COMMISSION REGULATION (EU) 2022/1440

of 31 August 2022

amending Regulation (EU) No 284/2013 as regards the information to be submitted for plant protection products and the specific data requirements for plant protection products containing micro-organisms

(Text with EEA relevance)

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 Article 78(1), point (b), thereof,

Whereas:

(1) Commission Regulation (EU) No 284/2013 ([2]) lays down the data requirements for plant protection products containing active substances. For plant protection products containing active substances that are chemicals, these are laid down in Part A of the Annex to that Regulation, and for plant protection products containing active substances that are micro-organisms, these are laid down in Part B of that Annex, with common requirements set out in the introductory part of that Annex.

(2) The Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system ([3]) aims at reducing dependency on and use of chemical plant protection products, including through facilitating the placing on the market of biological active substances such as micro-organisms. In order to reach those objectives, it is necessary to specify the data requirements related to plant protection products containing micro-organisms taking into account the most up-to-date scientific and technical knowledge which has evolved significantly.

(3) Currently available scientific knowledge on plant protection products containing micro-organisms, in particular concerning effectiveness, efficacy, relevance of impurities, and toxicity of certain chemical substances which may be present in these plant protection products, triggers the need to better specify certain definitions which apply for Part B of the Annex to Regulation (EU) No 284/2013. Taking into consideration that these definitions apply also to Part A of that Annex, concerning plant protection products containing chemical active substances, it is appropriate to amend the introduction of the Annex to Regulation (EU) No 284/2013.

(4) Since micro-organisms are living organisms, a specific approach is needed compared to chemical substances, in order to also take into account the new scientific knowledge that has emerged on the biology of micro-organisms. That scientific knowledge consists in new information on key characteristics of micro-organisms, such as their pathogenicity and infectivity, the possible production of metabolite(s) of concern and the capacity to transfer antimicrobial resistance genes to other micro-organisms which are pathogenic and occurring in European environments, potentially affecting the effectiveness of antimicrobials used in human or veterinary medicine.

([1]) OJ L 309, 24.11.2009, p. 1.

([2]) Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 93, 3.4.2013, p. 85).

([3]) Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions – A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system (COM/2020/381 final, https://eur-lex.europa.eu/legal-content/en/TXT/?qid=1590404602495&uri=CELEX:52020DC0381).

(5) The current state of scientific knowledge on plant protection products containing micro-organisms allows for a better and more specific approach for their assessment, which is based on the mode of action and ecological characteristics of the respective species and, where applicable, the respective strains of micro-organisms. As it allows for a more targeted risk assessment, such scientific knowledge should be taken into account when assessing the risks posed by plant protection products containing micro-organisms.

(6) In order to better reflect the latest scientific developments and the specific biological properties of plant protection products containing micro-organisms, while maintaining a high level of protection of human and animal health and of the environment, it is therefore necessary to adapt accordingly the existing data requirements.

(7) It is appropriate to amend Part B of the Annex to Regulation (EU) No 284/2013, in order to update the data requirements to the latest scientific developments and adapt them to the specific biological properties of micro-organisms.

(8) The current title of Part B of the Annex to Regulation (EU) No 284/2013 refers to plant protection products containing micro-organisms including viruses. However, Article 3, point (15), of Regulation (EC) No 1107/2009 already defines micro-organisms, and the definition includes viruses. It is appropriate to be consistent with Article 3, point (15), of that Regulation, and therefore there is no need to refer to viruses separately.

(9) It is appropriate to introduce a definition of 'Microbial Pest Control Agent as manufactured' ('MPCA as manufactured') because certain tests are required to be performed using a sample of the MPCA as manufactured, rather than using the active substance or the other components of the MPCA as manufactured after purification. It is indeed more appropriate to refer, with a unique term, to the micro-organism as manufactured and to those components included in the manufacturing batch which might be of relevance for the risk assessment, such as relevant contaminating micro-organisms and relevant impurities.

(10) New scientific knowledge has emerged on the capacity of micro-organisms to transfer antimicrobial resistance genes to other micro-organisms which are pathogenic and occurring in European environments, potentially affecting the effectiveness of antimicrobials used in human or veterinary medicine. This new scientific knowledge allows for a better and more specific approach for the assessment of which genes encoding for antimicrobial resistance are likely to be transferred to other micro-organisms, and which antimicrobials are those relevant for human or veterinary medicine. In addition, the EU Farm to Fork Strategy has set antimicrobial resistance-related targets. Therefore, further specification is needed on the data requirements to implement the most up-to-date scientific and technical knowledge on transferability of antimicrobial resistance, and allow an assessment to be made on whether the active substance may have harmful effects on human or animal health, as indicated in the approval criteria laid down in Article 4 of Regulation (EC) No 1107/2009.

(11) A reasonable period should be allowed to elapse before the amended data requirements become applicable in order to permit applicants to prepare themselves to meet those requirements.

(12) In order to permit Member States and interested parties to prepare themselves to meet the amended requirements, it is appropriate to lay down transitional measures concerning data submitted for applications for authorisation, renewal of authorisation and amendment to the authorisation of plant protection products containing active substances that are micro-organisms, and concerning data on the representative uses of plant protection products submitted in the context of applications for the approval, renewal of approval or amendment to the conditions of approval of active substances that are micro-organisms.

(13) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EU) No 284/2013

The Annex to Regulation (EU) No 284/2013 is amended as follows:

(a) the Introduction is replaced by the text set out in Annex I to this Regulation;

(b) Part B is replaced by the text set out in Annex II to this Regulation.

Article 2

Transitional measures as regards certain procedures concerning plant protection products containing active substances that are micro-organisms

1. Applicants shall submit data, in the context of applications for authorisation of plant protection products within the meaning of Regulation (EC) No 1107/2009 containing one or more active substances that are micro-organisms, in accordance with Part B of the Annex to Regulation (EU) No 284/2013 as it stood before being amended by this Regulation in either of the following cases:

(a) the application for authorisation is submitted by 21 November 2024;

(b) the dossiers for all the active substances contained in the plant protection product concerned have been submitted in accordance with Commission Regulation (EU) No 283/2013 ([4]) as it stood before being amended by Commission Regulation (EU) 2022/1441 ([5]).

2. As a derogation from paragraph 1, applicants may choose, from 21 November 2022 to submit data in accordance with Part B of the Annex to Regulation (EU) No 284/2013 as amended by this Regulation.

3. Where applicants choose to apply the option provided for in paragraph 2, they shall specify that choice in writing when submitting the application concerned. Such choice shall be irrevocable for the procedure concerned.

Article 3

Transitional measures as regards certain procedures concerning active substances that are micro-organisms and are contained in plant protection products

Regulation (EU) No 284/2013 as it stood before being amended by this Regulation shall continue to apply as regards data required on one or more representative uses of a plant protection product, submitted before 21 May 2023 to fulfil the requirements of one of the following provisions:

(a) Article 8(1), point (a), of Regulation (EC) No 1107/2009;

([4]) Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 93, 3.4.2013, p. 1).

([5]) Commission Regulation (EU) 2022/1441 of 31 August 2022 amending Regulation (EU) No 546/2011 as regards specific uniform principles for evaluation and authorisation of plant protection products containing micro-organisms (see page 70 of this Official Journal).

(b) Article 7(1), point (c), of Commission Implementing Regulation (EU) No 844/2012 ([6]);

(c) Article 6(2), point (c), of Commission Implementing Regulation (EU) 2020/1740 ([7]).

Article 4

Entry into force and application

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

It shall apply from 21 November 2022.

This Regulation shall be binding in its entirety and directly applicable in the Member States in accordance with the Treaties.

Done at Brussels, 31 August 2022.

For the Commission
The President
Ursula VON DER LEYEN

([6]) Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26).

([7]) Commission Implementing Regulation (EU) 2020/1740 of 20 November 2020 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and repealing Commission Implementing Regulation (EU) No 844/2012 (OJ L 392, 23.11.2020, p. 20).

ANNEX I

'INTRODUCTION

Information to be submitted, its generation and its presentation

1. For the purposes of this Annex, the following definitions apply:

(1) "**storage stability**" means the capacity of a plant protection product to maintain the initial properties and the specified content during the storage period under established storage conditions;

(2) "**effectiveness**" means the capacity of the plant protection product to produce a positive effect regarding the desired plant protection activity;

(3) "**efficacy**" means a measure concerning the overall effect of the application of a plant protection product on the agricultural system in which it is used (i.e. which includes positive effects of treatment in performing the desired plant protection activity and negative effects such as development of resistance, phytotoxicity or reduction of qualitative or quantitative yield);

(4) "**relevant impurity**" means a chemical impurity that is of concern for human health, animal health or the environment;

(5) "**toxicity**" means the degree of injury or damage in an organism caused by a toxin or a toxic substance;

(6) "**toxin**" means a substance that is produced within living cells or organisms and is able to injure or cause damage in a living organism.

The information submitted shall meet the requirements set out in points 1.1 to 1.15.

1.1. The information shall be sufficient to evaluate efficacy and the foreseeable risks, whether immediate or delayed, which the plant protection product may entail for humans, including vulnerable groups, animals and the environment and contain at least the information and results of the studies referred to in this Annex.

1.2. Any information including any known data on potentially harmful effects of the plant protection product on human and animal health or on groundwater shall be included as well as known and expected cumulative and synergistic effects.

1.3. Any information including any known data on potentially unacceptable effects of the plant protection product on the environment, plants and plant products shall be included as well as known and expected cumulative and synergistic effects.

1.4. The information shall include all relevant data from the scientific peer reviewed open literature on the active substance, relevant metabolites, and where relevant breakdown or reaction products, and plant protection products containing the active substance and dealing with side-effects on human and animal health, the environment and non-target species. A summary of that data shall be provided.

1.5. The information shall include a full and unbiased report of the studies conducted as well as a full description of them. Such information shall not be required, where a justification is provided showing that:

(a) it is not necessary owing to the nature of the plant protection product or its proposed uses, or it is not scientifically necessary; or

(b) it is technically not possible to supply.

1.6. Where relevant, the information shall be generated using test methods, which are included in the list referred to in point 6.

In the absence of suitable internationally or nationally validated test guidelines, test guidelines accepted by the competent authority shall be used. Any deviations from test guidelines shall be described and justified.

1.7. The information shall include a full description of the test methods used.

1.8. Where relevant, the information shall be generated in accordance with Directive 2010/63/EU of the European Parliament and of the Council ([1]).

1.9. The information shall include a list of endpoints for the plant protection product where relevant.

1.10. The information shall include the proposed classification and labelling of the plant protection product in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([2]), where relevant.

1.11. Information as provided for in Commission Regulation (EU) No 283/2013 ([3]) may be required by the competent authorities on co-formulants. Before requiring additional studies to be performed, the competent authorities shall assess all available information provided in accordance with other Union legislation.

1.12. The information provided for the plant protection product and that provided for the active substance, shall be sufficient to:

(a) decide whether or not the plant protection product is to be authorised;

(b) specify conditions or restrictions to be associated with any authorisation;

(c) permit an evaluation of short and long-term risks for non-target species - populations, communities and processes;

(d) identify relevant first aid measures as well as appropriate diagnostic and therapeutic measures to be followed in the event of poisoning in humans;

(e) permit a risk assessment of acute and chronic consumer exposure, including, where relevant, a cumulative risk assessment deriving from exposure to more than one active substance;

(f) permit an estimation of acute and chronic exposure of operators, workers, residents and bystanders including, where relevant, the cumulative exposure to more than one active substance;

(g) permit an evaluation to be made as to the nature and extent of the risks for humans, animals (species normally fed and kept by humans or food-producing animals) and of the risks for other non-target vertebrate species;

(h) predict the distribution, fate and behaviour in the environment, as well as the time courses involved;

(i) identify non-target species and populations for which risks arise because of potential exposure;

(j) permit an assessment of the impact of the plant protection product on non-target species;

(k) identify measures necessary to minimise contamination of the environment and impact on non-target species;

(l) classify the plant protection product as to hazard in accordance with Regulation (EC) No 1272/2008;

(m) specify the pictograms, the signal words, and relevant hazard and precautionary statements for the protection of human health, non-target species and the environment, which are to be used for labelling purposes.

1.13. Where relevant, tests shall be designed and data analysed using appropriate statistical methods. Details of the statistical analysis shall be reported transparently.

([1]) Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33).

([2]) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

([3]) Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 93, 3.4.2013, p. 1).

1.14. Exposure calculations shall refer to scientific methods accepted by the European Food Safety Authority, when available. The use of additional methods shall be justified.

1.15. For each section of this Annex, a summary of all data, information and evaluation made shall be submitted. This shall include a detailed and critical assessment in accordance with Article 4 of Regulation (EC) No 1107/2009.

2. The requirements set out in this Annex constitute the minimum set of data to be submitted. Member States may set out additional requirements at national level to address specific circumstances, specific exposure scenarios and specific patterns of use other than those taken into account for approval. The applicant shall pay careful attention to environmental, climatic and agronomic conditions when tests are set up subject to the approval by the Member State where the application has been submitted.

3. **Good laboratory practice (GLP)**

3.1. Tests and analyses shall be conducted in accordance with the principles laid down in Directive 2004/10/EC of the European Parliament and of the Council ([4]) where testing is done to obtain data on the properties or safety with respect to human or animal health or the environment.

3.2. By way of derogation from point 3.1, tests and analyses, required under Section 6 of Part A and Section 6 of Part B, may be conducted by official or officially recognised testing facilities or organisations, which satisfy at least the following requirements:

(a) they have at their disposal sufficient scientific and technical staff having the necessary education, training, technical knowledge and experience for their assigned functions;

(b) they have at their disposal suitable equipment required for correct performance of the tests and measurements which they claim to be competent to carry out; that equipment is properly maintained and calibrated, where appropriate, before being put into service and thereafter in accordance with an established programme;

(c) they have at their disposal appropriate experimental fields and, where necessary, greenhouses, growth cabinets or storage rooms; they ensure that environment in which the tests are undertaken does not invalidate their results or adversely affect the required accuracy of measurement;

(d) they make available to all relevant personnel operating procedures and protocols used for the trials;

(e) they make available, where requested by the competent authority, prior to the commencement of a test, information on its location and on the tested plant protection products;

(f) they ensure that the quality of the work performed is appropriate to its type, range, volume and intended purpose;

(g) they maintain records of all observations, calculations and derived data and calibrations records and final test report as long as the plant protection product concerned is authorised in a Member State.

3.3. Officially recognised testing facilities and organisations, and, where requested by the competent authorities, official facilities and organisations shall:

(a) report to the relevant national authority all information necessary to demonstrate that they can satisfy the requirements set out in point 3.2,

(b) permit at any time the inspections, which each Member State shall regularly organise on its territory in order to verify the compliance with point 3.2.

([4]) Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (OJ L 50, 20.2.2004, p. 44).

3.4. By way of derogation from point 3.1:

(a) For active substances that are micro-organisms, tests and analyses performed to obtain data on their properties and safety with respect to other aspects than human health, may be conducted by official or officially recognised testing facilities or organisations which satisfy at least the requirements specified in points 3.2 and 3.3.

(b) Studies conducted before the application of this Regulation, although not fully compliant with GLP principles or with current test methods, shall be considered for the assessment if carried out in accordance with the recognised international test guidelines in place at the time of conduction of the studies and/or scientifically valid, thereby avoiding repeating animal tests, especially for carcinogenicity and reprotoxicity studies. This derogation shall apply in particular to studies with vertebrate species.

4. **Test material**

4.1. Due to the influence that impurities and other components can have on toxicological and ecotoxicological behaviour, a detailed description (specification) of the test material used shall be provided for each study submitted. Studies shall be conducted using the plant protection product to be authorised or bridging principles may be applied, for example, by using a study on a plant protection product with a comparable/equivalent composition. A detailed description of the composition used shall be provided.

4.2. Where radio-labelled test material is used, radio-labels shall be positioned at sites (one or more as necessary), to facilitate elucidation of metabolic and transformation pathways and to facilitate investigation of the distribution of the active substance and of its metabolites, breakdown and reaction products.

4.3. Whenever a study implies the use of different doses, the relationship between the dose and the adverse effect shall be reported.

5. **Tests on vertebrate animals**

5.1. Tests on vertebrate animals shall be undertaken only where no other validated methods are available. Alternative methods shall include *in vitro* methods or *in silico* methods. Reduction and refinement methods for *in vivo* testing shall also be encouraged to keep the number of animals used in testing to a minimum.

5.2. The principles of replacement, reduction and refinement of the use of vertebrate animals shall be taken into account in the design of the test methods, in particular when appropriate validated methods become available to replace, reduce or refine animal testing.

5.3. Study designs shall be carefully considered from an ethical point of view, taking into account the scope for reduction, refinement and replacement of animal tests. For example, by including one or more additional dose groups or time points for blood sampling in one study, it may be possible to avoid the need for another study.

6. For purposes of information and harmonisation, the list of test methods and guidance documents referred to in this Annex shall be published in the *Official Journal of the European Union*. That list shall be regularly updated.'

ANNEX II

'PART B

PLANT PROTECTION PRODUCTS CONTAINING AN ACTIVE SUBSTANCE THAT IS A MICRO-ORGANISM

INTRODUCTION TO PART B

(i) This Introduction to Part B complements the Introduction to this Annex with points which are specific for plant protection products containing an active substance that is a micro-organism.

(ii) For the purposes of Part B, the following definitions apply:

(1) "**strain**" means a genetic variant of an organism in its taxonomic level (species) that is made up of the descendants of a single isolation in pure culture from the original matrix (e.g. the environment) and usually is made up of a succession of cultures ultimately derived from an initial single colony;

(2) "**colony-forming unit**" ("**CFU**") means a measurement unit used to estimate the number of bacterial or fungal cells in a sample, which have the ability to multiply under controlled growing conditions, with the consequence that one or more cells reproduce and multiply to form a single visible colony;

(3) "**Microbial Pest Control Agent as manufactured**" ("**MPCA as manufactured**") means the outcome of the manufacturing process of the micro-organism(s) intended to be used as active substance in plant protection products, consisting of the micro-organism(s) and any additives, metabolites (including metabolites of concern), chemical impurities (including relevant impurities), contaminating micro-organisms (including relevant contaminating micro-organisms) and the spent medium/rest fraction resulting from the manufacturing process or, in case of a continuous manufacturing processes where a strict separation between the manufacturing of the micro-organism(s) and the production process of the plant protection product is not possible, a non-isolated intermediate;

(4) "**additive**" means a component added to the active substance during its manufacturing, to preserve microbial stability and/or facilitate handling;

(5) "**purity**" means the content of the micro-organism present in the MPCA as manufactured expressed in a relevant unit and the maximum content of substances of concern in case they are identified;

(6) "**relevant contaminating micro-organism**" means a pathogenic/infective micro-organism unintentionally present in the MPCA as manufactured;

(7) "**seed stock**" means a microbial strain starter culture used to manufacture the MPCA as manufactured or the final plant protection product;

(8) "**spent medium/rest fraction**" means the fraction of the MPCA as manufactured consisting of remaining or transformed starting materials, and excluding the micro-organism(s) that is the active substance, metabolites of concern, additives, relevant contaminating micro-organisms, and relevant impurities;

(9) "**starting material**" means substances used in the manufacturing process of the MPCA as manufactured as substrate and/or buffering agent;

(10) "**infectivity**" means the ability of a micro-organism to cause an infection;

(11) "**infection**" means the non-opportunistic introduction or entry of micro-organism into a susceptible host, where the micro-organism is able to reproduce to form new infective units and persist in the host, whether or not the micro-organism causes pathological effects or disease;

(12) "**pathogenicity**" means the non-opportunistic ability of a micro-organism to inflict injury and damage to the host upon infection;

(13) "**non-opportunistic**" means a condition under which a micro-organism exerts an infection or inflicts an injury or damage when the host is not weakened by a predisposing factor (e.g. immune system impaired by an unrelated cause);

(14) "**opportunistic infection**" means an infection occurring in a host weakened by a predisposing factor (e.g. immune system impaired by an unrelated cause);

(15) "**metabolite of concern**" means a metabolite produced by the micro-organism under assessment, with known toxicity or known relevant antimicrobial activity, which is present in the MPCA as manufactured at levels that may present a risk to human health, animal health or the environment, and/or for which it cannot be adequately justified that *in-situ* production of the metabolite is not relevant for the risk assessment;

(16) "***in situ* production**" means the production of a metabolite by the micro-organism after application of the plant protection product containing that micro-organism;

(17) "**relevant antimicrobial activity**" means the antimicrobial activity caused by relevant antimicrobial agents;

(18) "**antimicrobial agent**" means any antibacterial, antiviral, antifungal, anthelmintic or antiprotozoal agent that is a substance of natural, semi-synthetic, or synthetic origin that at *in vivo* concentrations kills or inhibits the growth of micro-organisms by interacting with a specific target;

(19) "**relevant antimicrobial agents**" means all antimicrobial agents important for therapeutic use in humans or animals, as described in the latest available versions at the time of submission of the dossier:

— in a list adopted by means of Commission Regulation (EU) 2021/1760 ([1]) in accordance with Article 37(5) of Regulation (EU) 2019/6 of the European Parliament and of the Council ([2]), or

— by the World Health Organisation ([3]) in the lists of Critically Important Antimicrobials, Highly Important Antimicrobials and Important Antimicrobials for Human Medicine.

(iii) The information from scientific peer-reviewed literature as mentioned under the Introduction to this Annex, point 1.4, shall be provided at the relevant taxonomic level. An explanation on why the chosen taxonomic level is considered relevant for the addressed data requirement shall be provided.

(iv) Other available sources of information, such as medical reports, may also be provided and submitted in a summary.

(v) Where appropriate or specifically indicated in the data requirements, test guidelines as described in Part A shall be used also for this Part, upon adaptation in such a way that they are appropriate for chemical compounds present in the plant protection product containing an active substance that is a micro-organism.

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

(vii) In cases where a new plant protection product containing an active substance that is a micro-organism is to be dealt with, data extrapolation from Part B of the Annex to Regulation (EU) No 283/2013, may be acceptable, provided that all the possible toxic effects of the co-formulants and other components, are sufficiently characterized and evaluated as of no concern.

(viii) Alternative methods to test toxicity of plant protection products containing an active substance that is a micro-organism on vertebrates, may also be included in a weight of evidence approach.

([1]) Commission Delegated Regulation (EU) 2021/1760 of 26 May 2021 supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council by establishing the criteria for the designation of antimicrobials to be reserved for the treatment of certain infections in humans (OJ L 353, 6.10.2021, p. 1).

([2]) Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43).

([3]) https://www.who.int/publications/i/item/9789241515528.

1. **IDENTITY OF THE APPLICANT, IDENTITY OF THE PLANT PROTECTION PRODUCT AND MANUFACTURING INFORMATION**

The information provided, taken together with that provided for the active substance that is a micro-organism, shall be sufficient to precisely identify and define plant protection products. The information provided, shall be sufficient to identify if any factor could alter the properties of the active substance that is a micro-organism as a plant protection product, in comparison to the active substance as such, which is treated in Part B of the Annex to Regulation (EU) No 283/2013. The information and data referred to, unless otherwise specified, are required for all plant protection products.

1.1. **Applicant**

The name and address of the applicant shall be provided as well as the name, address, telephone number and email address of the contact point.

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

The name and address of the producer of the preparation and of each active substance that is a micro-organism in the preparation shall be provided, as well as the name and address of each manufacturing plant in which the preparation and active substance that is a micro-organism are manufactured. If the producer contracts a third party for the manufacturing process, same information shall be provided for such third party.

A contact point (preferable a central contact point, to include name, telephone number, email address and fax number) shall be provided for each producer.

If the active substance that is a micro-organism is manufactured by a producer whose data have not been submitted in accordance with Regulation (EU) No 283/2013, data to address the relevant requirements laid down in Regulation (EU) No 283/2013 shall be provided.

1.3. **Trade name or proposed trade name, and producer'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 shall be provided. Full detail of any differences shall be provided. The proposed trade name shall 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 as unequivocally belonging to a certain species, based on the latest scientific information, and named at the strain level, including any other designation which may be relevant to the micro-organism (e.g. isolate level, if relevant for viruses), as required by point 1.3 of Part B of the Annex to Regulation (EU) No 283/2013. The micro-organism shall be deposited at an internationally recognised culture collection and given an accession number. The scientific name shall 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 plant protection product shall be stated.

(ii) For preparations, the following information shall be reported:

— the minimum and maximum content of the active substance that is a micro-organism in the plant protection product, as required in point 1.4.1 of Part B of the Annex to Regulation (EU) No 283/2013,

— the minimum and maximum content of the MPCA as manufactured in the plant protection product,

— in case of presence of relevant contaminating micro-organisms, the identity and the maximum content of relevant contaminating micro-organisms expressed in appropriate microbial unit,

— in case of presence of chemical impurities that are relevant for human and animal health and/or the environment, including metabolites of concern (identified in accordance with point 2.8 of Part B of the Annex to Regulation (EU) No 283/2013) produced by the micro-organism as relevant impurities in the manufacturing batch, the identity and maximum content, expressed in appropriate units, shall be provided,

— the content of co-formulants, safeners and synergists in the plant protection product.

(iii) Co-formulants, safeners and synergists shall, 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 shall be provided. For each component of the co-formulants safeners and synergists the relevant EC (EINECS or ELINCS) number and CAS number, where they exist, shall be provided. Where the information provided does not lead to an identification, an appropriate specification shall be provided. The trade name of co-formulants, safeners and synergists, shall also be provided.

(iv) For co-formulants, the function shall be given as:

— adhesive (sticker),

— antifoaming agent,

— antifreeze,

— antioxidant,

— binder,

— buffer,

— carrier,

— deodorant,

— dispersing agent,

— dye,

— emetic,

— emulsifier,

— fertilising product,

— odorant,

— osmoprotectant,

— perfume,

— preservative,

— propellant,

— repellent,

— safener,

— solar protectant,

— solvent,

— stabiliser,

— thickener,

— wetting agent,

— miscellaneous (shall be specified).

(v) Relevant contaminating micro-organisms shall be identified as provided for under point 1.4.2.2 of Part B of the Annex to Regulation (EU) No 283/2013.

Chemicals (inert components, by-products, etc.) shall be identified as provided for under point 1.10 of Part A of the Annex to Regulation (EU) No 283/2013. Where the information provided does not fully identify a component (such as condensate, culture medium), detailed information on the composition shall be provided for each such component.

1.5. **Physical state and nature of the preparation**

The type and code of preparation shall be designated in accordance with relevant guidance documents. Where a particular preparation is not defined precisely in relevant guidance documents, a full description of the physical nature and state of the preparation shall be provided, together with a proposal for a suitable description of the type of preparation and a proposal for its definition.

1.6. **Method of production of the preparation and quality control**

Full information on how the plant protection product is produced in bulk shall be provided for all the steps of the manufacturing process. The type of manufacturing process (e.g. continuous or batch process) shall be indicated.

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

(i) Packaging to be used shall be described and specified in terms of the materials used, manner of construction (e.g. extruded, welded), size and capacity, size of opening, type of closure and seals.

(ii) The suitability of the packaging, including closures, in terms of its strength, leakproofness and resistance to normal transport, storage and handling conditions, shall be determined and reported.

(iii) The resistance of the packaging material to its content shall be reported.

2. **PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF THE PLANT PROTECTION PRODUCT**

2.1. **Appearance (colour and odour)**

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

2.2. **Explosivity and oxidising properties**

Explosivity and oxidising properties shall be reported as provided for under point 2.2 of Part A, unless it can be justified that it is technically or scientifically not necessary to perform such studies.

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

Flash point and flammability shall be reported, as provided for under point 2.3 of Part A, unless it can be justified that it is technically or scientifically not necessary to perform such studies.

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

Acidity, alkalinity and pH (before and after storage at the recommended conditions) shall be reported, as provided for under point 2.4 of Part A, unless it can be justified that it is technically or scientifically not necessary to perform such studies.

2.5. **Viscosity and surface tension**

Viscosity and surface tension shall be reported, as provided for under point 2.5 of Part A, unless it can be justified that it is technically or scientifically not necessary to perform such studies.

2.6. **Storage stability and shelf life**

2.6.1. *Use concentration*

The appropriate minimum and maximum use concentrations of the plant protection product, justifying the volume of the commercial packaging used in line with a reasonable storage period, shall be indicated, as well as the nature of the packaging material in line with the recommended storage conditions.

2.6.2. *Effects of temperature and packaging*

The optimal temperature and packaging to ensure the storage stability of the plant protection product in line with the recommended maximal shelf life shall also be stated. Where shelf life is less than two years, the shelf life in months, shall be reported.

At these conditions, information shall be provided on:

— the physical stability of the preparation during and after storage at the recommended storage temperature and, in case of liquid preparation, at low temperatures, evaluated by performing tests in the original packaging,

— the content of the active substance that is a micro-organism, which shall be in accordance with the minimum and maximum certified content declared by the applicant before and after storage at the recommended storage temperature and, if applicable, at low temperatures,

— growth of possible relevant contaminating micro-organisms, before and after storage at the recommended storage temperature, described in appropriate terms for micro-organisms (such as number of active units per volume or weight, colony forming units (CFU) or international units per volume or weight, or any other manner that is relevant to the micro-organism),

— presence of metabolites of concern identified in accordance with point 2.8 of Part B of the Annex to Regulation (EU) No 283/2013, before and after storage.

2.6.3. *Other factors affecting stability*

Effect of exposure to air, light, etc., on the plant protection product's stability shall be reported.

The optimal moisture conditions to ensure the storage stability of the plant protection product shall be stated. For dry preparations also the effects of contaminating water on viability of the micro-organism shall be described. This information may be provided by direct measurement of moisture content before and after storage or by describing packaging integrity and viability of the micro-organism before and after storage.

2.7. **Technical characteristics of the plant protection product**

The technical characteristics of plant protection products shall be determined and reported at appropriate concentrations.

2.7.1. *Wettability*

The wettability of solid plant protection products which are diluted for use (e.g. wettable powders and water dispersible granules), shall be determined and reported.

2.7.2. *Persistent foaming*

The persistence of foaming of plant protection products to be diluted with water shall be determined and reported.

2.7.3. *Suspensibility, spontaneity of dispersion and dispersion stability*

The suspensibility of water dispersible plant protection products (e.g. wettable powders, water dispersible granules, suspension concentrates) shall be determined and reported.

The spontaneity of dispersion of water dispersible plant protection products (e.g. suspension concentrates and water dispersible granules) shall be determined and reported.

The dispersion stability of plant protection products such as aqueous suspo-emulsions (SE), oil-based suspension concentrates (OD) or emulsifiable granules (EG) shall be determined and reported.

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 shall be conducted and reported. In the case of water dispersible plant protection products, a wet sieve test shall be conducted and reported.

The nominal size range of granules shall be determined and reported.

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 shall be determined and reported. The nominal size range of granules for direct application shall be determined and reported.

(ii) The dust content of granular plant protection products shall be determined and reported. If results show > 1 % w/w dust then the particle size of the dust generated shall be determined and reported. If relevant for operator exposure the particle size of dust shall be determined and reported.

(iii) The friability and attrition characteristics of granules and tablets, which are loose packed, shall be determined and reported.

(iv) The hardness and integrity of tablets shall be determined and reported.

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

(i) The emulsifiability, emulsion stability and re-emulsifiability of plant protection products which form emulsions, shall be determined and reported.

(ii) The stability of dilute emulsions and of plant protection products which are emulsions, shall be determined and reported.

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

(i) The flowability of granular plant protection products shall be determined.

(ii) The pourability (including rinsed residue) of suspension plant protection products (e.g. suspension concentrates, suspo-emulsions) shall be determined and reported.

(iii) The dustability of dustable powders shall be determined and reported.

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

2.8.1. *Physical compatibility*

If in the label claim a use in a mixture with other plant protection products or adjuvants is indicated, the physical compatibility of the plant protection product with different plant protection products and adjuvants, which are indicated in the label claim, to be used in the same recommended tank mixes shall be determined and reported.

2.8.2. *Chemical compatibility*

If in the label claim a use in a mixture with other plant protection products or adjuvants is indicated, the chemical compatibility of the plant protection product with different plant protection products or adjuvants in the same recommended tank mixes shall be determined and reported, except where after examination of the individual properties of the plant protection product it is established 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.

2.9. **Adherence and distribution to seeds**

In the case of plant protection products for seed treatment, distribution and adhesion of the plant protection product to the seeds shall be investigated and reported.

3. **DATA ON APPLICATION**

3.1. **Field of use envisaged**

The field(s) of use, existing and proposed, for plant protection product containing the micro-organism shall be specified as:

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

— protected crops (e.g. in greenhouses),

— non-cultivated areas,

— home gardening,

— houseplants,

— stored food/feed items,

— other (shall be specified).

3.2. **Mode of action on the target organism**

The information required in accordance with point 2.3 of Part B of the Annex to Regulation (EU) No 283/2013 shall be provided for the plant protection product. Additional information on the mode of action on the target organism shall be provided in case the chemical components (e.g. co-formulants) may have a relevant effect on efficacy, human and animal health or the environment.

3.3. **Function, target organisms and plants or plants products to be protected and possible risk mitigation measures**

The biological function shall be given as one of the following:

— control of bacteria,

— control of fungi,

— control of insects,

— control of mites,

— control of molluscs,

— control of nematodes,

— control of plants,

— other (shall be specified).

Details of the target organisms and plants or plant products to be protected shall be provided.

3.4. **Application rate**

For each method of application and each use, the rate of application per unit treated, in terms of g, kg, ml or l for the plant protection product and in terms of appropriate units for the micro-organism (e.g. number of active units, colony forming units (CFU) or international units per volume or weight) shall be provided. For protected crops and home gardening use rates shall be expressed in g or kg/100 m^2, or g or kg/m^3, ml or l/100 m^2, or ml or l/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, such as number of active unit per volume or weight, colony forming units (CFU) or international units per volume or weight, or any other manner that is relevant to the micro-organism.

3.6. **Method of application**

The method of application proposed shall be described, 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 of application, or volume of plant protection product.

3.7. **Number and timing of applications on the same crop, duration of protection and waiting period(s)**

The maximum number of applications to be used on the same crop and their timing shall be reported.

Where relevant, the growth stages of the crops to be protected and the development stages of the target organisms shall be indicated. Where applicable, the interval between applications, in days, shall be stated. The duration of protection afforded both by each application and by the maximum number of applications to be used shall be indicated.

3.8. **Proposed instructions for use**

The proposed instructions for use of the plant protection product to be printed on labels and leaflets shall be provided. Details on the risk mitigation measures (if relevant) shall be provided.

3.9. **Safety intervals and other precautions to protect human health, animal health and the environment**

The information provided shall follow from and be supported by the data provided for the micro-organism(s) and that provided under Sections 7 to 10.

(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 human and animal health, shall 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 humans to crops, buildings or spaces treated,

— withholding period (in days) for animal feeding stuffs and for post-harvest uses,

— 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 plant protection product may or may not be used shall be provided.

4. **FURTHER INFORMATION ON THE PLANT PROTECTION PRODUCT**

4.1. **Procedures for cleaning and decontaminating of application equipment**

Cleaning and decontaminating procedures for application equipment and protective clothing shall be described.

Such procedures shall aim at inactivating or destroying the active substance that is a micro-organism and at removing residues of the plant protection product (including metabolites of concern, if any were identified in accordance with point 2.8 of Part B of the Annex to Regulation (EU) No 283/2013).

Sufficient data shall be submitted to demonstrate the effectiveness of the cleaning and decontaminating procedures.

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

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

Where relevant, an assessment of the procedures shall be provided.

The nature and characteristics of protective clothing and equipment proposed shall be provided. The data provided shall be sufficient to evaluate obtainability, suitability and effectiveness under realistic conditions of use (e.g. field or greenhouse circumstances), resistance and compatibility with the plant protection product.

4.3. **Measures in case of accident**

Whether arising during transport, storage or use, detailed procedures to be followed in the event of an accident shall 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 residents, including bystanders,

— first-aid measures.

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

Procedures for destruction and decontamination shall be developed and described for both small quantities (e.g. user level) and large quantities (e.g. warehouse level). The procedures shall 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 effects on the environment and be the most cost effective and practical means of disposal feasible.

4.4.1. *Controlled incineration*

The applicant shall provide detailed instructions for safe disposal, taking into consideration that, 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.

4.4.2. *Others*

Other methods for destruction or decontamination of plant protection products, packaging and contaminated materials, where proposed, shall be described. Data shall be provided for such methods.

5. **ANALYTICAL METHODS**

Introduction

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

Descriptions of methods shall be provided and include details of equipment, materials and conditions used. The applicability of internationally recognised methods shall be reported.

On request of competent authorities, the following samples shall be provided:

(i) samples of the preparation;

(ii) samples of the MPCA as manufactured;

(iii) sample of the seed stock;

(iv) if technically possible, analytical standards of metabolites of concern (see point 2.8 of Part B of the Annex to Regulation (EU) No 283/2013) and all other components included in the residue definition;

(v) if technically possible and needed, analytical standards of relevant impurities.

As far as practicable, the post-authorisation methods shall employ the simplest approach, involve the minimum cost and require commonly available equipment.

5.1. **Methods for the analysis of the preparation**

The following methods shall be described:

— for identification and quantification of each micro-organism in the plant protection product, of which the active substance consists, including methods on how to distinguish between different micro-organisms, when the plant protection product includes more than one, and the most appropriate molecular analytical or phenotypic methods as described in point 4.1 of Part B of the Annex to Regulation (EC) No 283/2013,

— to establish microbiological purity of the plant protection product,

— to detect and enumerate relevant contaminating micro-organisms in the plant protection product,

— used to determine the storage stability and shelf life of the plant protection product.

5.2. **Methods to determine and quantify residues**

Analytical methods for the determination of densities of the micro-organism and residues, as provided for under point 4.2 of Part B of the Annex to Regulation (EU) No 283/2013, shall be submitted, unless the information already submitted in accordance with the requirements of point 4.2 of Part B of the Annex to Regulation (EU) No 283/2013 is sufficient.

6. **EFFICACY DATA**

Introduction

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

The design, analysis, conduct and reporting of trials shall be in accordance with the relevant standards, where available. Deviations from available relevant standards may only be acceptable if the trials design meets the minimum requirements of the relevant standards and it is described and justified. The report shall include a detailed and critical assessment of the data.

The number of trials to be conducted and reported shall depend on factors such as the extent to which the properties of the active substance that is a micro-organism in the plant protection product are known. This number may depend also on the variability of conditions that arise in the trials (e.g. variability of plant health or climatic conditions), on the range of agricultural practices, the uniformity of the crops, the mode of application, the type of target organism, the climatic region and the type of plant protection product.

Data submitted shall be sufficient to be representative for the regions and the range of conditions of use encountered in practice concerning the uses of the plant protection product. If properly justified and relevant based on case-by-case approach and expert judgement, the applicant may read-across data to support the application, including data generated on other relevant uses, crops, European environments or other relevant conditions.

If read-across cannot be applied in order to assess seasonal differences, if any, sufficient data shall be generated and submitted to confirm the efficacy of the plant protection product in each agronomically and climatically different region for each particular crop (or commodity)/target organism combination. Trials on efficacy or phytotoxicity, where relevant, in at least two growing seasons shall be reported.

Any effects, positive or negative, on any non-target organism, which are observed in the tests performed in accordance with the requirements of this Section, shall be reported.

6.1. **Preliminary tests**

When requested by the competent authority, summary reports of preliminary tests shall be submitted, including laboratory, greenhouse and field studies, used to assess the biological activity, mode of action and dose-range finding of the plant protection product and the active substance(s) it contains. These reports shall provide justification on the combination of several active substances, safeners and/or synergists, if applicable, and they shall provide additional information for the competent authority when it evaluates the plant protection product. Where this information is not submitted, a justification, which is acceptable to the competent authority, shall be provided.

6.2. **Minimum effective dose**

The minimum effective dose shall be reported, or a range of minimum doses, necessary to achieve with sufficient efficacy the claimed plant protection action, across the broad range of situations in which that plant protection product is to be applied.

6.3. **Testing effectiveness**

The tests shall provide sufficient data to permit an evaluation of the level, duration and consistency of intended effects of the plant protection product. Also, possible beneficial effects on treated crops shall be reported. Tests shall include an untreated control. In case of availability of suitable reference products, a comparison shall be performed between the plant protection product subject of the application and the reference product. Trials shall be designed to investigate specified issues, to minimise the effects of random variation between different parts of each testing site and to enable statistical analysis to be applied to results amenable to such analysis. The design, analysis and reporting of trials shall be in accordance with relevant standards or with guidelines satisfying at least the requirements of the corresponding relevant standards. The report shall include a detailed and critical assessment of the data. A statistical analysis of results amenable to such analysis shall be carried out. Where necessary, the test guideline used shall be adapted to enable such analysis.

6.4. **Information on possible development of resistance in target organisms**

Data on the occurrence and development of resistance or cross-resistance in populations of target organisms to the active substance that is a micro-organism shall be provided, unless the applicant shows that the data and information already submitted for the active substance under point 3.4 of Part B of the Annex to Regulation (EU) No 283/2013 are sufficient to permit an assessment to be performed.

If provision of data is required, such data may be generated in experimental studies (either in laboratories or under field condition) or retrieved from available scientific literature.

If provision of data is required and information is available for uses not directly relevant to the uses for which authorisation is sought or to be renewed, including information on different species of target organism or different crops, this information shall also be provided. Where there is evidence or information to suggest that, in commercial use, the development of resistance is likely, evidence shall be generated and submitted as to the sensitivity of the population of the target 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 shall be provided.

6.5. **Adverse effects on treated crops**

6.5.1. *Phytotoxicity to target plants (including different cultivars) or to target plant products*

For herbicides and for other plant protection products for which adverse effects, however transitory, are seen during the trials, the margins of selectivity on target crops shall be established, using twice the recommended rate of application. In this case, tests shall be performed to provide sufficient data to permit an evaluation of the possible occurrence of phytotoxicity after treatment with the plant protection product. Where serious phytotoxic effects are seen, an intermediate application rate shall 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 that claim is required. If necessary, yield measurement shall be submitted.

If testing is required, the safety of the plant protection product to the main cultivars of the main crops for which it is recommended shall 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 shall 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. The test may be performed with the main preparation 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 provisions laid down in this point shall apply for the mixture.

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

6.5.2. *Effects on the yield of treated plants or plant products*

Tests shall be performed to provide sufficient data to permit an evaluation of the efficacy of the plant protection product and of possible occurrence of yield reduction or loss in storage of treated plants or plant products.

The effects of plant protection products on the yield or yield components of treated plant products shall be determined, unless the applicant can properly justify that such data is not relevant. When treated plants or plant products are likely to be stored, possible effects on the yield after storage, including data on storage life, shall be reported.

6.5.3. *Effects on the quality of plants or plant products*

Appropriate observations of quality parameters may be required for individual crops (for example, cereal grain quality and sugar content). Such information may be gathered from appropriate assessments in trials described under points 6.3 and 6.5.1.

Where relevant, taint testing shall be conducted.

6.5.4. *Effects on transformation processes*

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, and they are required when all of the following circumstances apply:

— the treated plants or plant products are normally intended for use in transformation process (e.g. wine making, brewing or bread making),

— at harvest, significant residues are present (see Section 8), and

— at least one of the following two also apply:

  — there are indications that the use of the plant protection product could have an influence on the processes involved (e.g., in the case of active substance that is a micro-organism with fungicidal function, when used close to the harvest), or

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

When the test is required, it may be performed with the main preparation type to be authorised. The possibility of the occurrence of adverse effects on transformation processes shall be investigated and reported. 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.

6.5.5. *Impact on treated plants or plant propagating material*

Sufficient data shall 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, except where the proposed uses preclude use on crops intended for production of seeds, cuttings, runners or tubers for planting, as appropriate.

Observations shall be submitted for:

(i) seeds – viability, germination and vigour;

(ii) cuttings – rooting and growth rates;

(iii) runners – establishment and growth rates;

(iv) tubers – sprouting and normal growth.

Seeds testing shall be done in accordance with the relevant standards or with guidelines satisfying at least their requirements.

6.6. **Observations on undesirable or unintended side-effects on succeeding crops and other plants**

6.6.1. *Impact on succeeding crops*

The provision laid down in this point shall apply only for:

— plant-pathogenic micro-organisms, or

— metabolites of concern for which a hazard to plants was identified, and for which data provided in accordance with Section 9 shows that significant amounts of these metabolites of concern remain in soil or in plant materials, such as straw or organics material up to sowing or planting time of possible succeeding crops.

Sufficient data shall be reported to permit an evaluation of possible adverse effects of a treatment with the plant protection product on succeeding crops. Minimum waiting periods between the last application and sowing or planting of succeeding crops shall be stated. Limitations on choice of succeeding crops, if any, shall be stated. The duration of protection brought both by each application and by the maximum number of applications to be used shall be indicated.

6.6.2. *Impact on other plants, including adjacent crops*

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

Observations shall 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 drift.

6.7. **Compatibility in plant protection programmes**

Where the proposed label claim includes requirements for the use conditions with other plant protection products in tank mix, spray sequences or other relevant types of applications, potential effects (e.g. antagonism, fungicidal effects) on the activity of the micro-organism after mixing, spraying in sequence, or employing other relevant types of applications with other plant protection products shall be investigated. Appropriate information shall be provided.

A general precautionary statement shall be proposed on the label, alerting the user about possible loss of efficacy of the micro-organism due to interaction in tank mix, spray sequences or other relevant types of applications with plant protection products other than those indicated in the label. Known biological incompatibilities with other plant protection products shall be reported on the label.

Appropriate recommendations (e.g. intervals between application of the plant protection product and other products) shall be specified, where necessary to avoid potential negative effects on the activity of the micro-organism. Appropriate information supporting the recommendations shall be provided.

If relevant, potential adverse effects of the plant protection product on natural enemies (e.g. released biological control agents) or other practices (e.g. conservation biological control) under the expected condition of use of the plant protection product shall be reported. The assessment of those potential adverse effects shall be based on information provided on one or more of the following:

— host range of the micro-organism (point 2.3 of Part B of the Annex to Regulation (EU) No 283/2013),

— effects on bees (point 8.3 of Part B of the Annex to Regulation (EU) No 283/2013 and point 10.3 of Part B of the Annex to Regulation (EU) No 284/2013),

— effects on non-target arthropods other than bees (point 8.4 of Part B of the Annex to Regulation (EU) No 283/2013 and point 10.4 of Part B of the Annex to Regulation (EU) No 284/2013) or

— any other relevant information.

7. **EFFECT ON HUMAN HEALTH**

Introduction

For proper evaluation of risks for human and animal (i.e. species normally fed and kept by humans or food-producing animals) health linked to the use of a plant protection product containing an active substance that is a micro-organism, the infectivity and pathogenicity of the micro-organism have been already assessed in accordance with Section 5 of Part B of the Annex to Regulation (EU) No 283/2013. This assessment includes the micro-organism and any metabolite(s) of concern for human and animal health identified in accordance with point 2.8 of Part B of the Annex to that Regulation.

This Section identifies the relevant additional tests to be carried out to determine the classification and labelling of the plant protection product and the acceptability of the risks related to its use. In some cases, already existing information on toxicity of co-formulants and other non-active ingredients of the plant protection product may be sufficient to conclude on the toxicity of the plant protection product.

In view of determining the classification and labelling of the plant protection product, as well as the risks associated with its use, information on intrinsic toxicological properties of the co-formulants, safeners and synergists, shall be provided. Possible adverse synergistic effects and/or interaction among chemical substances present in the plant protection product (e.g. co-formulants, other active substance(s) and its/their impurities present in the same plant protection product) shall also be investigated. Available data concerning any possible adverse effect on human health shall be reported.

The information provided shall be sufficient to allow an evaluation of the risks to human health associated with the use of the plant protection products (e.g. operators, workers, bystanders, residents and consumers), the risks for human health handling treated crops, as well as the risk for human health and animals arising from residual traces remaining in food, feed and water. In addition, the information provided shall be sufficient to:

— permit a decision to be made as to whether, or not, the plant protection product may be authorised,

— specify appropriate conditions or restrictions to be associated with any authorisation,

— specify hazard and precautionary statements for the protection of human health, animal health and the environment to be included on packaging (containers),

— identify relevant first aid measures as well as appropriate diagnostic and therapeutic measures to be followed in the event of infection or another adverse effect in humans.

In the context of the possible contribution that relevant impurities and other components can have on the toxicological profile of the plant protection product, for each study submitted, a detailed description of the material used shall be provided. Tests shall be conducted using the plant protection product to be authorised. In particular, the information provided shall demonstrate that the micro-organism used in the plant protection product and the conditions of culturing it are the same for which information and data are submitted in accordance with Part B of the Annex to Regulation (EU) No 283/2013. While performing toxicology studies, all signs of adverse effects shall be reported.

Based on the information submitted, proposals for the classification and labelling of the plant protection product, using CLP calculation rules in accordance with Regulation (EC) No 1272/2008, where applicable, shall be submitted and justified, including:

— pictograms,

— signal words,

— hazard statements, and

— precautionary statements.

Where the information available is considered not to be robust enough to exclude possible adverse synergistic effects of substances present in the plant protection product (e.g. co-formulants, other active substance(s) and its/their impurities present in the same plant protection product), toxicological studies on possible adverse synergistic effects shall be required by the competent authority, as described under points 7.4 and 7.7.

7.1. **Medical data**

Any available information on possible adverse effect on human health shall be reported, including sensitisation and allergenic response of humans exposed to the plant protection product. In the case of adverse effects, special attention shall be paid to whether the individual's susceptibility may have been affected by e.g. pre-existing disease, medication, compromised immunity, pregnancy or breast-feeding. The information provided shall include details of level and duration of exposure, symptoms observed and other relevant clinical observation.

7.2. **Assessment of potential toxicity of the plant protection product**

Possible human health hazards related to pathogenic events linked to the use of the plant protection product are addressed through data on infectivity, pathogenicity, and clearance of the active substance that is a micro-organism in accordance with Section 5 of Part B of the Annex to Regulation (EU) No 283/2013.

Studies to determine the potential toxicity of the plant protection product shall be performed as required in point 7.3, unless the applicant demonstrates by following a weight of evidence approach, based on the information provided under Sections 2, 3, 4 and point 7.1 or retrieved from any other reliable sources (e.g. Integrated Approach to Testing and Assessment – IATA, CLP calculation rules in accordance with Regulation (EC) No 1272/2008 or read-across data from similar preparations) that no such effects are to be expected. An assessment of the potential toxicity of the plant protection product shall be submitted, taking into consideration information on the intrinsic properties of co-formulants, metabolites of concern identified in accordance with point 2.8 of Part B of the Annex to Regulation (EU) No 283/2013, relevant impurities, with consideration for possible adverse synergistic effects and/or interaction between them and with the proposal for classification and labelling. With this assessment, the applicant shall demonstrate whether or not sufficient information is available to classify the plant protection product in accordance with Regulation (EC) No 1272/2008 with regard to toxicity to humans and whether or not acute toxicity studies on animals as described in points 7.3.1 to 7.3.6 are needed.

7.3. **Acute toxicity**

Unless information can be provided to allow an assessment to be conducted on the possible human toxicity of the plant protection product as set out in point 7.2, the applicant shall define which of the tests described in points 7.3.1 to 7.3.6 is relevant for the plant protection product and perform the test(s) identified in accordance with the instruction provided in each respective relevant point. The studies indicated in points 7.3.1 to 7.3.6, data and information to be provided and evaluated shall 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 acute toxicity of the plant protection product,

— the time course and characteristics of the adverse effect with full details of behavioural changes and possible gross toxicological findings at post-mortem in animal studies,

— where possible, the mode of toxic action, and

— the relative hazard associated with the different routes of exposure.

The information generated shall also permit the plant protection product to be classified in accordance with Regulation (EC) No 1272/2008.

7.3.1. *Acute oral toxicity*

Unless information can be provided to allow an assessment to be conducted on the possible acute oral toxicity of the plant protection product as set out in point 7.2, a test for acute oral toxicity shall be carried out in accordance with the most appropriate guidelines.

7.3.2. *Acute dermal toxicity*

Unless information can be provided to allow an assessment to be conducted on the possible dermal toxicity of the plant protection product as set out in point 7.2, a test for dermal toxicity shall be carried out in accordance with the most appropriate guidelines.

7.3.3. *Acute inhalation toxicity*

Unless information can be provided to allow an assessment to be conducted on the possible inhalation toxicity of the plant protection product as set out in point 7.2, a test for acute inhalation toxicity shall be carried out if the plant protection product:

— is used with fogging equipment,

— is used as a smoke generating formulation,

— is used as a vapour releasing preparation,

— is to be applied from aircraft in cases where inhalation exposure is relevant (broadcast air-assisted sprayer),

— 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 in a manner which generates a significant proportion of particles or droplets of diameter < 50 micrometre (> 1 % on a weight basis), or

— contains a volatile component at greater than 10 %.

7.3.4. *Skin irritation*

Unless information can be provided to allow an assessment to be conducted on the skin irritation potential of the plant protection product from the available information regarding its components, including the active substance, co-formulants, safeners, synergists, and relevant impurities as set out in point 7.2, a test for skin irritation shall be carried out in accordance with the most appropriate guidelines.

The test shall provide the potential of skin irritancy of the plant protection product including the potential reversibility of the effects observed.

7.3.5. *Eye irritation*

A test for eye irritation shall be carried out in accordance with the most appropriate guidelines, unless:

— information can be provided to allow an assessment to be conducted on the eye irritating potential of the plant protection product as set out in point 7.2, or

— the micro-organism is an already known eye irritant or it is likely, as indicated in the test guideline, that severe effects on the eyes may be produced.

The test shall provide the potential for eye irritation of the plant protection product, including the potential reversibility of the effects observed.

7.3.6. *Skin sensitisation*

Unless information can be provided to allow an assessment to be conducted on the skin sensitisation properties of the plant protection product from the available information regarding its chemical components (i.e. co-formulants, metabolites of concern and relevant impurities) as set out in point 7.2, a test for skin sensitisation when available, shall be carried out in accordance with the most appropriate guidelines.

7.4. **Additional toxicity information**

If, based on results of the studies required in point 7.3, one or more substances of concern is present in the plant protection product (e.g. metabolites of concern and/or co-formulants) for which the risk is for human and animal health is considered not acceptable based on those studies already performed, relevant additional information on toxicity may be necessary for the plant protection product. The need to perform supplementary studies on the plant protection product shall be based on expert judgement case-by-case, in the light of the particular parameters to be investigated and the objectives to be achieved, for example, if concern on the toxicity of the plant protection products has arisen from studies described in points 7.3.1 to 7.3.6 or a conclusion on toxicity could not be reached.

7.5. **Data on exposure**

If, based on data provided in Section 5 of Part B of the Annex to Regulation (EU) No 283/2013 and this Section, effects on human health cannot be excluded, sufficient information and data shall 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. Study design shall take into account biological, physical, chemical and toxicological properties of the plant protection product as well as the type of the product (undiluted/diluted), preparation type, and the route, the degree and duration of exposure.

In the case where there is a particular concern for a possibility of dermal absorption of a toxic component of the plant protection product based on information provided in this Section, dermal absorption data shall be provided as provided for under point 7.3 of Part A.

Results from exposure monitoring during production and use of the plant protection product shall be submitted.

The information and data referred to in this point shall provide the basis for the selection of appropriate protective measures including personal protective equipment (see point 4.2) to be used by operators and workers and other appropriate risk mitigation measures (e.g. for bystanders and residents) and to be specified on the label.

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

Where relevant, the following information shall be submitted for each co-formulants, safeners and synergists:

(a) the registration number as referred to in Article 20(3) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council ([4]);

(b) the study summaries included in the technical dossier; 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.

7.7. **Supplementary studies for combinations of plant protection products**

Where the plant protection product label indicates the use of the plant protection product with other plant protection products and/or with adjuvants as a tank mix, the studies as referred to under points 7.3.1 to 7.3.6 shall be carried out for the relevant combination of plant protection products. Decisions as to the need for supplementary studies shall 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 plant protection products concerned and available information or practical experience with the plant protection products concerned or similar plant protection products.

([4]) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

The need to perform supplementary studies on the plant protection product shall be based on expert judgement case-by-case, in the light of the particular parameters to be investigated and the objectives to be achieved (for example, for plant protection products containing active substances or other components suspected to have synergistic or additive toxicological effects).

8. **RESIDUES IN OR ON TREATED PRODUCTS, FOOD AND FEED**

Data and information on residues in or on treated products, food and feed in accordance with Section 6 of Part B of the Annex to Regulation (EU) No 283/2013 shall be submitted, unless the applicant shows that the data and information already submitted for the active substance are sufficient to permit a risk assessment to be performed on the plant protection product.

9. **FATE AND BEHAVIOUR IN THE ENVIRONMENT**

Data and information in accordance with Section 7 of Part B of the Annex to Regulation (EU) No 283/2013 shall be submitted on the fate and behaviour of the plant protection product in the environment, unless the applicant shows that the data and information already submitted for the active substance are sufficient to permit a risk assessment to be performed on the plant protection product.

10. **EFFECTS ON NON-TARGET ORGANISMS**

Introduction

(i) The information provided, taken together with that for the active substance that is a micro-organism provided in accordance with Part B of the Annex to Regulation (EU) No 283/2013 (including possible metabolite(s) of concern as identified in accordance with point 2.8 of Part B of the Annex to Regulation (EU) No 283/2013) shall be sufficient to permit an assessment of the potential impact on non-target species of the plant protection product, when used as proposed. When submitting this information, the applicant shall take into account that the impact on non-target species can result from single, prolonged or repeated exposure and can be reversible or irreversible.

(ii) Where exposure data are necessary to decide whether a study shall be performed, the data obtained in accordance with Section 9 shall be used. For the estimation of exposure of organisms all relevant information on the plant protection product and on the micro-organism shall be taken into account. Where relevant, the data provided for under this Section shall be used. Where it appears from available data that the plant protection product has a stronger effect than the active substance that is a micro-organism, the data on effects on non-target organisms of the plant protection product shall be used for the calculation of relevant effect/exposure ratios.

(iii) Unless it can be justified that an assessment of effects on non-target organisms can be performed with the information already available, experimental data may be required. The duration of experimental studies shall be long enough to permit time for incubation, infection and manifestation of adverse effects in non-target organisms, but in line with the expected exposure under the proposed use. In order to distinguish between pathogenic and toxic effects, appropriate controls shall be used in addition to the no-dosed control group, such as inactivated controls and/or sterile filtrate/supernatant controls. Special attention shall be required when the plant protection product contains a micro-organism which is pathogenic to non-target organisms other than mammals and that was not isolated from a relevant European environment. The information provided shall be sufficient to assess environmental impacts.

(iv) The relevance of non-target organism species used for testing environmental effects shall be based on a weight of evidence approach, taking into consideration, for instance:

— information on the micro-organism (particularly on biological properties) as required in Part B of the Annex to Regulation (EU) No 283/2013,

— information concerning the co-formulants, safeners and synergists, as required in Sections 1 to 9, and

— proposed use patterns of the plant protection product (e.g. foliar or soil application).

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

(v) All the adverse effects observed in tests and trials performed with the plant protection product shall be reported, and additional studies, which may be necessary to investigate the mechanisms involved and assess the significance of these effects, shall be undertaken and reported.

(vi) Where adverse toxic effects are indicated in the studies considered for the risk assessment and risk identified may be considered not acceptable, additional toxicity studies under field conditions and in accordance with the proposed recommendations for use shall be conducted, if applicable.

The type of study to be performed depends on the effects and the affected non-target organism(s) observed in the studies required in points 10.1 to 10.7 and during efficacy testing and may have to include also further studies on additional non-target species (i.e. different than those initially tested). Special attention shall be given to possible effects on non-target organisms occurring in the relevant European environment and deliberately released organisms for biological control purposes.

(vii) The information provided for the plant protection product, together with other relevant information, and that provided for the micro-organism (including possible metabolites of concern as identified in point 2.8 of Part B of the Annex to Regulation (EU) No 283/2013) 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.

10.1. **Effects on terrestrial vertebrates**

The same information submitted on the micro-organism (and/or on a plant protection product containing that active substance with respect to a representative use), as detailed in points 8.1, 8.7 and 8.8 of Part B of the Annex to Regulation (EU) No 283/2013 shall be provided for the plant protection product subject of the application, unless the applicant can:

— justify the applicability and relevance of the outcome of the assessment made on the same data submitted for the micro-organism approval (and/or for a plant protection product containing that active substance with respect to a representative use),

— predict the effects of the plant protection product on the basis of the data available for the co-formulants (e.g. qualitative and quantitative composition), as well as for the micro-organism and possible metabolites of concern (based on data submitted in accordance with Section 8 of Part B of the Annex to Regulation (EU) No 283/2013 for the approval of the micro-organism(s) in the plant protection product), or

— justify that the non-target terrestrial vertebrates (e.g. mammals, birds, reptiles, and amphibians) will not be exposed to the plant protection product (based on data submitted in accordance with Section 9).

If generation of data is required based on the provisions laid down under this point, relevant studies shall be performed and they shall provide LD_{50} values and include gross pathological findings. The studies may be conducted on the species used in the studies referred to in point 8.1 of Part B of the Annex to Regulation (EU) No 283/2013.

10.2. **Effects on aquatic organisms**

10.2.1. *Effects on fish*

The same information submitted on the micro-organism (and/or on a plant protection product containing that active substance with respect to a representative use) as detailed in points 8.2.1, 8.7 and 8.8 of Part B of the Annex to Regulation (EU) No 283/2013 shall be provided for the plant protection product subject of the application, unless the applicant can:

— justify the applicability and relevance of the outcome of the assessment made on the same data submitted for the micro-organism approval (and/or on a plant protection product containing that active substance with respect to a representative use),

— predict the effects of the plant protection product on the basis of the data available for the co-formulants (e.g. qualitative and quantitative composition), as well as for the micro-organism and possible metabolites of concern (based on data submitted in accordance with Section 8 of Part B of the Annex to Regulation (EU) No 283/2013 for the approval of the active substance(s) in the plant protection product), or

— justify that fish will not be exposed to the components of the plant protection product (based on data submitted in accordance with Section 9).

If generation of data is required based on the provisions laid down under this point, relevant studies shall be performed and they shall provide LD_{50} values, and shall include gross pathological findings. The studies may be conducted on the species used in the studies referred to in point 8.2.1 of Part B of the Annex to Regulation (EU) No 283/2013.

10.2.2. *Effects on aquatic invertebrates*

The same information submitted on the micro-organism (and/or on a plant protection product containing that active substance with respect to a representative use)as detailed in points 8.2.2, 8.7 and 8.8 of Part B of the Annex to Regulation (EU) No 283/2013 shall be provided for the plant protection product subject of the application, unless the applicant can:

— justify the applicability and relevance of the outcome of the assessment made on the same data submitted for the micro-organism approval (and/or on a plant protection product containing that active substance with respect to a representative use),

— predict the effects of the plant protection product on the basis of the data available for the co-formulants (e.g. qualitative and quantitative composition), as well as for the micro-organism and possible metabolites of concern (based on data submitted in accordance with Section 8 of Part B of the Annex to Regulation (EU) No 283/2013 for the approval of the active substance(s) in the plant protection product), or

— justify that the aquatic invertebrates will not be exposed to the components of the plant protection product (based on data submitted in accordance with Section 9).

If generation of data is required based on the provisions laid down under this point, relevant studies shall be performed.

10.2.3. *Effects on algae*

The same information submitted on the micro-organism (and/or on a plant protection product containing that active substance with respect to a representative use) as detailed in points 8.2.3, 8.7 and 8.8 of Part B of the Annex to Regulation (EU) No 283/2013 shall be provided for the plant protection product subject of the application, unless the applicant can:

— justify the applicability and relevance of the outcome of the assessment made on the same data submitted for the micro-organism approval (and/or on a plant protection product containing that active substance with respect to a representative use),

— predict the effects of the plant protection product on the basis of the data available for the co-formulants (e.g. qualitative and quantitative composition), as well as for the micro-organism and possible metabolites of concern (based on data submitted in accordance with Section 8 of Part B of the Annex to Regulation (EU) No 283/2013 for the approval of the micro-organism(s) in the plant protection product), or

— justify that algae will not be exposed to the components of the plant protection product (based on data submitted in accordance with Section 9).

If generation of data is required based on the provisions laid down under this point, relevant studies shall be performed.

10.2.4. *Effects on aquatic macrophytes*

The same information submitted on the micro-organism (and/or on a plant protection product containing that active substance with respect to a representative use) as detailed in points 8.2.4, 8.7 and 8.8 of Part B of the Annex to Regulation (EU) No 283/2013 shall be provided for the plant protection product subject of the application, unless the applicant can:

— justify the applicability and relevance of the outcome of the assessment made on the same data submitted for the micro-organism approval (and/or on a plant protection product containing that active substance with respect to a representative use),

— predict the effects of the plant protection product on the basis of the data available for the co-formulants (e.g. qualitative and quantitative composition), as well as for the micro-organism and possible metabolites of concern (based on data submitted in accordance with in Section 8 of Part B of the Annex to Regulation (EU) No 283/2013 for the approval of the micro-organism(s) in the plant protection product), or

— justify that aquatic macrophytes will not be exposed to the components of the plant protection product (based on data submitted in accordance with Section 9).

If generation of data is required based on the provisions laid down under this point, relevant studies shall be performed.

10.3. **Effects on bees**

The same information submitted on the micro-organism (and/or on a plant protection product containing that active substance with respect to a representative use) as detailed in points 8.3, 8.7 and 8.8 of Part B of the Annex to Regulation (EU) No 283/2013 shall be provided for the plant protection product subject of the application, unless the applicant can:

— justify the applicability and relevance of the outcome of the assessment made on the same data submitted for the micro-organism approval (and/or on a plant protection product containing that active substance with respect to a representative use),

— predict the effects of the plant protection product on the basis of the data available for the co-formulants (e.g. qualitative and quantitative composition), as well as for the micro-organism and possible metabolites of concern (based on data submitted in accordance with Section 8 of Part B of the Annex to Regulation (EU) No 283/2013 for the approval of the micro-organism(s) in the plant protection product), or

— justify that bees will not be exposed to the components of the plant protection product (based on data submitted in accordance with Section 9).

If generation of data is required based on the provisions laid down under this point, relevant studies shall be performed.

10.4. **Effects on non-target arthropods other than bees**

The same information submitted on the micro-organism (and/or on a plant protection product containing that active substance with respect to a representative use) as detailed in points 8.4, 8.7 and 8.8 of Part B of the Annex to Regulation (EU) No 283/2013 shall be provided for the plant protection product subject of the application, unless the applicant can:

— justify the applicability and relevance of the outcome of the assessment made on the same data submitted for the micro-organism approval (and/or on a plant protection product containing that active substance with respect to a representative use),

— predict the effects of the plant protection product on the basis of the data available for the co-formulants (e.g. qualitative and quantitative composition), as well as for the micro-organism and possible metabolites of concern (based on data submitted in accordance with Section 8 of Part B of the Annex to Regulation (EU) No 283/2013 for the approval of the micro-organism(s) in the plant protection product), or

— justify that the non-target arthropods other than bees will not be exposed to the components of the plant protection product (based on data submitted in accordance with Section 9).

If generation of data is required based on the provisions laid down under this point, relevant studies shall be performed. Analyses might include further studies on additional species, or higher tier studies such as studies on selected non-target organisms using the formulated plant protection product. The choice of non-target arthropods test species playing an important role in integrated pest management may be based on several factors, such as biological properties of the micro-organism and the intended use (e.g. crop type).

10.5. **Effects on non-target meso- and macroorganisms in soil**

The same information submitted on the micro-organism (and/or on a plant protection product containing that active substance with respect to a representative use) as detailed in points 8.5, 8.7 and 8.8 of Part B of the Annex to Regulation (EU) No 283/2013 shall be provided for the plant protection product subject of the application, unless the applicant can:

— justify the applicability and relevance of the outcome of the assessment made on the same data submitted for the micro-organism approval (and/or on a plant protection product containing that active substance with respect to a representative use),

— predict the effects of the plant protection product on the basis of the data available for the co-formulants (e.g. qualitative and quantitative composition), as well as for the micro-organism and possible metabolites of concern (based on data submitted in accordance with Section 8 of Part B of the Annex to Regulation (EU) No 283/2013 for the approval of the micro-organism(s) in the plant protection product), or

— justify that the non-target meso- and macroorganisms in soil will not be exposed to the components of the plant protection product (based on data submitted in accordance with Section 9).

If generation of data is required based on the provisions laid down under this point, relevant studies shall be performed.

10.6. **Effects on non-target terrestrial plants**

The same information submitted on the micro-organism (and/or on a plant protection product containing that active substance with respect to a representative use) as detailed in points 8.6, 8.7 and 8.8 of Part B of the Annex to Regulation (EU) No 283/2013 shall be provided for the plant protection product subject of the application, unless the applicant can:

— justify the applicability and relevance of the outcome of the assessment made on the same data submitted for the micro-organism approval (and/or on a plant protection product containing that active substance with respect to a representative use),

— predict the effects of the plant protection product on the basis of the data available for the co-formulants (e.g. qualitative and quantitative composition), as well as for the micro-organism and possible metabolites of concern (based on data submitted in accordance with Section 8 of Part B of the Annex to Regulation (EU) No 283/2013 for the approval of the micro-organism(s) in the plant protection product), or

— justify that the non-target terrestrial plants will not be exposed to the components of the plant protection product (based on data submitted in accordance with Section 9).

If generation of data is required based on the provisions laid down under this point, relevant studies shall be performed.

10.7. **Additional toxicity studies**

Further data may be submitted or additional toxicity studies performed, if tests required in points 10.1 to 10.6 have shown adverse effects in one or more non-target organisms and the risk is considered not acceptable. The type of study to be performed shall be chosen based on the effects and the affected non-target organism(s) observed in the studies required in points 10.1 to 10.6 and during efficacy testing, and may have to include also further studies on additional non-target species.'