for use in transformation process such as wine making, brewing or bread making and when at harvest significant residues are present, the possibility of the occurrence of adverse effects must be investigated and reported where:

— there are indications that the use of the plant protection product could have an influence on the processes involved (for example in the case of use of plant growth regulators or fungicides close to the harvest), or

— other products based on the same or a closely similar active ingredient have been shown to have an adverse influence on these processes or its products.

It is generally sufficient to perform the test with the main formulation type to be authorised.

6.4.3. *Effects on the yield of treated plants or plant products*
Aim of the tests

The test shall provide sufficient data to permit an evaluation of the performance of the plant protection product and of possible occurrence of yield reduction or loss in storage of treated plants or plant products.
Circumstances in which required

The effects of plant protection products on the yield or yield components of treated plants or plant products must be determined where relevant. When treated plants or plant products are likely to be stored the effect on the yield after storage, including data on storage life must be determined where relevant.

This information will normally be available from the tests required in point 6.2.

6.5. *Phytotoxicity to target plants (including different cultivars), or to target plant products*
Aim of the tests

The test shall provide sufficient data to permit an evaluation of the performance of the plant protection product and of the possible occurrence of phytotoxicity after treatment with the plant protection product.
Circumstances in which required

For herbicides and for other plant protection products for which adverse effects, however transitory, are seen during the trials, performed in accordance to point 6.2, the margins of selectivity on target crops must be established, using twice the recommended rate of application. Where serious phytotoxic effects are seen, an intermediate application rate must also be investigated.

Where adverse effects occur, but are claimed to be unimportant in comparison with the benefits of use or transient, evidence to support this claim is required. If necessary yield measurement must be submitted.

The safety of a plant protection product to the main cultivars of the main crops for which it is recommended must be demonstrated, including effects of crop growth stage, vigour, and other factors which may influence susceptibility to damage or injury.

The extent of investigation necessary on other crops will depend on their degree of similarity to the main crops already tested, the quantity and quality of data available on those main crops and how far the manner of use of the plant protection product, if relevant, is similar. It is generally sufficient to perform the test with the main formulation type to be authorised.

Where proposed label claims include recommendations for the use of the plant protection product with other plant protection product(s), the previous paragraphs apply for the mixture.
Test guideline

Observations concerning phytotoxicity must be performed in the tests provided for in point 6.2.

Where phytotoxic effects are seen, they must be accurately assessed and recorded in accordance with EPPO guideline 135 or when a Member State requires so and when the test is carried out on the territory of this Member State, with guidelines satisfying at least the requirements of this EPPO guideline.

A statistical analysis of results amenable to such analysis must be carried out, where necessary the test guideline used must be adapted to enable such analysis.

6.6. *Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms, on succeeding crops, other plants or parts of treated plants used for propagating purposes (e.g. seeds, cuttings, runners)*

6.6.1. *Impact on succeeding crops*
Aim of the information required

Sufficient data must be reported to permit an evaluation of possible adverse effects of a treatment with the plant protection product on succeeding crops.
Circumstances in which required

Where data, generated in accordance with point 9.1, shows that significant residues of the active substance, its metabolites or degradation products, which have or may have biological activity on succeeding crops, remain in soil or in plant materials, such as straw or organic material up to sowing or planting time of possible succeeding crops, observations must be submitted on effects on the normal range of succeeding crops.

6.6.2. *Impact on other plants, including adjacent crops*
Aim of the information required

Sufficient data must be reported to permit an evaluation of possible adverse effects of a treatment with the plant protection product on other plants, including adjacent crops.
Circumstances in which required

Observations must be submitted on adverse effects on other plants, including the normal range of adjacent crops, when there are indications that the plant protection product could affect these plants via vapour drift.

6.6.3. *Impact on treated plants or plant products to be used for propagation*
Aim of the information required

Sufficient data must be reported to permit an evaluation of possible adverse effects of a treatment with the plant protection product on plants or plant products to be used for propagation.
Circumstances in which required

Observations must be submitted on the impact of plant protection products on plant parts used for propagation except where the proposed uses preclude use on crops intended for production of seeds, cuttings, runners or tubers for planting, as appropriate.

(i) for seeds — viability, germination and vigour;

(ii) for cuttings — rooting and growth rates;

(iii) for runners — establishment and growth rates;

(iv) for tubers — sprouting and normal growth.
Test guideline

Seeds testing shall be done in accordance with ISTA Methods[(12)].

6.6.4. *Effects on beneficial and other non-target organisms*

Any effects, positive or negative, on the incidence of other harmful organisms, observed in the tests performed in accordance with the requirements of this Section, shall be reported. Any observed environmental effects must also be reported, especially effects on wildlife and/or beneficial organisms.

6.7. *Summary and evaluation of data presented under 6.1 to 6.6*

A summary of all data and information provided under points 6.1 to 6.6 must be provided, together with a detailed and a critical assessment of the data, with particular reference to the benefits that the plant protection product offers, adverse effects that do or may arise and measures necessary to avoid or minimise adverse effects.

7. Toxicological studies

For proper evaluation of the toxicity of preparations sufficient information shall be available on acute toxicity, irritation and sensitisation of the active substance. If possible, additional information on mode of toxic action, toxicological profile and all other known toxicological aspects of the active substance shall be submitted.

In the context of the influence that impurities and other components can have on toxicological behaviour, it is essential that for each study submitted, a detailed description (specification) of the material used, be provided. Tests must be conducted using the plant protection product to be authorised.

7.1. *Acute toxicity*

The studies, data and information to be provided and evaluated, must be sufficient to permit the identification of effects following a single exposure to the plant protection product, to be assessed, and in particular to establish, or indicate:

— the toxicity of the plant protection products,
— toxicity of the plant protection product relative to the active substance,
— the time course and characteristics of the effect with full details of behavioural changes and possible gross pathological findings at post-mortem,
— where possible the mode of toxic action, and
— the relative hazard associated with the different routes of exposure.

While the emphasis must be on estimating the toxicity ranges involved, the information generated must also permit the plant protection product to be classified in accordance with Directive 1999/45/EC or Regulation (EC) No 1272/2008. The information generated through acute toxicity testing is of particular value in assessing hazards likely to arise in accident situations.

7.1.1. *Oral*
Circumstances in which required

An acute oral test shall always be carried only if the applicant cannot justify an alternative approach under Directive 1999/45/EC or Regulation (EC) No 1272/2008, where applicable.
Test method

The test must be carried out in accordance with Method B 1 bis or B 1 tris of Regulation (EC) No 440/2008.

7.1.2. *Percutaneous*
Circumstances in which required

An acute percutaneous test shall be conducted only if the applicant cannot justify an alternative approach under Directive 1999/45/EC or Regulation (EC) No 1272/2008, where applicable.
Test method

The test must be carried out in accordance with Method B 3 of Regulation (EC) No 440/2008.

7.1.3. *Inhalation*
Aim of the test

The test will provide the inhalation toxicity to rats of the plant protection product or of the smoke it generates.
Circumstances in which required

The test must be carried out where the plant protection product:
— is a gas or liquified gas,
— is a smoke generating formulation or fumigant,
— is used with fogging equipment,
— is a vapour releasing preparation,
— is an aerosol,
— is a powder containing a significant proportion of particles of diameter < 50 μm (> 1 % on a weight basis),
— is to be applied from aircraft in cases where inhalation exposure is relevant,
— contains an active substance with a vapour pressure > 1×10^{-2} Pa and is to be used in enclosed spaces such as warehouses or glasshouses,
— is to be applied in a manner which generates a significant proportion of particles or droplets of diameter < 50 μm (> 1 % on a weight basis).
Test method

The test must be carried out in accordance with Method B 2 of Regulation (EC) No 440/2008.

7.1.4. *Skin irritation*
Aim of the test

The test will provide the potential of skin irritancy of the plant protection product including the potential reversibility of the effects observed.
Circumstances in which required

The skin irritancy of the plant protection product must be determined except where it is likely, as indicated in the test guideline, that severe skin effects may be produced or that effects can be excluded.
Test method

The test must be carried out in accordance with Method B 4 of Regulation (EC) No 440/2008.

7.1.5. *Eye irritation*
Aim of the test

The test will provide the potential for eye irritation of the plant protection product, including the potential reversibility of the effects observed.
Circumstances in which required

Eye irritation tests must be conducted except where it is likely, as indicated in the test guideline, that severe effects on the eyes may be produced.
Test method

The eye irritation must be determined in accordance with Method B 5 of Regulation (EC) No 440/2008.

7.1.6. *Skin sensitisation*
Aim of the test

The test will provide sufficient information to assess the potential of the plant protection product to provoke skin sensitisation reactions.
Circumstances in which required

The tests must always be carried out except where the active substance(s) or co-formulants are known to have sensitising properties.
Test method

The tests have to be carried out in accordance with Method B 6 of Regulation (EC) No 440/2008.

7.1.7. *Supplementary studies for combinations of plant protection products*
Aim of the test

In certain cases it may be necessary to carry out the studies as referred to under points 7.1.1 to 7.1.6 for a combination of plant protection products where the product label includes requirements for use of the plant protection product with other plant protection products and/or with adjuvants as a tank mix. Decisions as to the need for supplementary studies must be made on a case by case basis, taking into account the results of the acute toxicity studies of the individual plant protection products, the possibility for exposure to the combination of the products concerned and available information or practical experience with the products concerned or similar products.

7.2. *Data on exposure*

When measuring exposure to a plant protection product in the air within the breathing area of operators, bystanders or workers the requirements of Council Directive 98/24/EC[(13)] and Directive 2004/37/EC of the European Parliament and of the Council[(14)] have to be taken into account.

7.2.1. *Operator exposure*

The risks for those using plant protection products depend on the physical, chemical and toxicological properties of the plant protection product as well as the type of the product (undiluted/diluted), and on the route, the degree and duration of exposure. Sufficient information and data must be generated and reported to permit an assessment of the extent of exposure to the active substance(s) and/or toxicologically relevant compounds in the plant protection product likely to occur under the proposed conditions of use. It must also provide a basis for the selection of the appropriate protective measures including personal protective equipment to be used by operators and to be specified on the label.

7.2.1.1. *Estimation of operator exposure*
Aim of the estimation

An estimation shall be made, using where available a suitable calculation model, in order to permit an evaluation of the operator exposure likely to arise under the proposed conditions of use.
Circumstances in which required

An estimation of operator exposure must always be completed.
Estimation conditions

An estimation shall be made for each type of application method and application equipment proposed for use of the plant protection product taking account of the requirements resulting from the implementation of the classification and labelling provisions of Directive 1999/45/EC or Regulation (EC) No 1272/2008 for handling the undiluted or diluted product as well as the different types and sizes of containers to be used, mixing, loading operations, application of the plant protection product, the climatic conditions and cleaning and routine maintenance of application equipment.

At first an estimation shall be made with the assumption that the operator is not using any personal protective equipment.

Where appropriate, a second estimation shall be made with the assumption that the operator is using effective and readily obtainable protective equipment which is feasible to be used by the operator. Where protective measures are specified on the label, the estimation will take these into account.

7.2.1.2. *Measurement of operator exposure*
Aim of the test

The test shall provide sufficient data to permit an evaluation of the operator exposure likely to arise under the proposed conditions of use.
Circumstances in which required

Actual exposure data for the relevant exposure route(s) must be reported where the risk assessment indicates that a health-based limit value is exceeded. This will, for example, be the case when the results of the estimation of operator exposure provided for under point 7.2.1.1 indicate that:

— the Acceptable Operator Exposure Level(s) (AOEL) established in the context of approval of the active substance, and/or

— the limit values established for the active substance and/or toxicologically relevant compound(s) of the plant protection product in accordance with Directives 98/24/EC and 2004/37/EC on the protection of workers,

may be exceeded.

Actual exposure data must also be reported when no appropriate calculation model or no appropriate data are available to do the estimation provided for under point 7.2.1.1.

In cases where dermal exposure is the most important exposure route, a dermal absorption test or the results of a sub-acute dermal study, if not already available, may be a useful alternative test to provide data in order to refine the estimate provided for under point 7.2.1.1.
Test conditions

The test must be done under realistic exposure conditions taking into account the proposed conditions of use.

7.2.2. *Bystander exposure*

Bystanders can be exposed during the application of plant protection products. Sufficient information and data must be reported to provide a basis for the selection of appropriate conditions of use, including the exclusion of bystanders from treatment areas and separation distances.
Aim of the estimation

An estimation shall be made, using where available a suitable calculation model in order to permit an evaluation of the bystander exposure likely to arise under the proposed conditions of use.

Circumstances in which required

An estimation of bystander exposure must always be completed.

Estimation conditions

An estimation of bystander exposure must be made for each type of application method. The estimation shall be made with the assumption that bystanders do not use any personal protective equipment.

Measurement of bystander exposure may be required when estimates indicate a cause for concern.

7.2.3. *Worker exposure*

Workers can be exposed following application of plant protection products, when entering treated fields or premises or handling treated plants or plant products on which residues remain. Sufficient information and data must be reported to provide a basis for the selection of appropriate protective measures, including waiting and re-entry periods.

7.2.3.1. *Estimation of worker exposure*

Aim of the estimation

An estimation shall be made using where available a suitable calculation model, in order to permit an evaluation of the worker exposure likely to arise under the proposed conditions of use.

Circumstances in which required

The estimation of worker exposure must always be completed.

Estimation conditions

An estimation of worker exposure must be made for each crop and task to be carried out.

At first the estimation shall be made using available data on the exposure to be expected with the assumption that the worker is not using any personal protective equipment.

Where appropriate, a second estimation shall be made with the assumption that the worker is using effective and readily obtainable protective equipment which is feasible to be used.

Where appropriate, a further estimation shall be made using data generated on the amount of dislodgeable residues under the proposed conditions of use.

7.2.3.2. *Measurement of worker exposure*

Aim of the test

The test shall provide sufficient data to permit an evaluation of the worker exposure likely to arise under the proposed conditions of use.

Circumstances in which required

Actual exposure data for the relevant exposure route(s) must be reported where the risk assessment indicates that a health-based limit value is exceeded. This will, for example, be the case where the results of the estimation of worker exposure provided for under point 7.2.3.1 indicate that:

— the AOEL(s) established in the context of approval of the active substance(s), and/or

— the limit values established for the active substance and/or toxicologically relevant compound(s) of the plant protection product in accordance with Directives 98/24/EC and 2004/37/EC,

may be exceeded.

Actual exposure data must also be reported when no appropriate calculation model or no appropriate data are available to do the estimation provided for under point 7.2.3.1.

Where dermal exposure is the most important exposure route, a dermal absorption test, if not already available, may be a useful alternative test to provide data in order to refine the estimate provided for under point 7.1.3.1.
Test conditions

The test must be done under realistic exposure conditions taking into account the proposed conditions of use.

7.3. *Dermal absorption*
Aim of the test

The test shall provide a measurement of the absorption of the active substance and toxicologically relevant compounds through the skin.
Circumstances in which required

The study must be conducted when dermal exposure is a significant exposure route and where the risk assessment indicates that a health-based limit value is exceeded. This will, for example, be the case where the results of the estimation or measurement of operator exposure provided for under points 7.2.1.1 or 7.2.1.2 indicate that:

— the AOEL(s) established in the context of approval of the active substance(s), and/or
— the limit values established for the active substance and/or toxicologically relevant compound(s) of the plant protection product in accordance with Directives 98/24/EC and 2004/37/EC,

may be exceeded.
Test conditions

In principle data of an *in vivo* rat skin absorption study must be reported. If, when the results of the estimation using these *in vivo* skin absorption data are incorporated in the risk assessment, there remains an indication of excessive exposure, it may be necessary to perform an *in vitro* comparative absorption study on rat and human skin.
Test guideline

The test must be carried out in accordance with Method B 44 or B 45 of Regulation (EC) No 440/2008.

7.4. *Available toxicological data relating to non-active substances*

Where relevant, the following information shall be submitted for each co-formulant:

(a) the registration number as referred to in Article 20(3) of Regulation (EC) No 1907/2006;

(b) the study summaries included in the technical dossier as referred to in Article 10(a)(vi) of Regulation (EC) No 1907/2006; and

(c) the safety data sheet as referred to in Article 31 of Regulation (EC) No 1907/2006.

All other available information shall be submitted.

8. Residues in or on treated products, food and feed

Introduction

The provisions of the introduction to Section 6 of the Annex to Regulation (EU) No 544/2011 apply.

8.1. *Metabolism, distribution and expression of residue in plants or livestock*

Aim of the tests

The objectives of these studies are:

— to provide an estimate of total terminal residues in the relevant portion of crops at harvest following treatment as proposed,

— to quantify the rate of degradation and excretion of the total residue in certain animal products (milk or eggs) and excreta,

— to identify the major components of the total terminal residue in crops and in edible animal products respectively,

— to indicate the distribution of residues between relevant crop parts and between relevant edible animal products respectively,

— to quantify the major components of the residue and to show the efficiency of extraction procedures for these components,

— to generate data from which a decision on the need for livestock feeding studies as provided for in point 8.3 can be made,

— to decide on the definition and expression of a residue.

Circumstances in which required

Supplementary metabolism studies only need to be performed where it is not possible to extrapolate from data obtained on the active substance in accordance with the requirements of points 6.1 and 6.2 of Part A of the Annex to Regulation (EU) No 544/2011. This might be the case for crops or for livestock for which data were not submitted in the framework of approval of the active substance(s) under Regulation (EC) No 1107/2009 or were not necessary for amending the conditions of its approval or where it could be expected that a different metabolism will occur.

Test conditions

The same provisions as provided under the corresponding paragraphs of points 6.1 and 6.2 of Part A of the Annex to Regulation (EU) No 544/2011 apply.

8.2. *Residue trials*

Aim of the tests

The objectives of these studies are:

— to quantify the highest likely residue levels in treated crops at harvest or outloading from store following the proposed good agricultural practice (GAP), and

— to determine, when appropriate, the rate of decline of pesticide deposits.

Circumstances in which required

Supplementary residue trials only need to be performed where it is not possible to extrapolate from data obtained on the active substance in accordance to the requirements of point 6.3 of Part A of the Annex to Regulation (EU) No 544/2011. This might be the case for special formulations, for special application methods or for crops for which data were not submitted in the framework of approval of the active substance or were not necessary for amending the conditions of its approval.

Test conditions

The same provisions as provided under the corresponding paragraphs of point 6.3 of Part A of the Annex to Regulation (EU) No 544/2011 apply.

8.3. *Livestock feeding studies*
Aim of the tests

The objective of these studies is to determine the residue in products of animal origin which will result from residues in feedingstuffs or fodder crops.
Circumstances in which required

Supplementary feeding studies for the purpose of assessing maximum residue levels for products of animal origin are only required where it is not possible to extrapolate from data obtained on the active substance in accordance to the requirements of point 6.4 of Part A of the Annex to Regulation (EU) No 544/2011. This might be the case where additional fodder crops are to be authorised which leads to an increased intake of residues of livestock for which data were not submitted in the framework of approval of the active substance(s) or were not necessary for amending the conditions of its approval.
Test conditions

The same provisions as provided under the corresponding paragraphs of point 6.4 of Part A of the Annex to Regulation (EU) No 544/2011 apply.

8.4. *Effects of industrial processing and/or household preparations*
Aim of the tests

The main objectives of these studies are:

— to establish whether or not breakdown or reaction products arise from residues in the raw products during processing which may require a separate risk assessment,

— to determine the quantitative distribution of residues in the various intermediate and end products, and to estimate transfer factors,

— to enable a more realistic estimate to be made of dietary intake of residues.

Circumstances in which required

Supplementary studies only need to be performed where it is not possible to extrapolate from data obtained on the active substance in accordance to the requirements of point 6.5 of Part A of the Annex to Regulation (EU) No 544/2011. This might be the case for crops for which data were not submitted in the framework of approval of the active substance or were not necessary for amending the conditions of its approval.
Test conditions

The same provisions as provided under the corresponding paragraphs of point 6.5 of Part A of the Annex to Regulation (EU) No 544/2011 apply.

8.5. *Residues in succeeding crops*
Aim of the test

The objective of these studies is to permit an evaluation of possible residues in succeeding crops.
Circumstances in which required

Supplementary studies are only required where it is not possible to extrapolate from data obtained on the active substance in accordance to the requirements of point 6.6 of Part A of the Annex to Regulation (EU) No 544/2011. This might be the case for special formulations, for special application methods or for crops for which data were not submitted in the framework of approval of the active substance or were not necessary for amending the conditions of its approval.
Test conditions

The same provisions as provided under the corresponding paragraphs of point 6.6 of Part A of the Annex to Regulation (EU) No 544/2011 apply.

8.6. *Proposed maximum residue levels (MRLs) and residue definition*

A full justification for the proposed MRLs must be provided, including, where relevant, full details of the statistical analysis used.

If the metabolism studies submitted in accordance with the provisions of point 8.1 indicate that the residue definition shall be changed taking into account the actual residue definition and the necessary judgement as outlined under the corresponding paragraph of point 6.7 of Part A of the Annex to Regulation (EU) No 544/2011, a re-evaluation of the active substance may be necessary.

8.7. *Proposed pre-harvest intervals for envisaged uses, or withholding periods or storage periods, in the case of post-harvest uses.*

A full justification for the proposals must be provided.

8.8. *Estimation of the potential and actual exposure through diet and other means*

Consideration will be given to the calculation of a realistic prediction of dietary intake. This may be done in a step-wise fashion leading to an increasingly realistic prediction of intake. Where relevant, other sources of exposure such as residues arising from the use of medicines or veterinary drugs have to be taken into account.

8.9. *Summary and evaluation of residue behaviour*

A summary and evaluation of all data presented in this Section shall be carried out in accordance with the guidance given by the competent authorities of the Member States concerning the format of such summaries and evaluations. It shall include a detailed and critical assessment of those data in the context of relevant evaluative and decision-making criteria and guidelines, with particular reference to the risks for man and animals that may or do arise, and the extent, quality and reliability of the data base.

Where metabolism data have been submitted the toxicological significance of any non-mammalian metabolites must be addressed.

A schematic diagram shall be prepared of the metabolic pathway in plants and animals with a brief explanation of the distribution and chemical changes involved if metabolism data have been submitted.

9. Fate and behaviour in the environment

Introduction

(i) The information provided, taken together with that for the active substance as provided for in the Annex to Regulation (EU) No 544/2011 must be sufficient to permit an assessment of the fate and behaviour of the plant protection product in the environment, and of the non-target species likely to be at risk from exposure to it.

(ii) In particular, the information provided for the plant protection product, together with other relevant information, and that provided for the active substance, should be sufficient to:

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

— predict the distribution, fate, and behaviour in the environment as well as the time courses involved,
— identify non-target species and populations for which hazards arise because of potential exposure, and
— identify measures necessary to minimise contamination of the environment and impact on non-target species.

(iii) Where radio-labelled test material is used, point (iv) of the introduction to Section 7 of Part A of the Annex to Regulation (EU) No 544/2011 applies.

(iv) Where relevant tests shall be designed and data analysed using appropriate statistical methods.

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

(v) Predicted environmental concentrations in soil (PEC_S), water (PEC_{SW} and PEC_{GW}) and air (PEC_A).

Justified estimates must be made of the expected concentrations of the active substance and relevant metabolites, degradation and reaction products, in soil, groundwater, surface water and air, following use as proposed or already occurring. In addition a realistic worst-case estimation must be made.

For the purposes of the estimation of such concentrations the following definitions apply:

— *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).

— *Predicted environmental concentration in surface water (PEC_{SW})*

The level of residues, in surface water to which non-target aquatic organisms may be exposed (acute and chronic exposure).

— *Predicted environmental concentration in groundwater (PEC_{GW})*

The level of residues in groundwater.

— *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).

For the estimation of these concentrations all relevant information on the plant protection product and on the active substance must be taken into account. A useful approach for these estimations is provided in the EPPO schemes for environmental risk assessment[15]. Where relevant the parameters provided for in this Section shall be used.

When models are used for estimation of predicted environmental concentrations they must:
— 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.

The information provided must, where relevant, include that referred to in Section 7 of Part A of the Annex to Regulation (EU) No 544/2011.

9.1. *Fate and behaviour in soil*

Where appropriate, the same provisions relating to the information to be provided on the soil used and on its selection apply as provided for under point 7.1 of Part A of the Annex to Regulation (EU) No 544/2011.

9.1.1. *Rate of degradation in soil*

9.1.1.1. *Laboratory studies*
Aim of the test

The soil degradation studies shall provide best possible estimates of the time taken for degradation of 50 and 90 % (DT_{50lab} and DT_{90lab}) of the active substance under laboratory conditions.
Circumstances in which required

The persistence and behaviour of plant protection products in soil must be investigated unless it is possible to extrapolate from data obtained on the active substance and relevant metabolites, degradation and reaction products in accordance to the requirements of point 7.1.1.2 of Part A of the Annex to Regulation (EU) No 544/2011. This extrapolation is, for example, not possible for slow release formulations.
Test conditions

The rate of aerobic and/or anaerobic degradation in soil must be reported.

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

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

9.1.1.2. *Field studies*

— *Soil dissipation studies*
Aim of the test

The soil dissipation studies shall provide best-possible 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 collected.
Circumstances in which required

The dissipation and behaviour of plant protection products in soil must be investigated unless it is possible to extrapolate from data obtained on the active substance and relevant metabolites, degradation and reaction products in accordance to the requirements of point 7.1.1.2 of Part A of the Annex to Regulation (EU) No 544/2011. This extrapolation is, for example, not possible for slow-release formulations.
Test conditions and test guideline

The same provisions as provided under the corresponding paragraph of point 7.1.1.2.2 of Part A of the Annex to Regulation (EU) No 544/2011 apply.

— *Soil residue studies*
Aim of the test

Soil residue studies shall provide estimates of the soil residue levels at harvest or at time of sowing or planting succeeding crops.
Circumstances in which required

Soil residue studies must be reported unless it is possible to extrapolate from data obtained on the active substance and relevant metabolites, degradation and reaction products in accordance with the requirements of point 7.1.1.2.2 of Part A of the Annex to Regulation (EU) No 544/2011. This extrapolation is, for example, not possible for slow-release formulations.
Test conditions

The same provisions as provided under the corresponding paragraph of point 7.1.1.2.2 of Part A of the Annex to Regulation (EU) No 544/2011 apply.
Test guideline

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

— *Soil accumulation studies*
Aim of the tests

The tests shall 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

Soil accumulation studies must be reported unless it is possible to extrapolate from data obtained on the active substance and relevant metabolites, degradation and reaction products in accordance with the requirements of point 7.1.1.2.2 of Part A of the Annex to Regulation (EU) No 544/2011. This extrapolation is, for example, not possible for slow-release formulations.
Test conditions

The same provisions as provided under the corresponding paragraph of point 7.1.1.2.2 of Part A of the Annex to Regulation (EU) No 544/2011 apply.
Test guideline

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

9.1.2. *Mobility in the soil*
Aim of the test

The test shall provide sufficient data to evaluate the mobility and leaching potential of the active substance and relevant metabolites, degradation and reaction products.

9.1.2.1. *Laboratory studies*
Circumstances in which required

The mobility of plant protection products in soil must be investigated unless it is possible to extrapolate from data obtained in accordance with the requirements of points 7.1.2 and 7.1.3.1 of Part A of the Annex to Regulation (EU) No 544/2011. This extrapolation is, for example, not possible for slow-release formulations.
Test guideline

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

9.1.2.2. *Lysimeter studies or field leaching studies*
Aim of the tests

The test shall provide data on:
— the mobility of the plant protection product in soil,

— the potential for leaching to ground water,

— the potential distribution in soils.

Circumstances in which required

Expert judgement will be necessary to decide whether field leaching studies or lysimeter studies shall be carried out, taking into account the results of degradation and mobility studies and the calculated PEC_S. The type of study to be conducted shall be discussed with the competent authorities.

These studies must be performed unless it is possible to extrapolate from data obtained on the active substance and relevant metabolites, degradation and reaction products in accordance with the requirements of point 7.1.3 of Part A of the Annex to Regulation (EU) No 544/2011. This extrapolation is, for example, not possible for slow release formulations.

Test conditions

The same provisions as provided for under the corresponding paragraph of point 7.1.3.3 of Part A of the Annex to Regulation (EU) No 544/2011 apply.

9.1.3. *Estimation of expected concentrations in soil*

PEC_S estimations must relate both to a single application at the highest rate of application for which authorisation is sought, and to the maximum number and highest rates of application for which authorisation is sought, for each relevant soil tested, and are expressed in terms of mg of active substance and of relevant metabolites, degradation and reaction products per kg of soil.

The factors to 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. For the purposes of PEC_S calculations, the bulk density of soils can be assumed to be 1,5 g/cm^3 dry weight, while the depth of the soil layer is assumed to be 5 cm for applications at the soil surface and 20 cm when incorporation in the soil is involved. Where ground cover is present at time of application, it is to be assumed that 50 % (minimum) of the applied dose reaches the soil surface unless actual experimental data give more specific information.

Initial, short-term and long-term PEC_S calculations (time weighted averages) must be provided:

— initial: immediately after application,

— short-term: 24 hours, 2 days and 4 days after last application,

— long-term: 7, 28, 50 and 100 days after last application, where relevant.

9.2. *Fate and behaviour in water*

9.2.1. *Estimation of concentrations in groundwater*

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

Suitable estimations (calculations) of predicted environmental concentration in groundwater PEC_{GW}, of active substance and relevant metabolites, degradation and reaction products, must be submitted.

PEC estimations must relate to the maximum number and highest rates of application, for which authorisation is sought.

Expert judgment is required to decide if additional field tests could provide useful information. Before performing these studies the applicant shall seek the agreement of the competent authorities on the type of study to be performed.

9.2.2. *Impact on water treatment procedures*

In cases where this information is necessary, the information provided should permit to establish or to estimate effectiveness of water treatment procedures (drinking water and sewage treatment), and impact on such procedures. Before performing any studies the applicant shall seek the agreement of the competent authorities on the type of information to be provided.

9.2.3. *Estimation of concentrations in surface water*

The surface water contamination routes have to 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}, of active substance and relevant metabolites, degradation and reaction products, must be submitted.

PEC estimations must relate to the maximum number and highest rates of application, for which authorisation is sought, and be relevant to lakes, ponds, rivers, canals, streams, irrigation/ drainage canals and drains.

The factors to be considered in making PEC_{SW} 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.

Initial, short-term and long-term PEC_{SW} calculations relevant to static and slow moving water bodies (time weighted averages) must be provided:

— initial: immediately after application,

— short-term: 24 hours, 2 days and 4 days after last application,

— long-term: 7, 14, 21, 28, and 42 days after last application, where relevant.

Expert judgment is required to decide if additional field tests could provide useful information. Before performing these studies the applicant shall seek the agreement of the competent authorities on the type of study to be performed.

9.3. *Fate and behaviour in air*

Appropriate guidelines are included in the report prepared by the FOCUS[16] Working Group on Pesticides in Air: 'PESTICIDES IN AIR: CONSIDERATIONS FOR EXPOSURE ASSESSMENT (2008)'.

10. **Ecotoxicological studies**

Introduction

(i) The information provided, taken together with that for the active substance(s), must be sufficient to permit an assessment of the impact on non-target species (flora and fauna), of the plant protection product, when used as proposed. Impact can result from single, prolonged or repeated exposure, and can be reversible, or irreversible.

(ii) In particular, the information provided for the plant protection product, together with other relevant information, and that provided for the active substance, shall be sufficient to:

— specify the hazard symbols, the indications of danger, and relevant risk and safety phrases or the pictograms, signal words, relevant hazard and precautionary statements, for the protection of the environment, to be mentioned on packaging (containers),

— permit an evaluation of the short- and long-term risks for non-target species — populations, communities, and processes as appropriate,

— permit an evaluation of whether special precautions are necessary for the protection of non-target species.

(iii) There is a need to report all potentially adverse effects found during routine ecotoxicological investigations and to undertake and report such additional studies which may be necessary to investigate the mechanisms involved and assess the significance of these effects.

(iv) In general, much of the data relating to impact on non-target species, required for authorisation of plant protection products, will have been submitted and evaluated for the approval of the active substance. The information on fate and behaviour in the environment, generated and submitted in accordance with points 9.1 to 9.3, and on residue levels in plants generated and submitted in accordance with point 8 is central to the assessment of impact on non-target species, in that it provides information on the nature and extent of potential or actual exposure. The final PEC estimations are to be adapted in accordance with the different groups of organisms taking in particular into consideration the biology of the most sensitive species.

The toxicological studies and information submitted in accordance with point 7.1 provide essential information as to toxicity to vertebrate species.

(v) Where relevant, tests shall be designed and data analysed using appropriate statistical methods. Full details of the statistical analysis shall be reported (e.g. all point estimates shall be given with confidence intervals, exact p-values should be given rather than stating significant/non significant).

(vi) Whenever a study implies the use of different doses, the relationship between dose and adverse effect must be reported.

(vii) Where exposure data are necessary to decide whether a study has to be performed, the data obtained in accordance with Section 9 of this Annex shall be used.

For the estimation of exposure of organisms all relevant information on the plant protection product and on the active substance must be taken into account. A useful approach for these estimations is provided in the EPPO/Council of Europe schemes for environmental risk assessment[17]. Where relevant the parameters provided for in this Section shall be used. Where it appears from available data that the plant protection product is more toxic as the active substance, the toxicity data of the plant protection product have to be used for the calculation of relevant toxicity/exposure ratios.

(viii) In the context of the influence that impurities can have on ecotoxicological behaviour, it is essential that for each study submitted, a detailed description (specification) of the material used, as provided for under point 1.4, be provided.

(ix) In order to facilitate the assessment of the significance of test results obtained the same strain of each relevant species shall where possible be used in the various toxicity tests specified.

10.1. *Effects on birds*

Possible effects on birds must be investigated except where the possibility that birds will be exposed, directly or indirectly, can be ruled out such as for use in enclosed spaces or wound healing treatments.

The acute toxicity/exposure ratio (TER_a), the short-term dietary toxicity/exposure ratio (TER_{st}) and the long-term dietary toxicity/exposure ratio (TER_{lt}) must be reported, where:

TER_a	=	LD_{50} (mg active substance/kg body weight)/ETE (mg active substance/kg body weight)
TER_{st}	=	LC_{50} (mg active substance/kg food)/ETE (mg active substance/kg food)
TER_{lt}	=	NOEC (mg active substance/kg food)/ETE (mg active substance/kg food)

where ETE = estimated theoretical exposure.

In the case of pellets, granules or treated seeds the amount of active substance in each pellet, granule or seed must be reported as well as the proportion of the LD_{50} for the active substance in 100 particles and per gram of particles. The size and shape of pellets or granules must be reported.

In the case of baits the concentration of active substance in the bait (mg/kg) must be reported.

10.1.1. *Acute oral toxicity*
Aim of the test

The test shall provide, where possible, LD_{50} values, the lethal threshold dose, time courses of response and recovery, the NOEL, and must include relevant gross pathological findings.
Circumstances in which required

The acute oral toxicity of preparations must be reported, where TER_a or TER_{st} for the active substance(s) in birds are between 10 and 100 or where results from mammal testing give evidence of a significantly higher toxicity of the preparation compared to the active substance unless it can be justified that it is not likely that birds are exposed to the plant protection product itself.
Test conditions

The study must be conducted on the most sensitive species identified in the studies provided for in point 8.1.1 or 8.1.2 of Part A of the Annex to Regulation (EU) No 544/2011.

10.1.2. *Supervised cage or field trials*
Aim of the test

The test will provide sufficient data to evaluate the nature and the extent of the risk in practical conditions of use.
Circumstances in which required

Where the TER_a and TER_{st} are > 100 and when there is no evidence of risk from any further study on the active substance (e.g. reproduction study) no further testing is required. In the other cases, expert judgement is necessary to decide whether there is a need to carry out further studies. This expert judgement will take into account, where relevant, foraging behaviour, repellency, alternative food, actual residue content in the food, persistence of the compound in the vegetation, degradation of the formulated product or treated produce, the amount of predation of the food, acceptance of bait, granules or treated seed and the possibility for bioconcentration.

Where TER_a and $TER_{st} \leq 10$ or $TER_{lt} \leq 5$, cage or field trials must be conducted and reported unless a final assessment is possible on the basis of studies in accordance with point 10.1.3.
Test conditions

Before performing these studies the applicant shall seek the agreement of the competent authorities on the type and conditions of the study to be performed.

10.1.3. *Acceptance of bait, granules or treated seeds by birds*
Aim of the test

The test will provide sufficient data to evaluate the possibility of consumption of the plant protection product or plant products treated with it.
Circumstances in which required

In the case of seed dressings, pellets, baits and preparations which are granules and where $TER_a \leq 10$, acceptability (palatability) tests must be conducted.

10.1.4. *Effects of secondary poisoning*

Expert judgment is required to decide whether the effects of secondary poisoning shall be investigated.

10.2. *Effects on aquatic organisms*

Possible effects on aquatic species must be investigated except where the possibility that aquatic species will be exposed can be ruled out.

TER_a and TER_{lt} must be reported, where:

TER_a = acute LC_{50} (mg active substance/l)/realistic worst case PEC_{SW} (initial or short-term, in mg active substance/l)
TER_{lt} = chronic NOEC (mg active substance/l)/long-term PEC_{SW} (mg active substance/l)

10.2.1. *Acute toxicity to fish, aquatic invertebrates or effects on algal growth*
Circumstances in which required

In principle tests shall be carried out on one species from each of the three groups of aquatic organisms (fish, aquatic invertebrates and algae) as referred to in point 8.2 of Part A of the Annex to Regulation (EU) No 544/2011 in case the plant protection product itself can contaminate water. However where the available information permits to conclude that one of these groups is clearly more sensitive, tests on only the most sensitive species of the relevant group have to be performed.

The test must be performed where:

— the acute toxicity of the plant protection product can not be predicted on the basis of the data for the active substance which is especially the case if the formulation contains two or more active substances or co-formulants such as solvents, emulgators, surfactants, dispersants, fertilisers which are able to increase the toxicity in comparison with the active substance, or
— the intended use includes direct application on water,

unless suitable studies referred to under point 10.2.4 are available.
Test conditions and test guidelines

The relevant provisions as under the corresponding paragraphs of points 8.2.1, 8.2.4 and 8.2.6 of Part A of the Annex to Regulation (EU) No 544/2011 apply.

10.2.2. *Microcosm or mesocosm study*
Aim of the test

The tests must provide sufficient data to evaluate the essential impact on aquatic organisms under field conditions.
Circumstances in which required

Where $TER_a \leq 100$ or where $TER_{lt} \leq 10$, expert judgment must be used to decide whether a microcosm or mesocosm study is appropriate. This judgment will take into account the results of any additional data over and above those required by the provisions of points 8.2 and 10.2.1 of Part A of the Annex to Regulation (EU) No 544/2011.

Test conditions

Before performing these studies the applicant shall seek the agreement of the competent authorities on the specific aims of the study to be performed and consequently on the type and conditions of the study to be performed.

The study shall include at least the highest likely exposure rate, whether from direct application, drift, drainage or run-off. The duration of the study must be sufficient to permit evaluation of all effects.

Test guideline

Appropriate guidelines are included in:

SETAC — Guidance document on testing procedures for pesticides in freshwater mesocosms/ Workshop Huntingdon, 3 and 4 July 1991

or

Freshwater field tests for hazard assessment of chemicals — European Workshop on Freshwater Field Tests (EWOFFT).

10.2.3. *Residue data in fish*

Aim of the test

The test will provide sufficient data to evaluate the potential for occurrence of residues in fish.

Circumstances in which required

In general data are available from bioconcentration studies in fish.

Where bioconcentration has been observed in the study performed in accordance with point 8.2.3 of Part A of the Annex to Regulation (EU) No 544/2011, expert judgement is required to decide whether a long-term microcosm or mesocosm study has to be carried out in order to establish the maximum residues likely to be encountered.

Test guideline

SETAC — Guidance document on testing procedures for pesticides in freshwater mesocosms/ Workshop Huntingdon, 3 and 4 July 1991.

10.2.4. *Additional studies*

The studies referred to in points 8.2.2 and 8.2.5 of Part A of the Annex to Regulation (EU) No 544/2011 may be required for particular plant protection products where it is not possible to extrapolate from data obtained in the corresponding studies on the active substance.

10.3. *Effects on terrestrial vertebrates other than birds*

Possible effects on wild vertebrate species must be investigated except where it can be justified that it is not likely that terrestrial vertebrates other than birds are exposed, directly or indirectly. TER_a, TER_{st} and TER_{lt} must be reported, where:

TER_a = LD_{50} (mg active substance/kg body weight)/ETE (mg active substance/ kg body weight)

TER_{st} = subchronic NOEL (mg active substance/kg food)/ETE (mg active substance/kg food)

TER_{lt} = chronic NOEL (mg active substance/kg food)/ETE (mg active substance/kg food)

where ETE = estimated theoretical exposure.

In principle the evaluation sequence for the assessment of risks to such species is similar to that for birds. In practice it is not often necessary to perform further testing as the studies conducted in accordance with the requirements of Section 5 of the Annex to Regulation (EU) No 544/2011 and Section 7 of this Annex would provide the required information.

Aim of the test

The test will provide sufficient information to evaluate the nature and the extent of risks for terrestrial vertebrates other than birds in practical conditions of use.

Circumstances in which required

Where TER_a and $TER_{st} > 100$ and where there is no evidence of risk from any further study no further testing is required. In the other cases, expert judgment is necessary to decide whether there is a need to carry out further studies. This expert judgment will take into account, where relevant, foraging behaviour, repellency, alternative food, actual residue content in the food, persistence of the compound in the vegetation, degradation of the formulated product or treated produce, the amount of predation of the food, acceptance of bait, granules or treated seed and the possibility for bioconcentration.

Where TER_a and $TER_{st} \leq 10$ or $TER_{lt} \leq 5$ cage or field trials or other appropriate studies must be reported.

Test conditions

Before performing these studies the applicant shall seek the agreement of the competent authorities on the type and conditions of the study to be performed and whether the effects of secondary poisoning shall be investigated.

10.4. *Effects on bees*

The possible effects on bees must be investigated except where the product is for exclusive use in situations where bees are not likely to be exposed such as:

— food storage in enclosed spaces,
— non-systemic seed dressings,
— non-systemic preparations for application to soil,
— non-systemic dipping treatments for transplanted crops and bulbs,
— wound sealing and healing treatments,
— rodenticidal baits,
— use in glasshouses without pollinators.

The hazard quotients for oral and contact exposure (Q_{HO} and Q_{HC}), must be reported:

Q_{HO} = dose/oral LD_{50} (µg active substance per bee)
Q_{HC} = dose/contact LD_{50} (µg active substance per bee)

where:

dose = the maximum application rate, for which authorisation is sought, in g of active substance per hectare.

10.4.1. *Acute oral and contact toxicity*

Aim of the test

The test shall provide the LD_{50} values (by oral and contact exposure).
Circumstances in which required

Testing is required if:
— the product contains more than one active substance,
— the toxicity of a new formulation cannot be reliably predicted to be either the same or lower than a formulation tested in accordance with the provisions of point 8.3.1.1 of Part A of the Annex to Regulation (EU) No 544/2011 or of this point.
Test guideline

The test must be carried out in accordance with EPPO Guideline 170.

10.4.2. *Residue test*
Aim of the test

The test shall provide sufficient information to evaluate possible risks to foraging bees from residual traces of plant protection products remaining on crops.
Circumstances in which required

Where $Q_{HC} \geq 50$, expert judgment is required to decide whether the effect of residues must be determined unless there is evidence that there are no significant residual traces remaining on crops which could affect foraging bees or unless sufficient information is available from cage, tunnel or field tests.
Test conditions

The median lethal time (LT_{50}) (in hours) following 24-hour exposure to residues on leaves aged during 8 hours must be determined, and reported. Where LT_{50} is more than 8 hours, no further testing is required.

10.4.3. *Cage tests*
Aim of the test

The test shall provide sufficient information to evaluate possible risks from the plant protection product for bee survival and behaviour.
Circumstances in which required

Where Q_{HO} and Q_{HC} are < 50, further testing is not required except if significant effects are observed in the bee brood feeding test or if there are indications for indirect effects such as delayed action or modification of bee behaviour, in those cases cage and/or field tests shall be carried out.

Where Q_{HO} and Q_{HC} are > 50, cage and/or field testing is required.

Where field testing is conducted and reported in accordance with point 10.4.4, it is not necessary to conduct cage tests. However, cage tests where conducted, must be reported.
Test conditions

The test shall be carried out using healthy bees. If bees have been treated, e.g. with a varroacide, it is necessary to wait for 4 weeks before using the colony.
Test guideline

The tests must be conducted in accordance with EPPO Guideline 170.

10.4.4. *Field tests*
Aim of the test

The test shall provide sufficient information to evaluate possible risks from the plant protection product on bee behaviour, colony survival and development.
Circumstances in which required

Field tests must be conducted where on the basis of expert judgement, taking into account the proposed manner of use and the fate and behaviour of the active substance, significant effects are observed in cage testing.
Test conditions

The test shall be carried out using healthy honeybee colonies of similar natural strength. If bees have been treated, e.g. with a varroacide, it is necessary to wait for 4 weeks before using the colony. The tests shall be conducted under conditions reasonably representative of the proposed use.

Special effects (larval toxicity, long residual effect, disorienting effects on bees) identified by the field tests may require further investigation using specific methods.
Test guideline

The tests must be conducted in accordance with EPPO Guideline 170.

10.4.5. *Tunnel tests*
Aim of the test

The test shall provide sufficient information to evaluate the impact on bees resulting from feeding on contaminated honey dew or flowers.
Circumstances in which required

Where it is not possible to investigate certain effects in cage or field trials, a tunnel test shall be carried out, e.g. in the case of plant protection products intended for control of aphids and other sucking insects.
Test conditions

The test shall be carried out using healthy bees. If bees have been treated, e.g. with a varroacide, it is necessary to wait for 4 weeks before using the colony.
Test guideline

The test must be carried out in accordance with EPPO Guideline 170.

10.5. *Effects on arthropods other than bees*

The effects of plant protection products on non-target terrestrial arthropods (e.g. predators or parasitoids of harmful organisms) must be investigated. The information obtained for these species can also be used to indicate the potential for toxicity to non-target species inhabiting the same environment.

10.5.1. *Laboratory, extended laboratory and semi-field tests*
Aim of the test

The test shall provide sufficient information to evaluate the toxicity of the plant protection product for selected arthropod species that are relevant to the intended use of the product.
Circumstances in which required

Testing is not required where severe toxicity (> 99 % effect on the organisms compared to control) can be predicted from relevant available data or where the plant protection product is for exclusive use in situations where non-target arthropods are not exposed such as:

— food storage in enclosed spaces,

— wound sealing and healing treatments,

— rodenticidal baits.

Testing is required when significant effects on the organisms in comparison with the control are reported in the laboratory tests at the maximum recommended dose, conducted in accordance with the requirements of point 8.3.2 of Part A of the Annex to Regulation (EU) No 544/2011. Effects on a particular test species are considered to be significant when they exceed the threshold values as defined in the EPPO schemes for the environmental risk assessment unless species-specific threshold values are defined in the respective test guidelines.

Testing is also required if:

— the product contains more than one active substance,

— the toxicity of a new formulation cannot be reliably predicted to be either the same or lower than a formulation tested in accordance with the provisions of point 8.3.2 of Part A of the Annex to Regulation (EU) No 544/2011 or of this point,

— on the basis of the proposed manner of use or on the basis of the fate and behaviour continued or repeated exposure can be anticipated,

— there is a significant change in the proposed use, e.g. from arable crops to orchards, and species relevant to the new use have not previously been tested,

— there is an increase in the recommended application rate, above that previously tested under the Annex to Regulation (EU) No 544/2011.

Test conditions

Where significant effects were observed in the studies performed in accordance with the requirements of point 8.3.2 of Part A of the Annex to Regulation (EU) No 544/2011 or in the case of change of use such as arable crops to orchards, the toxicity of two additional relevant species must be investigated and reported. These must be different to the relevant species already tested under point 8.3.2 of Part A of the Annex to Regulation (EU) No 544/2011.

For a new mixture or formulation, the toxicity shall initially be assessed using the two most sensitive species as identified in studies already performed for which the threshold values were exceeded but effects still remain below 99 %. This will enable a comparison to be made; if it is significantly more toxic two species relevant to its proposed use must be tested.

Testing must be conducted at a rate equivalent to the maximum rate of application for which authorisation is sought. A sequential testing approach shall be adopted, i.e. laboratory, and if necessary extended laboratory and/or semi-field.

Where there will be more than one application per season, the product shall be applied at twice the recommended application rate unless this information is already available from studies performed in accordance with point 8.3.2 of Part A of the Annex to Regulation (EU) No 544/2011.

Where on the basis of the proposed manner of use or on the basis of the fate and behaviour continued or repeated exposure can be anticipated (such as the product is to be applied more than three times per season with a re-application of 14 days or less), expert judgment is required to examine whether further testing is required, beyond initial laboratory testing, which will reflect the proposed use pattern. These tests may be performed in the laboratory or under semi-field conditions. When the test is done in the laboratory a realistic substrate such as plant material or a natural soil shall be used. However it may be more appropriate to carry out field tests.

Test guideline

Where relevant testing shall be done in accordance with appropriate guidelines which satisfy at least the requirements for testing as included in SETAC — Guidance document on regulatory testing procedures for pesticides with non-target arthropods.

10.5.2. *Field tests*
Aim of the test

The tests shall provide sufficient information to evaluate the risk of the plant protection product for arthropods under field conditions.
Circumstances in which required

Where significant effects are seen following laboratory and semi-field exposure, or where on the basis of the proposed manner of use or on the basis of the fate and behaviour continued or repeated exposure can be anticipated expert judgment is required to examine whether more extensive testing is necessary to permit an accurate risk assessment.
Test conditions

The tests must be conducted under representative agricultural conditions and in accordance with the proposed recommendations for use, resulting in a realistic worst case study.

A toxic standard shall be included in all tests.
Test guideline

Where relevant testing shall be done in accordance with appropriate guidelines which satisfy at least the requirements for testing as included in SETAC — Guidance document on regulatory testing procedures for pesticides with non-target arthropods.

10.6. *Effects on earthworms and other soil non-target macro-organisms, believed to be at risk*

10.6.1. *Effects on earthworms*

The possible impact on earthworms must be reported except where it can be justified that it is not likely that earthworms are exposed, directly or indirectly.

TER_a and TER_{lt} must be reported where:

TER_a = LC_{50} (mg active substance/kg)/realistic worst case PEC_S (initial or short-term, in mg active substance/kg)
TER_{lt} = NOEC (mg active substance/kg)/long-term PEC_S (mg active substance/kg).

10.6.1.1. *Acute toxicity tests*
Aim of the test

The test shall provide the LC_{50}, where possible the highest concentration causing no mortality and the lowest concentration causing 100 % mortality and must include observed morphological and behavioural effects.
Circumstances in which required

These studies are only required where:
— the product contains more than one active substance,
— the toxicity of a new formulation cannot be reliably predicted from the formulation tested in accordance with the provisions of point 8.4 of Part A of the Annex to Regulation (EU) No 544/2011 or of this point.

Test guideline

The tests must be conducted in accordance to OECD Method 207.

10.6.1.2. *Tests for sublethal effects*
Aim of the test

The test shall provide the NOEC and the effects on growth, reproduction and behaviour.
Circumstances in which required

These studies are only required where:

— the product contains more than one active substance,

— the toxicity of a new formulation cannot be reliably predicted from the formulation tested in accordance with the provisions of point 8.4 of Part A the Annex to Regulation (EU) No 544/2011 or of this point,

— there is an increase in the recommended application rate, above that previously tested.

Test conditions

The same provisions as under the corresponding paragraphs of point 8.4.2 of Part A of the Annex to Regulation (EU) No 544/2011 apply.

10.6.1.3. *Field studies*
Aim of the test

The test shall provide sufficient data to evaluate the effects on earthworms in field conditions.
Circumstances in which required

Where $TER_{lt} < 5$ a field study to determine effects under practical field conditions must be conducted and reported.

Expert judgment is required to decide whether residue contents of earthworms shall be investigated.
Test conditions

Fields selected shall have a reasonable earthworm population.

The test must be carried out at the maximum proposed application rate. A toxic reference product must be included in the test.

10.6.2. *Effects on other soil non-target macro-organisms*
Aim of the test

The test shall provide sufficient data to evaluate the impact of the plant protection product on macro-organisms that contribute to the breakdown of dead plant and animal organic matter.
Circumstances in which required

Testing is not required where in accordance with point 9.1 of this Annex, it is evident that DT_{90} values are less than 100 days, or the nature and manner of use of the plant protection product are such that exposure does not occur or when data from studies on the active substance performed in accordance with the provisions of points 8.3.2, 8.4 and 8.5 of Part A of the Annex to Regulation (EU) No 544/2011, indicate that there is no risk for soil macrofauna, earthworms or soil microflora.

Impact on organic matter breakdown must be investigated and reported, where the DT_{90f} values determined in field dissipation studies (point 9.1) are > 365 days.

10.7. *Effects on soil non-target micro-organisms*

10.7.1. *Laboratory testing*
Aim of the test

The test shall provide sufficient data to evaluate the impact of the plant protection product on soil microbial activity in terms of nitrogen transformation and carbon mineralisation.
Circumstances in which required

Where the DT_{90f} values determined in field dissipation studies (point 9.1) are > 100 days, impact on soil non-target micro-organisms must be investigated through laboratory testing. Testing is, however, not required if in the studies performed in accordance with the provisions of point 8.5 of Part A of the Annex to Regulation (EU) No 544/2011, deviations from control values in terms of metabolic activity of the microbial biomass after 100 days is < 25 %, and such data are relevant to the uses, nature, and properties of the particular preparation to be authorised.
Test guideline

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

10.7.2. *Additional testing*
Aim of the test

The test shall provide sufficient data to evaluate the impact of the plant protection product under field conditions on microbial activity.
Circumstances in which required

Where at the end of 100 days, measured activity deviates by more than 25 % from the control, in the laboratory testing further testing in the laboratory, under glass and/or in the field may be necessary.

10.8. *Available data from biological primary screening in summary form*

A summary of available data from preliminary tests used to assess the biological activity and dose range finding whether positive or negative, which provides information with respect to possible impact on non-target species, both flora and fauna, must be provided, together with a critical assessment as to its relevance to potential impact on non-target species.

11. Summary and evaluation of Sections 9 and 10

A summary and evaluation of all data presented in Sections 9 and 10 shall be carried out in accordance with the guidance given by the competent authorities of the Member States concerning the format of such summaries and evaluations. It shall include a detailed and critical assessment of those data in the context of relevant evaluative and decision making criteria and guidelines, with particular reference to the risks for the environment and non-target species that may or do arise, and the extent, quality and reliability of the data base. In particular the following issues shall be addressed:

— predicting distribution and fate in the environment, and the time courses involved,
— identifying non-target species and populations at risk, and predicting the extent of potential exposure,
— evaluation as to the short- and long-term risks for non-target species — populations, communities, and processes — as appropriate,
— evaluation as to the risk of fish kills, and fatalities in large vertebrates, or terrestrial predators, regardless of effects at population or community level, and
— identification of precautions necessary to avoid or minimise contamination of the environment, and for the protection of non-target species.

12. Further information

12.3. *Proposals including justification for the classification and labelling proposed in accordance with Regulation (EC) No 1272/2008 and Directive 1999/45/EC*

— hazard symbol(s) or hazard pictograms,
— indications of danger or signal words,
— risk phrases or hazard statements,
— safety phrases or precautionary statements.

12.4. *Proposals for risk and safety in accordance with the requirements of Article 65 of Regulation (EC) No 1107/2009 and of Commission Regulation (EU) No 547/2011*[18] *and proposed label.*

PART B

PREPARATIONS OF MICRO-ORGANISMS INCLUDING VIRUSES

Introduction

(i) This Part provides data requirements for the authorisation of a plant protection product based on preparations of micro-organisms including viruses.

The term 'micro-organism' as defined in the introduction to Part B of the Annex to Regulation (EU) No 544/2011, also applies to the Part B of this Annex.

(ii) Where relevant, data shall be analysed using appropriate statistical methods. Full details of the statistical analysis shall be reported (e.g. all point estimates shall be given with confidence intervals, exact p-values should be given rather than stating significant/non significant).

(iii) Pending the acceptance of specific guidelines at international level, the information required shall be generated using test guidelines accepted by the competent authority (e.g. USEPA guideline[19]); where appropriate test guidelines as described in Part A of the Annex to Regulation (EU) No 544/2011, shall be adapted in such a way that they are appropriate for micro-organisms. Testing shall include viable and, if appropriate, non-viable micro-organisms, and a blank control.

(iv) Whenever a study implies the use of different doses, the relationship between dose and adverse effect must be reported.

(v) Where testing is done, a detailed description (specification) of the material used and its impurities, in accordance with the provisions of point 1.4, must be provided.

(vi) In cases where a new preparation is to be dealt with, extrapolation from Part B of the Annex to Regulation (EU) No 544/2011, could be acceptable, provided that all the possible effects of the co-formulants and other components, especially on pathogenicity and infectiveness, are also evaluated.

1. Identity of the plant protection product

The information provided, taken together with that provided for the micro-organism(s), must be sufficient to precisely identify and define preparations. The information and data referred to, unless otherwise specified, are required for all plant protection products. This is with the view to identify if any factor could alter the properties of the micro-organism as a plant protection product in comparison to the micro-organism as such, which is treated in Part B of the Annex to Regulation (EU) No 544/2011.

1.1. *Applicant*

The name and address of the applicant must be provided as must the name, position, telephone and fax number of the appropriate person to contact.

Where, in addition, the applicant has an office, agent or representative in the Member State in which the authorisation is being sought, the name and address of the local office, agent or

representative shall be provided, as shall the name, position, telephone and fax number of the appropriate person to contact.

1.2. *Manufacturer of the preparation and the micro-organism(s)*

The name and address of the manufacturer of the preparation and of each micro-organism in the preparation must be provided as must the name and address of each manufacturing plant in which the preparation and micro-organism are manufactured.

A contact point (preferable a central contact point, to include name, telephone and fax numbers) must be provided for each manufacturer.

If the micro-organism originates from a producer from which data in accordance with Part B of the Annex to Regulation (EU) No 544/2011 had not been submitted previously, detailed information on the name and species description, as required in point 1.3 of Part B of the Annex to Regulation (EU) No 544/2011 and on impurities, as required in point 1.4 of Part B of the Annex to Regulation (EU) No 544/2011 have to be provided.

1.3. *Trade name or proposed trade name, and manufacturer's development code number of the preparation if appropriate*

All former and current trade names and proposed trade names and development code numbers of the preparation referred to in the dossier as well as the current names and numbers must be provided. Full detail of any differences must be provided. (The proposed trade name must not give rise to confusion with the trade name of already authorised plant protection products.)

1.4. *Detailed quantitative and qualitative information on the composition of the preparation*

(i) Each micro-organism that is subject to the application shall be identified and named at the species level. The micro-organism shall be deposited at a recognised culture collection and given an accession number. The scientific name must be stated, as well as the group assignment (bacteria, virus, etc.) and any other denomination relevant to the micro-organism (e.g. strain, serotype). In addition, the development phase of the micro-organism (e.g. spores, mycelium) in the marketed product shall be stated.

(ii) For preparations the following information must be reported:

— the content of the micro-organism(s) in the plant protection product and the content of the micro-organism in the material used for manufacturing of plant protection products. These must include the maximum, minimum and nominal content of the viable and non-viable material,

— the content of co-formulants,

— the content of other components (such as by-products, condensates, culture medium, etc.) and contaminating micro-organisms, derived from production process.

The contents shall be expressed in terms as provided for in Directive 1999/45/EC for chemicals and appropriate terms for micro-organisms (number of active units per volume or weight or any other manner that is relevant to the micro-organism).

(iii) Co-formulants must where possible, be identified either by their International Chemical Identification as given in Annex VI to Regulation (EC) No 1272/2008, or, if not included in that Regulation, in accordance with both IUPAC and CA nomenclature. Their structure or structural formula must be provided. For each component of the co-formulants the relevant EC (Einecs or ELINCS) number and CAS number where they exist, must be provided. Where the information provided does not fully identify

a co-formulant, an appropriate specification must be provided. The trade name of co-formulants, where they exist, must also be provided.

(iv) For co-formulants the function must be given:

— adhesive (sticker),
— antifoaming agent,
— antifreeze,
— binder,
— buffer,
— carrier,
— deodorant,
— dispersing agent,
— dye,
— emetic,
— emulsifier,
— fertiliser,
— odorant,
— perfume,
— preservative,
— propellant,
— repellent,
— safener,
— solvent,
— stabiliser,
— synergist,
— thickener,
— wetting agent,
— miscellaneous (specify).

(v) Identification of contaminating micro-organisms and other components derived from production process.

Contaminating micro-organisms must be identified as outlined in point 1.3 of Part B of the Annex to Regulation (EU) No 544/2011.

Chemicals (inert components, by-products, etc.) must be identified as outlined in point 1.10 of Part A of the Annex to Regulation (EU) No 544/2011.

Where the information provided does not fully identify a component, such as condensate, culture medium, etc. detailed information on the composition must be provided for each such component.

1.5. *Physical state and nature of the preparation*

The type and code of preparation must be designated in accordance with the ‘Catalogue of pesticide formulation types and international coding system (GIFAP Technical Monograph No 2, 1989)’.

Where a particular preparation is not defined precisely in that catalogue, a full description of the physical nature and state of the preparation must be provided, together with a proposal for a suitable description of the type of preparation and a proposal for its definition.

1.6. *Function*

The biological function must be specified from among the following:

— control of bacteria,
— control of fungi,
— control of insects,
— control of mites,
— control of molluscs,
— control of nematodes,
— control of weeds,
— other (must be specified).

2. Physical, chemical and technical properties of the plant protection product

The extent to which plant protection products for which authorisation is sought comply with relevant FAO specifications, as agreed by the Group of Experts on Pesticide Specification of the FAO Panel of Experts on Pesticide Specifications, Registration Requirements and Application Standards, must be stated. Divergences from FAO specifications must be described in detail, and justified.

2.1. *Appearance (colour and odour)*

A description of both the colour and odour, if any, and the physical state of the preparation, must be provided.

2.2. *Storage stability and shelf-life*

2.2.1. *Effects of light, temperature and humidity on technical characteristics of the plant protection product*

(i) The physical and biological stability of the preparation at the recommended storage temperature including information on the growth of contaminating micro-organisms must be determined and reported. The conditions under which the test has been performed must be justified.

(ii) Additionally in the case of liquid preparations, the effect of low temperatures on physical stability, must be determined and reported in accordance with CIPAC Methods MT 39, MT 48, MT 51 or MT 54 as appropriate.

(iii) The shelf life of the preparation at the recommended storage temperature must be reported. Where shelf life is less than 2 years, the shelf life in months, with appropriate temperature specifications, must be reported. Useful information is given in GIFAP Monograph No 17.

2.2.2. *Other factors affecting stability*

Effect of exposure to air, packaging, etc. on the product stability must be explored.

2.3. *Explosivity and oxidising properties*

Explosivity and oxidising properties will be determined as defined in point 2.2 of Part A of this Annex, unless it can be justified that it is technically or scientifically not necessary to perform such studies.

2.4. *Flash point and other indications of flammability or spontaneous ignition*

Flash point and flammability must be determined, as defined in point 2.3 of Part A of this Annex, unless it can be justified that it is technically or scientifically not necessary to perform such studies.

2.5. *Acidity, alkalinity and if necessary pH value*

Acidity, alkalinity and pH will be determined as defined in point 2.4 of Part A of this Annex, unless it can be justified that it is technically or scientifically not necessary to perform such studies.

2.6. *Viscosity and surface tension*

Viscosity and surface tension will be determined as defined in point 2.5 of Part A of this Annex, unless it can be justified that it is technically or scientifically not necessary to perform such studies.

2.7. *Technical characteristics of the plant protection product*

The technical characteristics of the preparation must be determined to permit a decision to be made as to its acceptability. If tests have to be performed, they must be done at temperatures compatible with survival of the micro-organism.

2.7.1. *Wettability*

The wettability of solid preparations which are diluted for use (e.g. wettable powders and water dispersible granules), must be determined and reported in accordance with CIPAC Method MT 53.3.

2.7.2. *Persistent foaming*

The persistence of foaming of preparations to be diluted with water, must be determined and reported in accordance with CIPAC Method MT 47.

2.7.3. *Suspensibility and suspension stability*

— The suspensibility of water dispersible products (e.g. wettable powders, water dispersible granules, suspension concentrates) must be determined and reported in accordance with CIPAC Method MT 15, MT 161 or MT 168 as appropriate.

— The spontaneity of dispersion of water dispersible products (e.g. suspension concentrates and water dispersible granules) must be determined and reported in accordance with CIPAC Method MT 160 or MT 174 as appropriate.

2.7.4. *Dry sieve test and wet sieve test*

In order to ensure that dustable powders have a suitable particle size distribution for ease of application, a dry sieve test must be conducted and reported in accordance with CIPAC Method MT 59.1.

In the case of water dispersible products, a wet sieve test must be conducted and reported in accordance with CIPAC Method MT 59.3 or MT 167 as appropriate.

2.7.5. *Particle size distribution (dustable and wettable powders, granules), content of dust/fines (granules), attrition and friability (granules)*

(i) The size distribution of particles in the case of powders, must be determined and reported in accordance with OECD Method 110.

The nominal size range of granules for direct application must be determined and reported in accordance with CIPAC MT 58.3, for water dispersible granules in accordance with CIPAC MT 170.

(ii) The dust content of granular preparations, must be determined and reported in accordance with CIPAC Method MT 171. If relevant for operator exposure the particle size of dust must be determined and reported in accordance with OECD Method 110.

(iii) The friability and attrition characteristics of granules, must be determined and reported once internationally agreed methods are available. Where already data are available they must be reported together with the method used.

2.7.6. *Emulsifiability, re-emulsifiability, emulsion stability*

(i) The emulsifiability, emulsion stability and re-emulsifiability of preparations which form emulsions, must be determined and reported in accordance with CIPAC Method MT 36 or MT 173 as appropriate.

(ii) The stability of dilute emulsions and of preparations which are emulsions, must be determined and reported in accordance with CIPAC Method MT 20 or MT 173.

2.7.7. *Flowability, pourability (rinsability) and dustability*

(i) The flowability of granular preparations must be determined and reported in accordance with CIPAC Method MT 172.

(ii) The pourability (including rinsed residue) of suspensions (e.g. suspension concentrates, suspo-emulsions), must be determined and reported in accordance with CIPAC Method MT 148.

(iii) The dustability of dustable powders must be determined and reported in accordance with CIPAC Method MT 34 or another suitable method.

2.8. *Physical, chemical and biological compatibility with other products including plant protection products with which its use is to be authorised*

2.8.1. *Physical compatibility*

The physical compatibility of recommended tank mixes must be determined and reported.

2.8.2. *Chemical compatibility*

The chemical compatibility of recommended tank mixes must be determined and reported except where examination of the individual properties of the preparations would establish beyond reasonable doubt that there is no possibility of reaction taking place. In such cases it is sufficient to provide that information as justification for not practically determining the chemical compatibility.

2.8.3. *Biological compatibility*

The biological compatibility of tank mixes must be determined and reported. Effects (e.g. antagonism, fungicidal effects) on the activity of the micro-organism after mixing with other micro-organisms or chemicals must be described. The possible interaction of the plant protection product with other chemical products to be applied on the crops under the expected condition of use of the preparation shall be investigated, based on the efficacy data. Intervals between application of the biological pesticide and chemical pesticides shall be specified, if appropriate, in order to avoid loss of efficacy.

2.9. *Adherence and distribution to seeds*

In the case of preparations for seed treatment, both distribution and adhesion must be investigated and reported; in the case of distribution in accordance with CIPAC Method MT 175.

3. **Data on application**

3.1. *Field of use envisaged*

The field(s) of use, existing and proposed, for preparations containing the micro-organism must be specified from among the following:

— field use, such as agriculture, horticulture, forestry and viticulture,
— protected crops (e.g. in glasshouses),
— amenity,
— weed control on non-cultivated areas,
— home gardening,
— house plants,
— stored products,
— other (specify).

3.2. *Mode of action*

The way by which uptake of the product may occur (e.g. contact, stomach, inhalation) or the pest controlling action (fungitoxic, fungistatic action, nutrient competition, etc.) must be stated.

It must also be stated whether or not the product is translocated in plants and, where relevant, if such translocation is apoplastic, symplastic or both.

3.3. *Details of intended use*

Details of the intended use, e.g. types of harmful organisms controlled and/or plants or plant products to be protected, must be provided.

Intervals between the application of the plant protection product containing micro-organisms and chemical pesticides, or a list with active substances of chemical plant protection products not to be used together with the plant protection product containing micro-organisms on the same crop, shall also be provided.

3.4. *Application rate*

For each method of application and each use, the rate of application per unit (ha, m^2, m^3) treated, in terms of g or kg or l for the preparation and in terms of appropriate units for the micro-organism, must be provided.

Application rates shall normally be expressed in g or kg/ha or in kg/m^3 and where appropriate in g or kg/tonne; for protected crops and home gardening use rates shall be expressed in g or kg/100 m^2 or g or kg/m^3.

3.5. *Content of micro-organism in material used (e.g. in the diluted spray, baits or treated seed)*

The content of micro-organism shall be reported, as appropriate, in number of active unit/ml or g or any other relevant unit.

3.6. *Method of application*

The method of application proposed must be described fully, indicating the type of equipment to be used, if any, as well as the type and volume of diluent to be used per unit of area or volume.

3.7. *Number and timing of applications and duration of protection*

The maximum number of applications to be used and their timing, must be reported. Where relevant the growth stages of the crop or plants to be protected and the development stages of the harmful organisms, must be indicated. Where possible and necessary the interval between applications, in days, must be stated.

The duration of protection afforded both by each application and by the maximum number of applications to be used, must be indicated.

3.8. *Necessary waiting periods or other precautions to avoid phytopathogenic effects on succeeding crops*

Where relevant, minimum waiting periods between last application and sowing or planting of succeeding crops, which are necessary to avoid phytopathogenic effects on succeeding crops, must be stated, and follow from the data provided under Section 6, point 6.6.

Limitations on choice of succeeding crops, if any, must be stated.

3.9. *Proposed instructions for use*

The proposed instructions for use of the preparation, to be printed on labels and leaflets, must be provided.

4. **Further information on the plant protection product**

4.1. *Packaging and compatibility of the preparation with proposed packaging materials*

(i) Packaging to be used must be fully described and specified in terms of the materials used, manner of construction (e.g. extruded, welded, etc.), size and capacity, size of opening, type of closure and seals. It must be designed in accordance with the criteria and guidelines specified in the FAO ‘Guidelines for the Packaging of Pesticides’.

(ii) The suitability of the packaging, including closures, in terms of its strength, leakproofness and resistance to normal transport and handling, must be determined and reported in accordance with ADR methods 3552, 3553, 3560, 3554, 3555, 3556, 3558, or appropriate ADR Methods for intermediate bulk containers, and, where for the preparation child-resistant closures are required, in accordance with ISO standard 8317.

(iii) The resistance of the packaging material to its contents must be reported in accordance with GIFAP Monograph No 17.

4.2. *Procedures for cleaning application equipment*

Cleaning procedures for both application equipment and protective clothing must be described in detail. The effectiveness of the cleaning procedure must be determined, using e.g. biotests, and reported.

4.3. *Re-entry periods, necessary waiting periods or other precautions to protect man, livestock and the environment*

The information provided must follow from and be supported by the data provided for the micro-organism(s) and that provided under Sections 7 and 8.

(i) Where relevant pre-harvest intervals, re-entry periods or withholding periods necessary to minimise the presence of residues in or on crops, plants and plant products, or in treated areas or spaces, with a view to protecting man or livestock, must be specified e.g.:

— pre-harvest interval (in days) for each relevant crop,

— re-entry period (in days) for livestock, to areas to be grazed,

— re-entry period (in hours or days) for man to crops, buildings or spaces treated,

— withholding period (in days) for animal feedingstuffs,

— waiting period (in days), between application and handling treated products.

(ii) Where necessary, in the light of the test results, information on any specific agricultural, plant health or environmental conditions under which the preparation may or may not be used must be provided.

4.4. *Recommended methods and precautions concerning: handling, storage, transport or fire*

The recommended methods and precautions concerning handling procedures (detailed) for the storage, at both warehouse and user level of plant protection products, for their transport and in the event of fire must be provided. Where relevant, information on combustion products must be provided. The risks likely to arise and the methods and procedures to minimise the hazards arising, must be specified. Procedures to preclude or minimise the generation of waste or leftovers must be provided.

Where relevant, assessment has to be done in accordance with ISO TR 9122.

The nature and characteristics of protective clothing and equipment proposed must be provided. The data provided must be sufficient to evaluate the suitability and effectiveness under realistic conditions of use (e.g. field or glasshouse circumstances).

4.5. *Measures in the case of an accident*

Whether arising during transport, storage or use, detailed procedures to be followed in the event of an accident, must be provided and include:

— containment of spillages,

— decontamination of areas, vehicles and buildings,

— disposal of damaged packaging, adsorbents and other materials,

— protection of emergency workers and bystanders,

— first aid measures.

4.6. *Procedures for destruction or decontamination of the plant protection product and its packaging*

Procedures for destruction and decontamination must be developed for both small quantities (user level) and large quantities (warehouse level). The procedures must be consistent with provisions in place relating to the disposal of waste and of toxic waste. The means of disposal proposed shall be without unacceptable influence on the environment and be the most cost effective and practical means of disposal feasible.

4.6.1. *Controlled incineration*

In many cases the preferred or sole means to safely dispose of plant protection products and in particular the co-formulants contained in it, contaminated materials, or contaminated packaging, is through controlled incineration in a licensed incinerator.

The applicant must provide detailed instructions for safe disposal.

4.6.2. *Others*

Other methods to dispose of plant protection products, packaging and contaminated materials, where proposed, must be fully described. Data must be provided for such methods, to establish their effectiveness and safety.

5. Analytical methods

Introduction

The provisions of this Section only cover analytical methods required for post-registration control and monitoring purposes.

It is desirable to have a plant protection product without contaminants, if possible. The level of acceptable contaminants shall be judged from a risk assessment point of view, by the competent authority.

Both production and product must be subject to a continuous quality control by the applicant. The quality criteria for the product shall be submitted.

For analytical methods used for generation of data as required in this Regulation or for other purposes the applicant has to provide a justification for the method used; where necessary separate guidance will be developed for such methods on the basis of the same requirements as defined for methods for post-registration control and monitoring purposes.

Descriptions of methods must be provided and include details of equipment, materials and conditions used. The applicability of existing CIPAC methods must be reported.

As far as practicable these methods must employ the simplest approach, involve the minimum cost, and require commonly available equipment.

For this Section the following applies:

Impurities, metabolites, relevant metabolites, residues	As defined in Article 3 of Regulation (EC) No 1107/2009
Relevant impurities	Impurities, as defined above, that are of concern for human or animal health and/or the environment

On request the following samples must be provided:

(i) samples of the preparation;

(ii) samples of the micro-organism as manufactured;

(iii) analytical standards of the pure micro-organism;

(iv) analytical standards of relevant metabolites and all other components included in the residue definition;

(v) if available, samples of reference substances for the relevant impurities.

5.1. *Methods for the analysis of the preparation*

— Methods, which must be described in full, must be provided for the identification and the determination of the content of the micro-organism in the preparation. In the

case of a preparation containing more than one micro-organism, methods capable of identifying and determining the content of each one should be provided.

— Methods to establish regular control of the final product (preparation) in order to show that it does not contain other organisms than the indicated ones and to establish its uniformity.

— Methods to identify any contaminating micro-organisms of the preparation.

— Methods used to determine the storage stability and shelf life of the preparation must be provided.

5.2. *Methods to determine and quantify residues*

Analytical methods for the determination of residues, as defined in point 4.2 of Part B of the Annex to Regulation (EU) No 544/2011 must be submitted unless it is justified that the information already submitted in accordance with the requirements of point 4.2 of Part B of the Annex to Regulation (EU) No 544/2011 is sufficient.

6. Efficacy data

General

The data supplied must be sufficient to permit an evaluation of the plant protection product to be made. In particular it must be possible to evaluate the nature and extent of benefits that accrue following use of the preparation, where they exist in comparison to suitable reference products and damage thresholds, and to define its conditions of use.

The number of trials to be conducted and reported depends mainly on factors such as the extent to which the properties of the active substance(s) it contains are known and on the range of conditions that arise, including variability in plant health conditions, climatic differences, the range of agricultural practices, the uniformity of the crops, the mode of application, the type of harmful organism and the type of plant protection product.

Sufficient data must be generated and submitted to confirm that patterns determined hold for the regions and the range of conditions, likely to be encountered in the regions concerned, for which its use is to be recommended. Where an applicant claims that tests in one or more of the proposed regions of use are unnecessary because conditions are comparable with those in other regions where tests have been carried out, the applicant must substantiate the claim for comparability with documentary evidence.

In order to assess seasonal differences, if any, sufficient data must be generated and submitted to confirm the performance of the plant protection product in each agronomically and climatically different region for each particular crop (or commodity)/harmful organism combination. Normally trials on effectiveness or phytotoxicity, where relevant, in at least two growing seasons must be reported.

If to the opinion of the applicant the trials from the first season adequately confirm the validity of claims made on the basis of extrapolation of results from other crops, commodities or situations or from tests with closely similar preparations, a justification, which is acceptable to the competent authority for not carrying out a second season's work must be provided. Conversely, where, because of climatic or plant health conditions or other reasons the data obtained in any particular season are of limited value for the assessment of performance, trials in one or more further seasons must be conducted and reported.

6.1. *Preliminary tests*

Reports in summary form of preliminary tests, including glasshouse and field studies, used to assess the biological activity and dose range finding of the plant protection product and of the active substance(s) it contains, must be submitted when requested by the competent authority.

These reports will provide additional information for the competent authority when it evaluates the plant production product. Where this information is not submitted a justification which is acceptable to the competent authority must be provided.

6.2. *Testing effectiveness*

Aim of the tests

The tests shall provide sufficient data to permit an evaluation of the level, duration and consistency of control or protection or other intended effects of the plant protection product in comparison to suitable reference products, where they exist.

Test conditions

Normally a trial consists of three components: test product, reference product and untreated control.

The performance of the plant protection product must be investigated in relation to suitable reference products, where they exist. A suitable reference product is defined as an authorised plant protection product which has proved a sufficient performance in practice under the agricultural, plant health and environmental (including climatic) conditions in the area of proposed use. In general, formulation type, effects on the harmful organisms, working spectrum and method of application shall be close to those of the tested plant protection product.

Plant protection products must be tested in circumstances where the target harmful organism has been shown to have been present at a level causing or known to cause adverse effects (yield, quality, operational benefit) on an unprotected crop or area or on plants or plant products which have not been treated or where the harmful organism is present at such a level that an evaluation of the plant protection product can be made.

Trials to provide data on plant protection products for control of harmful organisms must show the level of control of the species of harmful organisms concerned or of species representative of groups for which claims are made. Trials must include the different stages of growth of life cycle of the harmful species, where this is relevant and the different strains or races, where these are likely to show different degrees of susceptibility.

Similarly, trials to provide data on plant protection products which are plant growth regulators, must show the level of effects on the species to be treated, and include investigation of differences in the response of a representative sample of the range of cultivars on which its use is proposed.

In order to clarify the dose response, dose rates lower than the recommended one must be included in some trials in order to enable to assess whether the recommended rate is the minimum necessary to achieve the desired effect.

The duration of the effects of treatment must be investigated in relation to the control of the target organism or effect on the treated plants or plant products, as appropriate. When more than one application is recommended, trials must be reported which establish the duration of the effects of an application, the number of applications necessary and the desired intervals between them.

Evidence must be submitted to show that the dose, timing and method of application recommended give adequate control, protection or have the intended effect in the range of circumstances likely to be encountered in practical use.

Unless there are clear indications that the performance of the plant protection product is unlikely to be affected to a significant degree by environmental factors, such as temperature or rain, an investigation of the effects of such factors on performance must be carried out and reported, particularly where it is known that the performance of chemically related products is so affected.

Where proposed label claims include recommendations for the use of the plant protection product with other plant protection product(s) or adjuvant(s) information on the performance of the mixture must be provided.
Test guideline

Trials must be designed to investigate specified issues, to minimise the effects of random variation between different parts of each site and to enable statistical analysis to be applied to results amenable to such analysis. The design, analysis and reporting of trials must be in accordance with European and Mediterranean Plant Protection Organisation (EPPO) guidelines 152 and 181. The report shall include a detailed and critical assessment of the data.

The trials must be carried out in accordance to specific EPPO guidelines, where available, or with guidelines satisfying at least the requirements of the corresponding EPPO guideline.

A statistical analysis of results amenable to such analysis must be carried out; where necessary the test guideline used must be adapted to enable such analysis.

6.3. *Information on the occurrence or possible occurrence of the development of resistance*

Laboratory data and where it exists, field information relating to the occurrence and development of resistance or cross-resistance in populations of harmful organisms to the active substance(s), or to related active substances, must be provided. Where such information is not directly relevant to the uses for which authorisation is sought or to be renewed (different species of harmful organism or different crops), it must, if available, nevertheless be provided, as it may provide an indication of the likelihood of resistance developing in the target population.

Where there is evidence or information to suggest that, in commercial use, the development of resistance is likely, evidence must be generated and submitted as to the sensitivity of the population of the harmful organism concerned to the plant protection product. In such cases a management strategy designed to minimise the likelihood of resistance or cross-resistance developing in target species must be provided.

6.4. *Effects on the yield of treated plants or plant products in terms of quantity and/or quality*

6.4.1. *Effects on the quality of plants or plant products*
Aim of the tests

The tests shall provide sufficient data to permit an evaluation of the possible occurrence of taint or odour or other quality aspects of plants or plant products after treatment with the plant protection product.
Circumstances in which required

The possibility of the occurrence of taint or odour in food crops must be investigated and be reported where:

— the nature of the products or its use is such that a risk of occurrence of taint or odour might be expected, or

— other products based on the same or a closely similar active ingredient have been shown to present a risk of occurrence of taint or odour.

The effects of plant protection products on other quality aspects of treated plants or plant products must be investigated and reported where:

— the nature of the plant protection product or it use could have an adverse influence on other quality aspects (for example in the case of use of plant growth regulators close to the harvest), or

— other products based on the same or a closely similar active ingredient have been shown to have an adverse influence on the quality.

Testing shall be conducted initially on the main crops on which the plant protection product is to be used, at twice the normal rates of application and using, where relevant, the main methods of processing. Where effects are observed it is necessary to perform testing at the normal rate of application.

The extent of investigation necessary on other crops will depend on their degree of similarity of the main crops already tested, the quantity and quality of data available on those main crops and how far the manner of use of the plant protection product and methods of processing the crops, are similar. It is generally sufficient to perform the test with the main formulation type to be authorised.

6.4.2. *Effects on transformation processes*
Aim of the tests

The tests shall provide sufficient data to permit an evaluation of the possible occurrence of adverse effects after treatment with the plant protection product on transformation processes or on the quality of their products.
Circumstances in which required

When the treated plants or plant products are normally intended for use in transformation process such as wine making, brewing or bread making and when at harvest significant residues are present, the possibility of the occurrence of adverse effects must be investigated and reported where:

— there are indications that the use of the plant protection product could have an influence on the processes involved (for example in the case of use of plant growth regulators or fungicides close to the harvest), or

— other products based on the same or a closely similar active ingredient have been shown to have an adverse influence on these processes or its products.

It is generally sufficient to perform the test with the main formulation type to be authorised.

6.4.3. *Effects on the yield of treated plants or plant products*
Aim of the tests

The test shall provide sufficient data to permit an evaluation of the performance of the plant protection product and of possible occurrence of yield reduction or loss in storage of treated plants or plant products.
Circumstances in which required

The effects of plant protection products on the yield or yield components of treated plant products must be determined where relevant. When treated plants or plant products are likely to be stored the effect on the yield after storage, including data on storage life must be determined where relevant.

This information will normally be available from the tests required under the provisions of point 6.2.

6.5. *Phytotoxicity to target plants (including different cultivars), or to target plant products*
Aim of the tests

The test shall provide sufficient data to permit an evaluation of the performance of the plant protection product and of the possible occurrence of phytotoxicity after treatment with the plant protection product.

Circumstances in which required

For herbicides and for other plant protection products for which adverse effects, however transitory, are seen during the trials, performed in accordance with point 6.2, the margins of selectivity on target crops must be established, using twice the recommended rate of application. Where serious phytotoxic effects are seen, an intermediate application rate must also be investigated.

Where adverse effects occur, but are claimed to be unimportant in comparison with the benefits of use or transient, evidence to support this claim is required. If necessary, yield measurement must be submitted.

The safety of a plant protection product to the main cultivars of the main crops for which it is recommended must be demonstrated, including effects of crop growth stage, vigour, and other factors which may influence susceptibility to damage or injury.

The extent of investigation necessary on other crops will depend on their degree of similarity to the main crops already tested, the quantity and quality of data available on those main crops and how far the manner of use of the plant protection product, if relevant, is similar. It is generally sufficient to perform the test with the main formulation type to be authorised.

Where proposed label claims include recommendations for the use of the plant protection product with other plant protection product(s), the previous paragraphs apply for the mixture.
Test guideline

Observations concerning phytotoxicity must be performed in the tests provided for in point 6.2.

Where phytotoxic effects are seen, they must be accurately assessed and recorded in accordance with EPPO guideline 135 or when a Member State requires so and when the test is carried out on the territory of this Member State, with guidelines satisfying at least the requirements of this EPPO guideline.

A statistical analysis of results amenable to such analysis must be carried out, where necessary the test guideline used must be adapted to enable such analysis.

6.6. *Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms, on succeeding crops, other plants or parts of treated plants used for propagating purposes (e.g. seeds, cuttings, runners)*

6.6.1. *Impact on succeeding crops*
Aim of the information required

Sufficient data must be reported to permit an evaluation of possible adverse effects of a treatment with the plant protection product on succeeding crops.
Circumstances in which required

Where data, generated in accordance with point 9.1, shows that significant residues of the active substance, its metabolites or degradation products, which have or may have biological activity on succeeding crops, remain in soil or in plant materials, such as straw or organic material up to sowing or planting time of possible succeeding crops, observations must be submitted on effects on the normal range of succeeding crops.

6.6.2. *Impact on other plants, including adjacent crops*
Aim of the information required

Sufficient data must be reported to permit an evaluation of possible adverse effects of a treatment with the plant protection product on other plants, including adjacent crops.

Circumstances in which required

Observations must be submitted on adverse effects on other plants, including the normal range of adjacent crops, when there are indications that the plant protection product could affect these plants via vapour drift.

6.6.3. *Impact on treated plants or plant products to be used for propagation*
Aim of the information required

Sufficient data must be reported to permit an evaluation of possible adverse effects of a treatment with the plant protection product on plants or plant products to be used for propagation.
Circumstances in which required

Observations must be submitted on the impact of plant protection products on plant parts used for propagation except where the proposed uses preclude use on crops intended for production of seeds, cuttings, runners or tubers for planting, as appropriate.

(i) for seeds — viability, germination and vigour;

(ii) for cuttings — rooting and growth rates;

(iii) for runners — establishment and growth rates;

(iv) for tubers — sprouting and normal growth.
Test guideline

Seeds testing shall be done in accordance with ISTA Methods.

6.6.4. *Effects on beneficial and other non-target organisms*

Any effects, positive or negative, on the incidence of other harmful organisms, observed in the tests performed in accordance with the requirements of this Section, shall be reported. Any observed environmental effects must also be reported, especially effects on wildlife and/or beneficial organisms.

6.7. *Summary and evaluation of data presented under 6.1 to 6.6*

A summary of all data and information provided under points 6.1 to 6.6 must be provided, together with a detailed and a critical assessment of the data, with particular reference to the benefits that the plant protection product offers, adverse effects that do or may arise and measures necessary to avoid or minimise adverse effects.

7. Effects on human health

For proper evaluation of the toxicity including potential for pathogenicity and infectiveness of preparations sufficient information shall be available on acute toxicity, irritation and sensitisation of the micro-organism. If possible, additional information on mode of toxic action, toxicological profile and all other known toxicological aspects of the micro-organism shall be submitted. Special attention shall be given to co-formulants.

While performing toxicology studies, all signs of infection or pathogenicity shall be noted. Toxicology studies shall include clearance studies.

In the context of the influence that impurities and other components can have on toxicological behaviour, it is essential that for each study submitted, a detailed description (specification) of the material used, be provided. Tests must be conducted using the plant protection product to be authorised. In particular, it must be clear that the micro-organism used in the preparation, and

the conditions of culturing it, are the same for which information and data are submitted in the context of Part B of the Annex to Regulation (EU) No 544/2011.

A tiered testing system will be applied to the study of the plant protection product.

7.1. *Basic acute toxicity studies*

The studies, data and information to be provided and evaluated, must be sufficient to permit the identification of effects following a single exposure to the plant protection product, and in particular to establish, or indicate:

— the toxicity of the plant protection product,
— toxicity of the plant protection product relative to the micro-organism,
— the time course and characteristics of the effect with full details of behavioural changes and possible gross pathological findings at post-mortem,
— where possible the mode of toxic action, and
— the relative hazard associated with the different routes of exposure.

While the emphasis must be on estimating the toxicity ranges involved, the information generated must also permit the plant protection product to be classified in accordance with Directive 1999/45/EC or Regulation (EC) No 1272/2008. The information generated through acute toxicity testing is of particular value in assessing hazards likely to arise in accident situations.

7.1.1. *Acute oral toxicity*
Circumstances in which required

An acute oral test shall always be carried only if the applicant cannot justify an alternative approach under Directive 1999/45/EC or Regulation (EC) No 1272/2008, where applicable.
Test method

The test must be carried out in accordance with Method B 1 bis or B 1 tris of Regulation (EC) No 440/2008.

7.1.2. *Acute inhalation toxicity*
Aim of the test

The test will provide the inhalation toxicity to rats of the plant protection product.
Circumstances in which required

The test must be carried out where the plant protection product:

— is used with fogging equipment,
— is an aerosol,
— is a powder containing a significant proportion of particles of diameter < 50 micrometre (> 1 % on a weight basis),
— is to be applied from aircraft in cases where inhalation exposure is relevant,
— is to be applied in a manner which generates a significant proportion of particles or droplets of diameter < 50 micrometre (> 1 % on a weight basis),
— contains a volatile component at greater than 10 %.

Test method

The test must be carried out in accordance with Method B 2 of Regulation (EC) No 440/2008.

7.1.3. *Acute percutaneous toxicity*
Circumstances in which required

An acute percutaneous test shall be conducted only if the applicant cannot justify an alternative approach under Directive 1999/45/EC or Regulation (EC) No 1272/2008, where applicable.
Test method

The test must be carried out in accordance with Method B 3 of Regulation (EC) No 440/2008.

7.2. *Additional acute toxicity studies*

7.2.1. *Skin irritation*
Aim of the test

The test will provide the potential of skin irritancy of the plant protection product including the potential reversibility of the effects observed.
Circumstances in which required

The skin irritancy of the plant protection product must always be determined, except where the co-formulants are not expected to be skin irritant or the micro-organism is shown not to be skin irritant or where it is likely, as indicated in the test guideline, that severe skin effects can be excluded.
Test method

The test must be carried out in accordance with Method B 4 of Regulation (EC) No 440/2008.

7.2.2. *Eye irritation*
Aim of the test

The test will provide the potential for eye irritation of the plant protection product, including the potential reversibility of the effects observed.
Circumstances in which required

The eye irritancy of the plant protection product must be determined, where the co-formulants are suspected to be eye irritant, except where the micro-organism is eye irritant or where it is likely, as indicated in the test guideline, that severe effects on the eyes may be produced.
Test method

The eye irritation must be determined in accordance with Method B 5 of Regulation (EC) No 440/2008.

7.2.3. *Skin sensitisation*
Aim of the test

The test will provide sufficient information to assess the potential of the plant protection product to provoke skin sensitisation reactions.
Circumstances in which required

The test must be carried out where the co-formulants are suspected to have skin sensitising properties, except where the micro-organism(s) or the co-formulants are known to have skin sensitising properties.
Test method

The tests have to be carried out in accordance with Method B 6 of Regulation (EC) No 440/2008.

7.3. *Data on exposure*

The risks for those in contact with plant protection products (operators, bystanders, workers), depend on the physical, chemical and toxicological properties of the plant protection product as well as the type of the product (undiluted/diluted), formulation type, and on the route, the degree and duration of exposure. Sufficient information and data must be generated and reported to

permit an assessment of the extent of exposure to the plant protection product likely to occur under the proposed conditions of use.

In the cases where there is particular concern on the possibility of dermal absorption based on the information for the micro-organism available in Section 5 of Part B of the Annex to Regulation (EU) No 544/2011, or from the information provided for the preparation in this Section, further dermal absorption data can be necessary.

Results from exposure monitoring during production or use of the product must be submitted.

The abovementioned information and data must provide the basis for the selection of appropriate protective measures including personal protective equipment to be used by operators and workers and to be specified on the label.

7.4. *Available toxicological data relating to non-active substances*

Where relevant, the following information shall be submitted for each co-formulant:

(a) the registration number as referred to in Article 20(3) of Regulation (EC) No 1907/2006;

(b) the study summaries included in the technical dossier as referred to in Article 10(a)(vi) of Regulation (EC) No 1907/2006; and

(c) the safety data sheet as referred to in Article 31 of Regulation (EC) No 1907/2006.

All other available information shall be submitted.

7.5. *Supplementary studies for combinations of plant protection products*
Aim of the test

In certain cases it may be necessary to carry out the studies as referred to under points 7.1 to 7.2.3 for a combination of plant protection products where the product label includes requirements for use of the plant protection product with other plant protection products and/or with adjuvants as a tank mix. Decisions as to the need for supplementary studies must be made on a case-by-case basis, taking into account the results of the acute toxicity studies of the individual plant protection products, the possibility for exposure to the combination of the products concerned and available information or practical experience with the products concerned or similar products.

7.6. *Summary and evaluation of health effects*

A summary of all data and information provided under paragraphs 7.1 through 7.5, must be submitted, and include a detailed and critical assessment of those data in the context of relevant evaluative and decision-making criteria and guidelines, with particular reference to the risks for man and animals that may or do arise, and the extent, quality and reliability of the database.

8. Residues in or on treated products, food and feed

The same provisions as detailed in Section 6 of Part B of the Annex to Regulation (EU) No 544/2011 apply; the information required in accordance with this Section has to be provided unless it is possible to extrapolate the residue behaviour of the plant protection product on the basis of the data available for the micro-organism. Special attention shall be paid towards the influence of formulation substances on the residue behaviour of the micro-organism and its metabolites.

9. Fate and behaviour in the environment

The same provisions as detailed in Section 7 of Part B of the Annex to Regulation (EU) No 544/2011 apply; the information required in accordance with this Section has to be provided unless it is possible to extrapolate the fate and behaviour of the plant protection product in the environment on the basis of the data available in Section 7 of Part B of the Annex to Regulation (EU) No 544/2011.

10. **Effects on non-target organisms**

Introduction

(i) The information provided, taken together with that for the micro-organism(s), must be sufficient to permit an assessment of the impact on non-target species (flora and fauna), of the plant protection product, when used as proposed. Impact can result from single, prolonged or repeated exposure, and can be reversible, or irreversible.

(ii) The choice of the appropriate non-target organisms for testing of environmental effects shall be based on the information on the micro-organism, as required in Part B of the Annex to Regulation (EU) No 544/2011, and on the information on the co-formulants and other components, as required by Sections 1 to 9 of this Annex. From such knowledge it would be possible to choose the appropriate test organisms, such as organisms closely related to the target organism.

(iii) In particular, the information provided for the plant protection product, together with other relevant information, and that provided for the micro-organism, shall be sufficient to:

— specify the hazard symbols, the indications of danger, and relevant risk and safety phrases or the pictograms, signal words, relevant hazard and precautionary statements, for the protection of the environment, to be mentioned on packaging (containers),

— permit an evaluation of the short- and long-term risks for non-target species — populations, communities, and processes as appropriate,

— permit an evaluation whether special precautions are necessary for the protection of non-target species.

(iv) There is a need to report all potentially adverse effects found during routine investigations of environmental effects and to undertake and report such additional studies which may be necessary to investigate the mechanisms involved and assess the significance of these effects.

(v) In general, much of the data relating to impact on non-target species, required for authorisation of plant protection products, will have been submitted and evaluated for the approval of the micro-organism(s).

(vi) Where exposure data are necessary to decide whether a study has to be performed, the data obtained in accordance with Section 9 of Part B of this Annex, shall be used.

For the estimation of exposure of organisms all relevant information on the plant protection product and on the micro-organism must be taken into account. Where relevant the parameters provided for in this Section shall be used. Where it appears from available data that the plant protection product has a stronger effect than the micro-organism, the data on effects on non target organisms of the plant protection product have to be used for the calculation of relevant effect/exposure ratios.

(vii) In order to facilitate the assessment of the significance of test results obtained, the same strain of each relevant species shall where possible be used in the various specified tests for effects on non target organisms.

10.1. *Effects on birds*

The same information as provided in point 8.1 of Part B of the Annex to Regulation (EU) No 544/2011 has to be reported where it is not possible to predict the effects of the plant protection product on the basis of the data available for the micro-organism, unless it can be justified that exposure of birds is unlikely to occur.

10.2. *Effects on aquatic organisms*

The same information as provided in point 8.2 of Part B of the Annex to Regulation (EU) No 544/2011 has to be reported where it is not possible to predict the effects of the plant protection product on the basis of the data available for the micro-organism, unless it can be justified that exposure of aquatic organisms is unlikely to occur.

10.3. *Effects on bees*

The same information as provided in point 8.3 of Part B of the Annex to Regulation (EU) No 544/2011 has to be reported where it is not possible to predict the effects of the plant protection product on the basis of the data available for the micro-organism, unless it can be justified that exposure of bees is unlikely to occur.

10.4. *Effects on arthropods other than bees*

The same information as provided in point 8.4 of Part B of the Annex to Regulation (EU) No 544/2011 has to be reported where it is not possible to predict the effects of the plant protection product on the basis of the data available for the micro-organism, unless it can be justified that exposure of arthropods other than bees is unlikely to occur.

10.5. *Effects on earthworms*

The same information as provided in point 8.5 of Part B of the Annex to Regulation (EU) No 544/2011 has to be reported where it is not possible to predict the effects of the plant protection product on the basis of the data available for the micro-organism, unless it can be justified that exposure of earthworms is unlikely to occur.

10.6. *Effects on soil micro-organisms*

The same information as provided in point 8.6 Part B of the Annex to Regulation (EU) No 544/2011 has to be reported where it is not possible to predict the effects of the plant protection product on the basis of the data available for the micro-organism, unless it can be justified that exposure of non target soil micro-organisms is unlikely to occur.

10.7. *Additional studies*

Expert judgement is required to decide whether additional studies are necessary. Such decision will take into consideration the available information in this and other Sections, in particular data on the specificity of the micro-organism, and the expected exposure. Useful information may also be available from the observations carried out in efficacy testing.

Special attention shall be given to possible effects on naturally occurring and deliberately released organisms of importance in IPM. In particular the compatibility of the product with IPM shall be taken into consideration.

Additional studies might include further studies on additional species or higher tier studies such as studies on selected non-target organisms.

Before performing such studies, the applicant shall seek agreement of the competent authorities on the type of study to be performed.

11. **Summary and evaluation of environmental impact**

A summary and evaluation of all data relevant to the environmental impact shall be carried out in accordance with the guidance given by the competent authorities of the Member States concerning the format of such summaries and evaluations. It shall include a detailed and critical assessment of those data in the context of relevant evaluative and decision making criteria and guidelines, with particular reference to the risks for the environment and non-target species that may or do arise, and the extent, quality and reliability of the database. In particular the following issues shall be addressed:

— prediction of distribution and fate in the environment, and the time courses involved,

— identification of non-target species and populations at risk, and prediction of the extent of potential exposure,

— identification of precautions necessary to avoid or minimise contamination of the environment, and for the protection of non-target species.

(**1**) OJ L 309, 24.11.2009, p. 1.

(**2**) OJ L 230, 19.8.1991, p. 1.

(**3**) OJ L 142, 31.5.2008, p. 1.

(**4**) OJ L 358, 18.12.1986, p. 1.

(**5**) OJ L 50, 20.2.2004, p. 44.

(**6**) OJ L 200, 30.7.1999, p. 1.

(**7**) OJ L 353, 31.12.2008, p. 1.

(**8**) See page 1 of this Official Journal.

(**9**) OJ L 396, 30.12.2006, p. 1.

(**10**) Collaborative International Pesticides Analytical Council.

(**11**) International Group of National Pesticide Manufacturers' Associations.

(**12**) International rules for seed testing, 1985. Proceedings of the International Seed Testing Association, *Seed Science and Technology*, Volume 13, No 2, 1985.

(**13**) OJ L 131, 5.5.1998, p. 11.

(**14**) OJ L 158, 30.4.2004, p. 50.

(**15**) OEPP/EPPO (1993). Decision-making schemes for the environmental risk assessment of plant protection products. Bulletin OEPP/EPPO Bulletin 23, 1-154 and Bulletin 24, 1-87.

(**16**) FOrum for the Coordination of pesticide fate models and their USe.

(**17**) OEPP/EPPO (1993). Decision-making schemes for the environmental risk assessment of plant protection products. *Bulletin OEPP/EPPO Bulletin 23*, 1-154 and *Bulletin 24*, 1-87.

(**18**) See page 176 of this Official Journal.

(**19**) *USEPA Microbial Pesticide Test Guidelines, OPPTS Series 885, February 1996* (http://www.epa.gov/oppbppd1/biopesticides/guidelines/series885.htm).

Status:
Point in time view as at 10/06/2011.

Changes to legislation:
There are outstanding changes not yet made to Commission Regulation (EU) No 545/2011 (repealed). Any changes that have already been made to the legislation appear in the content and are referenced with annotations.