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

(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 29(6) and Article 78(1)(c) thereof,

Whereas:

(1) Commission Regulation (EU) No 546/2011 ([2]) provides for uniform principles for evaluation and authorisation of plant protection products. Part I and Part II of the Annex to Regulation (EU) No 546/2011 lay down, for plant protection products containing chemical substances and micro-organisms respectively, the existing uniform principles for assessing whether the plant protection products may have harmful effects on human health, animal health or unacceptable effects on the environment in view of their authorisation.

(2) The Farm to Fork Strategy for a fair, healthy and environmentally friendly food system of the Commission ([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 these objectives, it is necessary to specify the uniform principles 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) Since micro-organisms are living organisms, a specific approach is needed compared to chemical substances, in order to also take into account the current state of Science regarding the biology of micro-organisms. That scientific knowledge consists of 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.

(4) The currently available 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 the ecological characteristics of the respective species and, where applicable, the respective strains of micro-organisms. As it allows 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.

(5) In order to better reflect the latest scientific developments and the specificities of micro-organisms, while maintaining a high level of protection of human and animal health and of the environment, it is therefore necessary to adapt the existing uniform principles accordingly.

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

([2]) Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products (OJ L 155, 11.6.2011, p. 127).

([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).

(6) Currently available scientific knowledge about the capacity of micro-organisms to transfer antimicrobial resistance genes to other micro-organisms which are pathogenic and occurring in European environments, hence potentially affecting the effectiveness of antimicrobials used in human or veterinary medicine 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 updated scientific and technical knowledge on transferability of antimicrobial resistance, and ensure for 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.

(7) For the sake of clarity of the uniform principles, various points that currently appear in sections A, B and C of both Part I and Part II of the Annex should be consolidated in a general introduction.

(8) The current Annex to Regulation (EU) No 546/2011 contains references to Commission Regulations (EU) No 544/2011 ([4]) and (EU) No 545/2011 ([5]), which are no longer in force. It is therefore appropriate to update these references and refer to Commission Regulation (EU) No 283/2013 ([6]) and Commission Regulation (EU) No 284/2013 ([7]), respectively, which replaced Regulations (EU) No 544/2011 and (EU) No 545/2011.

(9) The uniform principles for evaluation and authorisation of plant protection products aim to ensure that evaluations and decisions with regard to authorisation of plant protection products by Member States result in a high level of protection of human and animal health and the environment as required by Regulation (EC) No 1107/2009. The uniform principles also give some explanations on how the Member States are to assess data submitted by applicants in accordance with the data requirements as set out in the relevant legislation. Considering that the legislation setting out the data requirements is being amended by Commission Regulation (EU) 2022/1441 ([8]) it is necessary to ensure consistency in the application of new rules, so that new applications are submitted according to the amended data requirements.

(10) Part A of the Annexes to Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013 sets out the requirements for the data to be assessed in accordance with the uniform principles, and refers to chemical active substances and plant protection products containing them, respectively. For the sake of legal certainty, clarity and consistency with Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013, Part I of the Annex to Regulation (EU) No 546/2011 should be renamed as 'Part A'.

(11) Part B of the Annexes to Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013 sets out the requirements for the data to be assessed in accordance with the uniform principles, and refers to active substances that are micro-organisms and plant protection products containing them, respectively. For the sake of legal certainty, clarity and consistency with Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013, Part II of the Annex to Regulation (EU) No 546/2011 should be renamed as 'Part B'.

([4]) Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances (OJ L 155, 11.6.2011, p. 1).

([5]) Commission Regulation (EU) No 545/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for plant protection products (OJ L 155, 11.6.2011, p. 67).

([6]) 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).

([7]) 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).

([8]) Commission Regulation (EU) 2022/1441 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 (see page 70 of this Official Journal).

(12) 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

The Annex to Regulation (EU) No 546/2011 is replaced by the text set out in the Annex to this Regulation.

Article 2

Regulation (EU) No 546/2011 as it stood prior to being amended by this Regulation shall continue to apply to applications for authorisation of plant protection products, within the meaning of Regulation (EC) No 1107/2009, for which data is submitted in accordance with Commission Regulation (EU) No 284/2013 in the version applicable before 21 November 2022.

Article 3

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 all Member States.

Done at Brussels, 31 August 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

'ANNEX

GENERAL INTRODUCTION

1. **GENERAL PRINCIPLES**

1.1. The objective of the principles developed in this Annex is to ensure a high level of protection of human and animal (species normally fed and kept by humans or food-producing animals) health and the environment in evaluations and decisions by Member States with regard to authorisation of plant protection products, implementing the requirements of Article 29(1)(e) in conjunction with Article 4(3) and Article 29(1)(f), (g) and (h) of Regulation (EC) No 1107/2009. For the purpose of this Annex, the following definitions apply:

(1) **'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);

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

(3) **'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.

1.2. In evaluating applications for granting authorisations Member States shall:

(a)

— ensure that dossiers supplied are in accordance with the requirements of the Annex to Commission Regulation (EU) No 284/2013 ([1]), at the latest at the time of finalisation of the evaluation for the purpose of decision-making, without prejudice, where relevant, to Articles 33, 34 and 59 of Regulation (EC) No 1107/2009,

— ensure that the data submitted by the applicant are acceptable in terms of quantity, quality, consistency and reliability and sufficient to permit a proper evaluation of the dossier,

— evaluate, where relevant, justifications submitted by the applicant for not supplying certain data;

(b) take into account the data concerning the active substance in the plant protection product of the Annex to Commission Regulation (EU) No 283/2013 ([2]), submitted for the purpose of approval of the active substance under Regulation (EC) No 1107/2009, and the results of the evaluation of those data, without prejudice, where relevant, to the provisions of Article 33(3) and of Articles 34 and 59 of Regulation (EC) No 1107/2009;

(c) take into consideration other relevant technical or scientific information with regard to the efficacy of the plant protection product or to the potentially adverse effects of the plant protection product its components or its residues, where relevant.

1.3. Where, in the specific principles on evaluation, reference is made to the data of the Annex to Regulation (EU) No 283/2013 this shall be understood as being the data referred to in point 1.2(b) of this Annex.

([1]) 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).

([2]) 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).

1.4. Where the data and information provided are sufficient to permit completion of the evaluation for one of the proposed uses, Member States shall evaluate applications and make a decision for the proposed use.

Taking account of justifications provided and with the benefit of any subsequent clarifications, Member States shall reject applications for granting authorisations for which the data gaps are such that it is not possible to finalise the evaluation and to make a reliable decision for at least one of the proposed uses.

1.5. During the process of evaluation and decision-making, Member States shall cooperate with the applicants in order to resolve any questions on the dossier quickly or to identify at an early stage any additional studies necessary for a technically complete dossier that allows for a proper evaluation, or to amend any proposed conditions for the use of the plant protection product or to modify its nature or its composition in order to ensure full compliance with the requirements of this Annex and more generally with the provisions of Regulation (EC) No 1107/2009.

1.6. During the process of evaluation and decision-making, Member States shall base their assessment on scientific principles, preferably recognised at international level, and this process shall be made with the benefit of expert advice.

1.7. Member States shall take into account those guidance documents applicable at the date of the submission of the application for the authorisation.

2. **EVALUATION, GENERAL PRINCIPLES**

2.1. Having regard to current scientific and technical knowledge, Member States shall evaluate the information referred to in point 1.2, and in particular:

(a) identify the risks arising, assess their significance and the expected exposure, and make a judgement as to the likely risks to humans, animals or the environment;

(b) assess efficacy in terms of effectiveness (including possible development of resistance or cross-resistance of the target organism(s)) and adverse effects (including phytotoxicity/pathogenicity) on crops (including treated crops, succeeding crops and adjacent crops) of the plant protection product for each use for which authorisation is sought.

2.2. Member States shall evaluate the quality and the methodology of tests, especially where there are no standardised test methods, as well as the following characteristics of the methods described, when available:

relevance; representativeness; sensitivity; specificity; reproducibility.

2.3. In interpreting the results of evaluations, Member States shall take into consideration and report possible elements of uncertainty in the information obtained during the evaluation, in order to ensure that the chances of failing to detect adverse effects or of underestimating their importance are reduced to a minimum. The decision-making process shall be examined to identify critical decision points or items of data for which uncertainties could lead to a false classification of risk.

2.4. In accordance with Article 29 of Regulation (EC) No 1107/2009, Member States shall ensure that evaluations carried out have regard to the proposed practical conditions of use and, in particular, to the purpose of use, the application dose, the application method, frequency and timing of applications, and the nature and composition of the plant protection product.

In accordance with the requirements for proper use as set out in Article 55 of Regulation (EC) No 1107/2009, Member States shall take into account the provisions of Directive 2009/128/EC of the European Parliament and of the Council [3] and, in particular, the principles of integrated pest management.

2.5. In the evaluation, Member States shall consider the agricultural, plant health or environmental (including climatic) conditions in the areas of use.

[3] Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides (OJ L 309, 24.11.2009, p. 71).

2.6. Where specific principles in Section 1 of Part A or Section 1 of Part B (as applicable) provide for the use of calculation models in the evaluation of a plant protection product, those models shall:

(a) make a best possible estimation in an appropriate way of all relevant processes involved taking into account realistic parameters and assumptions;

(b) be submitted to an evaluation as referred to in point 2.3;

(c) be reliably validated with measurements carried out under circumstances relevant for the use of the model;

(d) be relevant to the conditions in the area of use;

(e) in cases the models have not been validated, be supported with details indicating how the model calculates estimates provided, and explanations of all the inputs to the model and details of how they have been derived.

2.7. Where metabolites are referred to in the specific principles, only those that are relevant for the proposed criterion shall be taken into consideration. For Part A this concerns also degradation or reaction products. For Part B this concerns what is defined as "metabolites of concern".

3. **DECISION-MAKING, GENERAL PRINCIPLES**

3.1. Where appropriate, Member States shall impose conditions or restrictions on the authorisations they grant. The nature and severity of these conditions or restrictions shall be selected on the basis of, and be appropriate to, the nature and extent of the expected advantages and the risks likely to arise.

3.2. Member States shall ensure that decisions taken to grant authorisations take account of the agricultural, plant health or environmental (including climatic) conditions in the areas of envisaged use. Such considerations may result in specific conditions and restrictions on use, and in authorisation being granted for some but not other areas within the Member State in question.

3.3. Member States shall ensure that the authorised application rates and number of applications, are the minimum necessary to achieve the desired effect even where higher rates would not result in unacceptable risks to human or animal health or to the environment. The authorised rates shall be differentiated in accordance with, and be appropriate to, the agricultural, plant health or environmental (including climatic) conditions in the various areas for which an authorisation is granted. However, the application rates and the number of applications may not give rise to undesirable effects such as the development of resistance in the target organism.

3.4. Member States shall ensure that decisions taken to grant authorisations consider integrated pest management as set out in Directive 2009/128/EC. In particular, Member States shall ensure that a warning phrase is indicated on the label in case negative effects are expected on beneficial organisms that are deliberately released as part of integrated pest management strategies.

3.5. Since the evaluation is to be based on data concerning a limited number of representative non-target species, Member States shall ensure that use of plant protection products does not have any long-term repercussions for the abundance and diversity of non-target species.

3.6. Before issuing an authorisation, Member States shall ensure that the label of the plant protection product:

(a) fulfils the requirements setting out in Regulation (EU) No 547/2011;

(b) also contains the information on protection of operators, workers, bystanders and residents required by EU legislation on worker protection;

(c) specifies in particular the conditions or restrictions under which the plant protection product may or may not be used as referred to in points 3.1 to 3.5 of this general introduction.

The authorisation shall mention the particulars indicated in Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([4]).

3.7. Before issuing authorisations, Member States shall:

(a) ensure that the proposed packaging is in accordance with the provisions of Regulation (EC) No 1272/2008;

(b) ensure that the following procedures are in accordance with the relevant regulatory provisions:

— the procedures for destruction of the plant protection product,

— the procedures for neutralisation of any adverse effects of the plant protection product if it is accidentally dispersed, and

— the procedures for the decontamination and destruction of the packaging.

3.8. No authorisation shall be granted unless all the requirements referred to in Section 2 of Part A or Section 2 of Part B (as applicable) are satisfied. However:

(a) when one or more of the specific decision-making requirements referred to in points 2.1, 2.2, 2.3 or 2.7 of Part A, or point 2.3 of Part B, respectively, are not satisfied, authorisations shall be granted only where the advantages of the use of the plant protection product under the proposed conditions of use outweigh the possible adverse effects of its use. Any restrictions on use of the plant protection product relating to non-compliance with some of the aforementioned requirements must be mentioned on the label, and non-compliance with the requirements referred to in point 2.7 of Part A (if Part A applies) shall not compromise proper use of the plant protection product. These advantages can be in terms of:

— advantages for and compatibility with integrated control measures or organic farming,

— facilitating strategies to minimise the risk of development of resistance,

— the need for a greater diversity of types of active substances or biochemical modes of action, e.g. for use in strategies to avoid accelerated breakdown in the soil,

— reduced risk for operators and consumers,

— reduced contamination of the environment and reduced impact on non-target species.

(b) where the criteria referred to in point 2.6 of Part A or point 2.4 of Part B, respectively, are not fully satisfied because of limitations in current analytical science and technology, authorisation shall be granted for a limited period if the methods submitted prove adequate for the purposes intended. In this case, the applicant shall be required to develop and submit analytical methods that are in accordance with those criteria by a specific deadline. The authorisation shall be reviewed on expiry of that deadline;

(c) where the reproducibility of the submitted analytical methods referred to in point 2.6 of Part A or point 2.4 of Part B, respectively has only been verified in two laboratories, an authorisation shall be granted for 1 year to permit the applicant to demonstrate the reproducibility of those methods in accordance with agreed criteria in at least a third laboratory.

3.9. Where an authorisation has been granted in accordance with the requirements provided for in this Annex, Member States may, by virtue of Article 44 of Regulation (EC) No 1107/2009:

(a) define, where possible, preferably in close cooperation with the applicant, measures to improve the efficacy of the plant protection product; and/or

(b) define, where possible, in close cooperation with the applicant, measures to reduce further the exposure that could occur during and after use of the plant protection product.

([4]) 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).

Member States shall inform applicants of any measures identified under (a) or (b) and shall require applicants to provide any supplementary data and information necessary to demonstrate efficacy or acceptability of risks arising under the changed conditions.

3.10. Member States shall ensure, as far as it is practically possible, that for all active substances contained in plant protection products that are considered for an authorisation, the applicant has taken into account all available relevant knowledge and information in scientific literature at the time of submission of the dossier on the plant protection product.

PART A

Uniform principles for evaluation and authorisation of chemical plant protection products

1. **EVALUATION**

Member States shall, for the evaluation of the data and information submitted in support of applications, and without prejudice to the general principles of Section 2 of the general introduction, implement the following principles.

1.1. **Efficacy**

1.1.1. Where the proposed use concerns the control of or protection against an organism, Member States shall evaluate the possibility that this organism could be harmful under the agricultural, plant health and environmental (including climatic) conditions in the area of the proposed use.

1.1.2. Where the proposed use concerns an effect other than the control of or protection against an organism, Member States shall evaluate whether significant damage, loss or inconvenience could occur under the agricultural, plant health and environmental (including climatic) conditions in the area of proposed use if the plant protection product were not used.

1.1.3. Member States shall evaluate the efficacy data on the plant protection product as provided for in the Annex to Regulation (EU) No 284/2013 having regard to the degree of control or the extent of the effect desired and having regard to the relevant experimental conditions such as:

— the choice of the crop or cultivar,

— the agricultural and environmental (including climatic) conditions,

— the presence and density of the harmful organism,

— the development stage of crop and organism,

— the amount of the plant protection product used,

— if required on the label, the amount of adjuvant added,

— the frequency and timing of the applications,

— the type of application equipment.

1.1.4. Member States shall evaluate the performance of the plant protection product in a range of agricultural, plant health and environmental (including climatic) conditions likely to be encountered in practice in the area of proposed use and in particular:

(i) the level, consistency and duration of the effect sought in relation to the dose in comparison with a suitable reference product or products and an untreated control;

(ii) where relevant, effect on yield or reduction of loss in storage, in terms of quantity and/or quality, in comparison with a suitable reference product or products and an untreated control.

Where no suitable reference product exists, Member States shall evaluate the performance of the plant protection product to determine whether there is a consistent and defined benefit under the agricultural, plant health and environmental (including climatic) conditions in the area of proposed use.

1.1.5. Where the product label includes requirements for use of the plant protection product with other plant protection products and/or with adjuvants as a tank mix, Member States shall make the evaluations referred to in points 1.1.1 to 1.1.4 in relation to the information supplied for the tank mix.

Where the product label includes recommendations for use of the plant protection product with other plant protection products and/or with adjuvants as a tank mix, Member States shall evaluate the appropriateness of the mix and of its conditions of use.

1.2. **Absence of unacceptable effects on plants or plant products**

1.2.1. Member States shall evaluate the degree of adverse effects on the treated crop after use of the plant protection product in accordance with the proposed conditions of use in comparison, where relevant, with a suitable reference product or products, where they exist, and/or an untreated control.

(a) This evaluation shall take into consideration the following information:

(i) the efficacy data provided for in the Annex to Regulation (EU) No 284/2013;

(ii) other relevant information on the plant protection product such as nature of the preparation, dose, method of application, number and timing of applications;

(iii) all relevant information on the active substance as provided for in of the Annex to Regulation (EU) No 283/2013, including mode of action, vapour pressure, volatility and water solubility.

(b) This evaluation shall include:

(i) the nature, frequency, level and duration of observed phytotoxic effects and the agricultural, plant health and environmental (including climatic) conditions that affect them;

(ii) the differences between main cultivars with regard to their sensitivity to phytotoxic effects;

(iii) the part of the treated crop or plant products where phytotoxic effects are observed;

(iv) the adverse impact on the yield of the treated crop or plant products in terms of quantity and/or quality;

(v) the adverse impact on treated plants or plant products to be used for propagation, in terms of viability, germination, sprouting, rooting and establishment;

(vi) where volatile products are concerned, the adverse impact on adjacent crops.

1.2.2. Where the available data indicate that the active substance or significant metabolites, degradation and reaction products persist in soils and/or in or on plant substances in significant quantities after use of the plant protection product in accordance with the proposed conditions of use, Member States shall evaluate the degree of adverse effects on subsequent crops. This evaluation shall be carried out as specified in point 1.2.1.

1.2.3. Where the product label includes requirements for use of the plant protection product with other plant protection products or with adjuvants as a tank mix, the evaluation as specified in point 1.1.1 shall be carried out in relation to the information supplied for the tank mix.

1.3. **Impact on vertebrates to be controlled**

Where the proposed use of the plant protection product aims to have an effect on vertebrates, Member States shall evaluate the mechanism by which this effect is obtained and the observed effects on the behaviour and health of the target animals; when the intended effect is to kill the target animal they shall evaluate the time necessary to obtain the death of the animal and the conditions under which death occurs.

This evaluation shall take into consideration the following information:

(i) all relevant information as provided for in the Annex to Regulation (EU) No 283/2013 and the results of the evaluation thereof, including the toxicological and metabolism studies;

(ii) all relevant information on the plant protection product as provided for in the Annex to Regulation (EU) No 284/2013, including toxicological studies and efficacy data.

1.4. **Impact on human or animal health**

1.4.1. Impact on human or animal health arising from the plant protection product

1.4.1.1. Member States shall evaluate operator exposure to the active substance and/or to toxicologically relevant compounds in the plant protection product likely to occur under the proposed conditions of use (including in particular dose, application method and climatic conditions) using by preference realistic data on exposure and, if such data are not available, a suitable, validated calculation model.

(a) This evaluation shall take into consideration the following information:

(i) the toxicological and metabolism studies as provided for in the Annex to Regulation (EU) No 283/2013 and the results of the evaluation thereof including the acceptable operator exposure level (AOEL). The acceptable operator exposure level is the maximum amount of active substance to which the operator may be exposed without any adverse health effects. The AOEL is expressed as milligrams of the chemical per kilogram body weight of the operator. The AOEL is based on the highest level at which no adverse effect is observed in tests in the most sensitive relevant animal species or, if appropriate data are available, in humans;

(ii) other relevant information on the active substances such as physical and chemical properties;

(iii) the toxicological studies provided for in the Annex to Regulation (EU) No 284/2013, including where appropriate dermal absorption studies;

(iv) other relevant information as provided for in the Annex to Regulation (EU) No 284/2013 such as:

— composition of the preparation,

— nature of the preparation,

— size, design and type of packaging,

— field of use and nature of crop or target,

— method of application including handling, loading and mixing of product,

— exposure reduction measures recommended,

— protective clothing recommendations,

— maximum application rate,

— minimum spray application volume stated on the label,

— number and timing of applications.

(b) This evaluation shall be made for each type of application method and application equipment proposed for use of the plant protection product as well as for the different types and sizes of containers to be used, taking account of mixing, loading operations, application of the plant protection product and cleaning and routine maintenance of application equipment.

1.4.1.2. Member States shall examine information relating to the nature and characteristics of the packaging proposed with particular reference to the following aspects:

— the type of packaging,

— its dimensions and capacity,

— the size of the opening,

— the type of closure,

— its strength, leakproofness and resistance to normal transport and handling,

— its resistance to and compatibility with the contents.

1.4.1.3. Member States shall examine the nature and characteristics of the protective clothing and equipment proposed with particular reference to the following aspects:

— obtainability and suitability,

— ease of wearing taking into account physical stress and climatic conditions.

1.4.1.4. Member States shall evaluate the possibility of exposure of other humans (bystanders or workers exposed after the application of the plant protection product) or animals to the active substance and/or to other toxicologically relevant compounds in the plant protection product under the proposed conditions of use.

This evaluation shall take into consideration the following information:

(i) the toxicological and metabolism studies on the active substance as provided for in the Annex to Regulation (EU) No 283/2013 and the results of the evaluation thereof, including the acceptable operator exposure level;

(ii) the toxicological studies provided for in the Annex to Regulation (EU) No 284/2013, including where appropriate dermal absorption studies;

(iii) other relevant information on the plant protection product as provided for in the Annex to Regulation (EU) No 284/2013 such as:

— re-entry periods, necessary waiting periods or other precautions to protect humans and animals,

— method of application, in particular spraying,

— maximum application rate,

— maximum spray application volume,

— composition of the preparation,

— excess remaining on plants and plant products after treatment,

— further activities whereby workers are exposed.

1.4.2. Impact on human and animal health arising from residues

1.4.2.1. Member States shall evaluate the specific information on toxicology as provided for in the Annex to Regulation (EU) No 283/2013 and in particular:

— the determination of an acceptable daily intake (ADI),

— the identification of metabolites, degradation and reaction products in treated plants or plant products,

— behaviour of residues of the active substance and its metabolites from the time of application until harvest, or in the case of postharvest uses, until outloading of stored plant products.

1.4.2.2. Prior to evaluating the residue levels in the reported trials or in products of animal origin Member States shall examine the following information:

— data on the proposed good agricultural practice, including data on application as provided for in the Annex to Regulation (EU) No 284/2013 and proposed pre-harvest intervals for envisaged uses, or withholding periods or storage periods, in the case of post-harvest uses,

— nature of the preparation,

— analytical methods and the residue definition.

1.4.2.3. On the basis of suitable statistical models Member States shall evaluate the residue levels observed in the reported trials. This evaluation shall be made for each proposed use and shall take into consideration:

(i) the proposed conditions of use of the plant protection product;

(ii) the specific information on residues in or on treated plants, plant products, food and feed as provided for in the Annex to Regulation (EU) No 284/2013 and the distribution of residues between edible and non-edible parts;

(iii) the specific information on residues in or on treated plants, plant products, food and feed as provided for in the Annex to Regulation (EU) No 283/2013 and the results of the evaluation thereof;

(iv) the realistic possibilities of extrapolating data from one crop to another.

1.4.2.4. Member States shall evaluate the residue levels observed in products of animal origin, taking into consideration the information provided for in Section 8 of Part A of the Annex to Regulation (EU) No 284/2013 and residues resulting from other uses.

1.4.2.5. Member States shall estimate the potential exposure of consumers through diet and, where relevant, other ways of exposure, using a suitable calculation model. This evaluation shall take account, where relevant, of other sources of information such as other authorised uses of plant protection products containing the same active substance or which give rise to the same residues.

1.4.2.6. Member States shall, where relevant, estimate the exposure of animals, taking into account the residue levels observed in treated plants or plant products intended to be fed to animals.

1.5. **Influence on the environment**

1.5.1. Fate and distribution in the environment

In the evaluation of the fate and distribution of the plant protection product in the environment, Member States shall have regard to all aspects of the environment, including biota, and in particular to the following:

1.5.1.1. Member States shall evaluate the possibility of the plant protection product reaching the soil under the proposed conditions of use; if this possibility exists they shall estimate the rate and the route of degradation in the soil, the mobility in the soil and the change in the total concentration (extractable and non-extractable ([5])) of the active substance and of relevant metabolites, degradation and reaction products that could be expected in the soil in the area of envisaged use after use of the plant protection product in accordance with the proposed conditions of use.

This evaluation shall take into consideration the following information:

(i) the specific information on fate and behaviour in soil as provided for in the Annex to Regulation (EU) No 283/2013 and the results of the evaluation thereof;

(ii) other relevant information on the active substance such as:

— molecular weight,

— solubility in water,

— octanol/water partition coefficient,

— vapour pressure,

— volatilisation rate,

— dissociation constant,

— photodegradation rate and identity of breakdown products,

— hydrolysis rate in relation to pH and identity of breakdown products.

(iii) all information on the plant protection product as provided for in the Annex to Regulation (EU) No 284/2013, including the information on distribution and dissipation in soil;

(iv) where relevant, other authorised uses of plant protection products in the area of proposed use containing the same active substance or which give rise to the same residues.

([5]) Non-extractable residues (sometimes referred to as 'bound' or 'non-extracted' residues) in plants and soils are defined as chemical species originating from pesticides used in accordance with good agricultural practice that cannot be extracted by methods which do not significantly change the chemical nature of these residues. These non-extractable residues are not considered to include fragments through metabolic pathways leading to natural products.

1.5.1.2. Member States shall evaluate the possibility of the plant protection product reaching the groundwater under the proposed conditions of use; if this possibility exists, they shall estimate, using a suitable calculation model validated at EU level, the concentration of the active substance and of relevant metabolites, degradation and reaction products that could be expected in the groundwater in the area of envisaged use after use of the plant protection product in accordance with the proposed conditions of use.

As long as there is no validated EU calculation model, Member States shall base their evaluation especially on the results of mobility and persistence in soil studies as provided for in the Annex to Regulation (EU) No 283/2013 and to Regulation (EU) No 284/2013.

This evaluation shall also take into consideration the following information:

(i) the specific information on fate and behaviour in soil and water as provided for in the Annex to Regulation (EU) No 283/2013 and the results of the evaluation thereof;

(ii) other relevant information on the active substance such as:

— molecular weight,

— solubility in water,

— octanol/water partition coefficient,

— vapour pressure,

— volatilisation rate,

— hydrolysis rate in relation to pH and identity of breakdown products,

— dissociation constant;

(iii) all information on the plant protection product as provided for in the Annex to Regulation (EU) No 284/2013, including the information on distribution and dissipation in soil and water;

(iv) where relevant, other authorised uses of plant protection products in the area of envisaged use containing the same active substance or which give rise to the same residues;

(v) where relevant, data on dissipation including transformation and sorption in the saturated zone;

(vi) where relevant, data on the procedures for drinking water abstraction and treatment in the area of envisaged use;

(vii) where relevant, monitoring data on the presence or absence of the active substance and relevant metabolites, degradation or reaction products in groundwater as a result of previous use of plant protection products containing the same active substance or which give rise to the same residues; such monitoring data shall be interpreted in a consistent scientific way.

1.5.1.3. Member States shall evaluate the possibility of the plant protection product reaching surface water under the proposed conditions of use; if this possibility exists they shall estimate, using a suitable calculation model validated at EU level, the short-term and long-term predicted concentration of the active substance and of metabolites, degradation and reaction products that could be expected in the surface water in the area of envisaged use after use of the plant protection product in accordance with the proposed conditions of use.

If there is no validated EU calculation model, Member States shall base their evaluation especially on the results of mobility and persistence in soil studies and the information on run-off and drift as provided for in the Annex to Regulation (EU) No 283/2013 and to Regulation (EU) No 284/2013.

This evaluation shall also take into consideration the following information:

(i) the specific information on fate and behaviour in soil and water as provided for in the Annex to Regulation (EU) No 283/2013 and the results of the evaluation thereof;

(ii) other relevant information on the active substance such as:

— molecular weight,

— solubility in water,

— octanol/water partition coefficient,

— vapour pressure,

— volatilisation rate,

— hydrolysis rate in relation to pH and identity of breakdown products,

— dissociation constant;

(iii) all relevant information on the plant protection product as provided for in the Annex to Regulation (EU) No 284/2013, including the information on distribution and dissipation in soil and water;

(iv) possible routes of exposure:

— drift,

— run-off,

— overspray,

— discharge via drains,

— leaching,

— deposit from the atmosphere;

(v) where relevant, other authorised uses of plant protection products in the area of envisaged use containing the same active substance or which give rise to the same residues;

(vi) where relevant, data on the procedures for drinking water abstraction and treatment in the area of envisaged use.

1.5.1.4. Member States shall evaluate the possibility of the plant protection product being dissipated in the air under the proposed conditions of use; if this possibility exists they shall make the best possible estimation, using where appropriate a suitable, validated calculation model, of the concentration of the active substance and of relevant metabolites, degradation and reaction products that could be expected in the air after use of the plant protection product in accordance with the proposed conditions of use.

This evaluation shall take into consideration the following information:

(i) the specific information on fate and behaviour in soil, water and air as provided for in the Annex to Regulation (EU) No 283/2013 and the results of the evaluation thereof;

(ii) other relevant information on the active substance such as:

— vapour pressure,

— solubility in water,

— hydrolysis rate in relation to pH and identity of breakdown products,

— photochemical degradation in water and air and identity of breakdown products,

— octanol/water partition coefficient;

(iii) all relevant information on the plant protection product as provided for in the Annex to Regulation (EU) No 284/2013, including the information on distribution and dissipation in air.

1.5.1.5. Member States shall evaluate the procedures for destruction or decontamination of the plant protection product and its packaging.

1.5.2. Impact on non-target species

When calculating toxicity/exposure ratios Member States shall take into consideration toxicity to the most sensitive relevant organism used in the tests.

1.5.2.1. Member States shall evaluate the possibility of exposure of birds and other terrestrial vertebrates to the plant protection product under the proposed conditions of use; if this possibility exists they shall evaluate the extent of the short-term and long-term risk to be expected for these organisms, including their reproduction, after use of the plant protection product in accordance with the proposed conditions of use.

(a) This evaluation shall take into consideration the following information:

(i) the specific information relating to toxicological studies on mammals and to the effects on birds and other non-target terrestrial vertebrates, including effects on reproduction, and other relevant information concerning the active substance as provided for in the Annex to Regulation (EU) No 283/2013 and the results of the evaluation thereof;

(ii) all relevant information on the plant protection product as provided for in the Annex to Regulation (EU) No 284/2013, including the information on effects on birds and other non-target terrestrial vertebrates;

(iii) where relevant, other authorised uses of plant protection products in the area of envisaged use containing the same active substance or which give rise to the same residues.

(b) This evaluation shall include:

(i) the fate and distribution, including persistence and bioconcentration, of the active substance and of relevant metabolites, breakdown and reaction products in the various parts of the environment after application of the plant protection product;

(ii) the estimated exposure of the species likely to be exposed at the time of application or during the period that residues are present, taking into account all relevant routes of exposure such as ingestion of the formulated product or treated food, predation on invertebrates, feeding on vertebrate prey, contact by overspraying or with treated vegetation;

(iii) a calculation of the acute, short-term and, where necessary, long-term toxicity/exposure ratio. The toxicity/exposure ratios are defined as respectively the quotient of LD_{50}, LC_{50} or non-observable effects of concentration (NOEC) expressed on an active substance basis and the estimated exposure expressed in mg/kg body weight.

1.5.2.2. Member States shall evaluate the possibility of exposure of aquatic organisms to the plant protection product under the proposed conditions of use; if this possibility exists they shall evaluate the degree of short-term and long-term risk to be expected for aquatic organisms after use of the plant protection product in accordance with the proposed conditions of use.

(a) This evaluation shall take into consideration the following information:

(i) the specific information relating to the effects on aquatic organisms as provided for in the Annex to Regulation (EU) No 283/2013 and the results of the evaluation thereof;

(ii) other relevant information on the active substance such as:

— solubility in water,

— octanol/water partition coefficient,

— vapour pressure,

— volatilisation rate,

— KOC,

— biodegradation in aquatic systems and in particular the ready biodegradability,

— photodegradation rate and identity of breakdown products,

— hydrolysis rate in relation to pH and identity of breakdown products.

(iii) all relevant information on the plant protection product as provided for in the Annex to Regulation (EU) No 284/2013 and in particular the effects on aquatic organisms;

(iv) where relevant, other authorised uses of plant protection products in the area of envisaged use, containing the same active substance or which give rise to the same residues.

(b) This evaluation shall include:

(i) the fate and distribution of residues of the active substance and of relevant metabolites, breakdown and reaction products in water, sediment or fish;

(ii) a calculation of the acute toxicity/exposure ratio for fish and Daphnia. This ratio is defined as the quotient of respectively acute LC_{50} or EC_{50} and the predicted short-term environmental concentration;

(iii) a calculation of the algal growth inhibition/exposure ratio for algae. This ratio is defined as the quotient of the EC_{50} and the predicted short-term environmental concentration;

(iv) a calculation of the long-term toxicity/exposure ratio for fish and Daphnia. The long-term toxicity/exposure ratio is defined as the quotient of the NOEC and the predicted long-term environmental concentration;

(v) where relevant, the bioconcentration in fish and possible exposure of predators of fish, including humans;

(vi) if the plant protection product is to be applied directly to surface water, the effect on the change of surface water quality, such as pH or dissolved oxygen content.

1.5.2.3. Member States shall evaluate the possibility of exposure of honeybees to the plant protection product under the proposed conditions of use; if this possibility exists they shall evaluate the short-term and long-term risk to be expected for honeybees after use of the plant protection product in accordance with the proposed conditions of use.

(a) This evaluation shall take into consideration the following information:

(i) the specific information on toxicity to honeybees as provided for in the Annex to Regulation (EU) No 283/2013 and the results of the evaluation thereof;

(ii) other relevant information on the active substance such as:

— solubility in water,

— octanol/water partition coefficient,

— vapour pressure,

— photodegradation rate and identity of breakdown products,

— mode of action (e. g. insect growth regulating activity);

(iii) all relevant information on the plant protection product as provided for in the Annex to Regulation (EU) No 284/2013, including the toxicity to honeybees;

(iv) where relevant, other authorised uses of plant protection products in the area of envisaged use, containing the same active substance or which give rise to the same residues.

(b) This evaluation shall include:

(i) the ratio between the maximum application rate expressed in grams of active substance per hectare and the contact and oral LD_{50} expressed in µg of active substance per bee (hazard quotients) and where necessary the persistence of residues on or, where relevant, in the treated plants;

(ii) where relevant, the effects on honeybee larvae, honeybee behaviour, colony survival and development after use of the plant protection product in accordance with the proposed conditions of use.

1.5.2.4. Member States shall evaluate the possibility of exposure of beneficial arthropods other than honeybees to the plant protection product under the proposed conditions of use; if this possibility exists they shall assess the lethal and sublethal effects on these organisms to be expected and the reduction in their activity after use of the plant protection product in accordance with the proposed conditions of use.

This evaluation shall take into consideration the following information:

(i) the specific information on toxicity to honeybees and other beneficial arthropods as provided for in the Annex to Regulation (EU) No 283/2013 and the results of the evaluation thereof;

(ii) other relevant information on the active substance such as:

— solubility in water,

— octanol/water partition coefficient,

— vapour pressure,

— photodegradation rate and identity of breakdown products,

— mode of action (e. g. insect growth regulating activity);

(iii) all relevant information on the plant protection product as provided for in the Annex to Regulation (EU) No 284/2013 such as:

— effects on beneficial arthropods other than bees,

— toxicity to honeybees,

— available data from biological primary screening,

— maximum application rate,

— maximum number and timetable of applications;

(iv) where relevant, other authorised uses of plant protection products in the area of envisaged use, containing the same active substance or which give rise to the same residues.

1.5.2.5. Member States shall evaluate the possibility of exposure of earthworms and other non-target soil macro-organisms to the plant protection product under the proposed conditions of use; if this possibility exists they shall evaluate the degree of short-term and long-term risk to be expected to these organisms after use of the plant protection product in accordance with the proposed conditions of use.

(a) This evaluation shall take into consideration the following information:

(i) the specific information relating to the toxicity of the active substance to earthworms and to other non-target soil macro-organisms as provided for in the Annex to Regulation (EU) No 283/2013 and the results of the evaluation thereof;

(ii) other relevant information on the active substance such as:

— solubility in water,

— octanol/water partition coefficient,

— Kd for adsorption,

— vapour pressure,

— hydrolysis rate in relation to pH and identity of breakdown products,

— photodegradation rate and identity of breakdown products,

— DT_{50} and DT_{90} for degradation in the soil.

(iii) all relevant information on the plant protection product as provided for in the Annex to Regulation (EU) No 284/2013, including the effects on earthworms and other non-target soil macro-organisms;

(iv) where relevant, other authorised uses of plant protection products in the area of envisaged use, containing the same active substance or which give rise to the same residues.

(b) This evaluation shall include:

(i) the lethal and sublethal effects;

(ii) the predicted initial and long-term environmental concentration;

(iii) a calculation of the acute toxicity/exposure ratio (defined as the quotient of LC_{50} and predicted initial environmental concentration) and of the long-term toxicity/exposure ratio (defined as the quotient of the NOEC and predicted long-term environmental concentration);

(iv) where relevant, the bioconcentration and persistence of residues in earthworms.

1.5.2.6. Member States shall, where the evaluation carried out under point 1.5.1.1 does not exclude the possibility of the plant protection product reaching the soil under the proposed conditions of use, evaluate the impact on microbial activity such as the impact on nitrogen and carbon mineralisation processes in the soil after use of the plant protection product in accordance with the proposed conditions of use.

This evaluation shall take into consideration the following information:

(i) all relevant information on the active substance, including the specific information relating to the effects of non-target soil micro-organisms as provided for in the Annex to Regulation (EU) No 283/2013 and the results of the evaluation thereof;

(ii) all relevant information on the plant protection product as provided for in the Annex to Regulation (EU) No 284/2013, including the effects on non-target soil micro-organisms;

(iii) where relevant, other authorised uses of plant protection products in the area of proposed use, containing the same active substance or which give rise to the same residues;

(iv) all available information from biological primary screening.

1.6. **Analytical methods**

Member States shall evaluate the analytical methods proposed for post-registration control and monitoring purposes, to determine:

1.6.1. for formulation analysis:

the nature and quantity of the active substance(s) in the plant protection product and, where appropriate, any toxicologically, ecotoxicologically or environmentally significant impurities and co-formulants.

This evaluation shall take into consideration the following information:

(i) the data on analytical methods as provided for in the Annex to Regulation (EU) No 283/2013 and the results of the evaluation thereof;

(ii) the data on analytical methods as provided for in the Annex to Regulation (EU) No 284/2013 and in particular:

— the specificity and linearity of the proposed methods,

— the importance of interferences,

— the precision of the proposed methods (intralaboratory repeatability and interlaboratory reproducibility);

(iii) the limit of detection and determination of the proposed methods for impurities.

1.6.2. for residue analysis:

the residues of the active substance, metabolites, breakdown or reaction products resulting from authorised uses of the plant protection product and which are of toxicological, ecotoxicological or environmental significance.

This evaluation shall take into consideration the following information:

(i) the data on analytical methods as provided for in the Annex to Regulation (EU) No 283/2013 and the results of the evaluation thereof;

(ii) the data on analytical methods as provided for in the Annex to Regulation (EU) No 284/2013 and in particular:

— the specificity of the proposed methods,

— the precision of the proposed methods (intralaboratory repeatability and interlaboratory reproducibility),

— the recovery rate of the proposed methods at appropriate concentrations;

(iii) the limit of detection of the proposed methods;

(iv) the limit of determination of the proposed methods.

1.7. **Physical and chemical properties**

1.7.1. Member States shall evaluate the actual active substance content of the plant protection product and its stability during storage.

1.7.2. Member States shall evaluate the physical and chemical properties of the plant protection product and in particular:

— where a suitable FAO (Food and Agriculture Organisation of the United Nations) specification exists, the physical and chemical properties addressed in that specification,

— where no suitable FAO specification exists, all the relevant physical and chemical properties for the formulation as referred to in the 'Manual on development and use of FAO and WHO specifications for pesticides'.

This evaluation shall take into consideration the following information:

(i) the data on the physical and chemical properties of the active substance as provided for in the Annex to Regulation (EU) No 283/2013 and the results of the evaluation thereof;

(ii) the data on the physical and chemical properties of the plant protection product as provided for in the Annex to Regulation (EU) No 284/2013.

1.7.3. Where proposed label claims include requirements or recommendations for use of the plant protection product with other plant protection products or adjuvants as a tank mix, the physical and chemical compatibility of the products in the mixture must be evaluated.

2. **DECISION-MAKING**

These principles shall apply without prejudice to the general principles referred to in Section 3 of the general introduction.

2.1. **Efficacy**

2.1.1. Where the proposed uses include recommendations for the control of or protection against organisms which are not considered to be harmful on the basis of experience acquired or scientific evidence under normal agricultural, plant health and environmental (including climatic) conditions in the areas of proposed use or where the other intended effects are not considered to be beneficial under those conditions, no authorisation shall be granted for those uses.

2.1.2. The level, consistency and duration of control or protection or other intended effects must be similar to those resulting from the use of suitable reference products. If no suitable reference product exists, the plant protection product must be shown to give a defined benefit in terms of the level, consistency and duration of control or protection or other intended effects under the agricultural, plant health and environmental (including climatic) conditions in the area of proposed use.

2.1.3. Where relevant, yield response when the product is used and reduction of loss in storage must be quantitatively and/or qualitatively similar to those resulting from the use of suitable reference products. If no suitable reference product exists, the plant protection product must be shown to give a consistent and defined quantitative and/or qualitative benefit in terms of yield response and reduction of loss in storage under the agricultural, plant health and environmental (including climatic) conditions in the area of proposed use.

2.1.4. Conclusions as to the performance of the preparation must be valid for all areas of the Member State in which it is to be authorised, and must hold for all conditions under which its use is proposed, except where the proposed label specifies that the preparation is intended for use in certain specified circumstances (e.g. light infestations, particular soil types or particular growing conditions).

2.1.5. Where proposed label claims include requirements for use of the preparation with other specified plant protection products or adjuvants as a tank mix, the mixture must achieve the desired effect and comply with the principles referred to in points 2.1.1 to 2.1.4.

Where proposed label claims include recommendations for use of the preparation with specified plant protection products or adjuvants as a tank mix, Member States shall not accept the recommendations unless they are justified.

2.2. **Absence of unacceptable effects on plants or plant products**

2.2.1. There must be no relevant phytotoxic effects on treated plants or plant products except where the proposed label indicates appropriate limitations of use.

2.2.2. There must be no reduction of yield at harvest due to phytotoxic effects below that which could be obtained without the use of the plant protection product, unless this reduction is compensated for by other advantages such as an enhancement of the quality of the treated plants or plant products.

2.2.3. There must be no unacceptable adverse effects on the quality of treated plants or plant products, except in the case of adverse effects on processing where proposed label claims specify that the preparation must not be applied to crops to be used for processing purposes.

2.2.4. There must be no unacceptable adverse effects on treated plants or plant products used for propagation or reproduction, such as effects on viability, germination, sprouting, rooting and establishment, except where proposed label claims specify that the preparation should not be applied to plants or plant products to be used for propagation or reproduction.

2.2.5. There must be no unacceptable impact on succeeding crops, except where proposed label claims specify that particular crops, which would be affected, must not be grown following the treated crop.

2.2.6. There must be no unacceptable impact on adjacent crops, except where proposed label claims specify that the preparation should not be applied when particular sensitive adjacent crops are present.

2.2.7. Where proposed label claims include requirements for use of the preparation with other plant protection products or adjuvants, as a tank mix, the mixture must comply with the principles referred to in points 2.2.1 to 2.2.6.

2.2.8. The proposed instructions for cleaning the application equipment must be both practical and effective so that they can be applied with ease to ensure the removal of residual traces of the plant protection product which could subsequently cause damage.

2.3. **Impact on vertebrates to be controlled**

An authorisation for a plant protection product intended to eliminate vertebrates shall be granted only when:

— death is synchronous with the extinction of consciousness, or

— death occurs immediately, or

— vital functions are reduced gradually without signs of obvious suffering.

For repellent products, the intended effect shall be obtained without unnecessary suffering and pain for the target animals.

2.4. **Impact on human or animal health**

2.4.1. Impact on human or animal health arising from the plant protection product

2.4.1.1. No authorisation shall be granted if the extent of operator exposure in handling and using the plant protection product under the proposed conditions of use, including dose and application method, exceeds the AOEL.

Moreover, the conditions of the authorisation shall be in compliance with the limit value established for the active substance and/or toxicologically relevant compound(s) of the product in accordance with Council Directive 98/24/EC ([6]) and in accordance with Directive 2004/37/EC of the European Parliament and of the Council ([7]).

2.4.1.2. Where the proposed conditions of use require use of items of protective clothing and equipment, no authorisation shall be granted unless those items are effective and in accordance with the relevant EU provisions and are readily obtainable by the user and unless it is feasible to use them under the circumstances of use of the plant protection product, taking into account climatic conditions in particular.

2.4.1.3. Plant protection products which because of particular properties or if mishandled or misused could lead to a high degree of risk must be subject to particular restrictions such as restrictions on the size of packaging, formulation type, distribution, use or manner of use.

Moreover, those plant protection products may not be authorised for use by non-professional users which are classified as:

(i) acute toxicity category 1 and 2 for any route of uptake, provided the ATE (acute toxicity estimate) of the product does not exceed 25 mg/kg bw for the oral route of uptake or 0,25 mg/l/4h for the inhalation of dust, mist or fume;

(ii) STOT (single exposure), category 1 (oral), provided their classification is due to the presence of classified substances showing significant non-lethal toxic effects at guidance values below 25 mg/kg bw;

(iii) STOT (single exposure), category 1 (dermal), provided their classification is due to the presence of classified substances showing significant non-lethal toxic effects at guidance values below 50 mg/kg bw;

(iv) STOT (single exposure), category 1 (inhalation of gas/vapour), provided their classification is due to the presence of classified substances showing significant non-lethal toxic effects at guidance values below 0,5 mg/l/4h;

(v) STOT (single exposure), category 1 (inhalation of dust/mist/fume), provided their classification is due to the presence of classified substances showing significant non-lethal toxic effects at guidance values below 0,25 mg/l/4h.

2.4.1.4. Waiting and re-entry safety periods or other precautions must be such that the exposure of bystanders or workers exposed after the application of the plant protection product does not exceed the AOEL levels established for the active substance or toxicologically relevant compound(s) in the plant protection product nor any limit values established for those compounds in accordance with the EU provisions referred to in point 2.4.1.1.

2.4.1.5. Waiting and re-entry safety periods or other precautions must be established in such a way that no adverse impact on animals occurs.

2.4.1.6. Waiting and re-entry periods or other precautions to ensure that the AOEL levels and limit values are respected must be realistic; if necessary special precautionary measures must be prescribed.

([6]) Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11).

([7]) Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p. 50).

2.4.2. Impact on human or animal health arising from residues

2.4.2.1. Authorisations must ensure that residues occurring reflect the minimum quantities of the plant protection product necessary to achieve adequate control corresponding to good agricultural practice, applied in such a manner (including pre-harvest intervals or withholding periods or storage periods) that the residues at harvest, slaughter or after storage, as appropriate, are reduced to a minimum.

2.4.2.2. Where the new circumstances under which the plant protection product is to be used do not correspond to those under which a MRL (maximum residue limit) was established previously, Member States shall not grant an authorisation for the plant protection product unless the applicant can provide evidence that its recommended use shall not exceed the MRL established under Regulation (EC) No 396/2005 of the European Parliament and of the Council ([8]).

2.4.2.3. Where a MRL exists Member States shall not grant an authorisation for the plant protection product unless the applicant can provide evidence that its recommended use shall not exceed that MRL, or unless a new MRL has been established under Regulation (EC) No 396/2005.

2.4.2.4. In the cases referred to in points 2.4.2.2, each application for an authorisation must be accompanied by a risk assessment taking into account worst-case potential exposure of consumers in the Member State concerned on the basis of good agricultural practice.

Taking into account all registered uses, the proposed use shall not be authorised if the best possible estimate of dietary exposure exceeds the ADI.

2.4.2.5. Where the nature of residues is affected during processing, a separate risk assessment may need to be carried out under the conditions provided for in point 2.4.2.4.

2.4.2.6. Where the treated plants or plant products are intended to be fed to animals, residues occurring shall not have an adverse effect on animal health.

2.5. **Influence on the environment**

2.5.1. Fate and distribution in the environment

2.5.1.1. No authorisation shall be granted if the active substance and, where they are of significance from the toxicological, ecotoxicological or environmental point of view, metabolites and breakdown or reaction products, after use of the plant protection product under the proposed conditions of use:

— during tests in the field, persist in soil for more than 1 year (i.e. DT_{90} > 1 year and DT_{50} > 3 months), or

— during laboratory tests, form non-extractable residues in amounts exceeding 70 % of the initial dose after 100 days with a mineralisation rate of less than 5 % in 100 days,

unless it is scientifically demonstrated that under field conditions there is no accumulation in soil at such levels that unacceptable residues in succeeding crops occur and/or that unacceptable phytotoxic effects on succeeding crops occur and/or that there is an unacceptable impact on the environment, in accordance with the relevant requirements provided for in points 2.5.1.2, 2.5.1.3, 2.5.1.4 and 2.5.2.

2.5.1.2. No authorisation shall be granted if the concentration of the active substance or of relevant metabolites, degradation or reaction products in groundwater, may be expected to exceed, as a result of use of the plant protection product under the proposed conditions of use, the lower of the following limit values:

(i) the maximum permissible concentration laid down by Council Directive 98/83/EC ([9]); or

([8]) Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

([9]) Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption (OJ L 330, 5.12.1998, p. 32).

(ii) the maximum concentration laid down when approving the active substance in accordance with Regulation (EC) No 1107/2009, on the basis of appropriate data, in particular toxicological data, or, where that concentration has not been laid down, the concentration corresponding to one tenth of the ADI laid down when the active substance was approved in accordance with Regulation (EC) No 1107/2009,

unless it is scientifically demonstrated that under relevant field conditions the lower concentration is not exceeded.

2.5.1.3. No authorisation shall be granted if the concentration of the active substance or of relevant metabolites, breakdown or reaction products to be expected after use of the plant protection product under the proposed conditions of use in surface water:

— exceeds, where the surface water in or from the area of envisaged use is intended for the abstraction of drinking water, concentrations above which compliance with drinking water quality established in accordance with Directive 2000/60/EC of the European Parliament and of the Council ([10]) is compromised, or

— has an impact deemed unacceptable on non-target species, including animals, in accordance with the relevant requirements provided for in point 2.5.2.

The proposed instructions for use of the plant protection product, including procedures for cleaning application equipment, must be such that the likelihood of accidental contamination of surface water is reduced to a minimum.

2.5.1.4. No authorisation shall be granted if the airborne concentration of the active substance under the proposed conditions of use is such that either the AOEL or the limit values for operators, bystanders or workers as referred to in point 2.4.1 are exceeded.

2.5.2. Impact on non-target species

2.5.2.1. Where there is a possibility of birds and other non-target terrestrial vertebrates being exposed, no authorisation shall be granted if:

— the acute and short-term toxicity/exposure ratio for birds and other non-target terrestrial vertebrates is less than 10 on the basis of LD_{50} or the long-term toxicity/exposure ratio is less than 5, unless it is clearly established through an appropriate risk assessment that under field conditions no unacceptable impact occurs after use of the plant protection product in accordance with the proposed conditions of use,

— the bioconcentration factor (BCF, related to fat tissue) is greater than 1, unless it is clearly established through an appropriate risk assessment that under field conditions no unacceptable effects occur — directly or indirectly — after use of the plant protection product in accordance with the proposed conditions of use.

2.5.2.2. Where there is a possibility of aquatic organisms being exposed, no authorisation shall be granted if:

— the toxicity/exposure ratio for fish and Daphnia is less than 100 for acute exposure and less than 10 for long-term exposure, or

— the algal growth inhibition/exposure ratio is less than 10, or

— the maximum bioconcentration factor (BCF) is greater than 1 000 for plant protection products containing active substances which are readily biodegradable or greater than 100 for those which are not readily biodegradable,

([10]) Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1).

unless it is clearly established through an appropriate risk assessment that under field conditions no unacceptable impact on the viability of exposed species (predators) occurs — directly or indirectly — after use of the plant protection product in accordance with the proposed conditions of use.

2.5.2.3. Where there is a possibility of honeybees being exposed, no authorisation shall be granted if the hazard quotients for oral or contact exposure of honeybees are greater than 50, unless it is clearly established through an appropriate risk assessment that under field conditions there are no unacceptable effects on honeybee larvae, honeybee behaviour, or colony survival and development after use of the plant protection product in accordance with the proposed conditions of use.

2.5.2.4. Where there is a possibility of beneficial arthropods other than honeybees being exposed, no authorisation shall be granted if more than 30 % of the test organisms are affected in lethal or sublethal laboratory tests conducted at the maximum proposed application rate, unless it is clearly established through an appropriate risk assessment that under field conditions there is no unacceptable impact on those organisms after use of the plant protection product in accordance with the proposed conditions of use. Any claims for selectivity and proposals for use in integrated pest management systems shall be substantiated by appropriate data.

2.5.2.5. Where there is a possibility of earthworms being exposed, no authorisation shall be granted if the acute toxicity/exposure ratio for earthworms is less than 10 or the long-term toxicity/exposure ratio is less than 5, unless it is clearly established through an appropriate risk assessment that under field conditions earthworm populations are not at risk after use of the plant protection product in accordance with the proposed conditions of use.

2.5.2.6. Where there is a possibility of non-target soil micro-organisms being exposed, no authorisation shall be granted if the nitrogen or carbon mineralisation processes in laboratory studies are affected by more than 25 % after 100 days, unless it is clearly established through an appropriate risk assessment that under field conditions there is no unacceptable impact on microbial activity after use of the plant protection product in accordance with the proposed conditions of use, taking account of the ability of micro-organisms to multiply.

2.6. **Analytical methods**

The methods proposed must reflect the state of the art. The following criteria must be met in order to permit validation of the analytical methods proposed for post-registration control and monitoring purposes:

2.6.1. for formulation analysis:

the method must be able to determine and to identify the active substance(s) and where appropriate any toxicologically, ecotoxicologically or environmentally significant impurities and co-formulants;

2.6.2. for residue analysis:

(i) the method must be able to determine and confirm residues of toxicological, ecotoxicological or environmental significance;

(ii) the mean recovery rates should be between 70 % and 110 % with a relative standard deviation of ≤ 20 %;

(iii) the repeatability must be less than the following values for residues in foodstuffs:

Residue level mg/kg	Difference mg/kg	Difference in %
0,01	0,005	50
0,1	0,025	25
1	0,125	12,5
>1		12,5

Intermediate values shall be determined by interpolation from a log-log graph;

(iv) the reproducibility must be less than the following values for residues in foodstuffs:

Residue level mg/kg	Difference mg/kg	Difference in %
0,01	0,01	100
0,1	0,05	50
1	0,25	25
>1		25

Intermediate values are determined by interpolation from a log-log graph;

(v) in the case of residue analysis in treated plants, plant products, foodstuffs, feedingstuffs or products of animal origin, except where the MRL or the proposed MRL is at the limit of determination, the sensitivity of the methods proposed must satisfy the following criteria:

Limit of determination in relation to the proposed provisional or EU MRL:

MRL (mg/kg)	limit of determination (mg/kg)
> 0,5	0,1
0,5 – 0,05	0,1 – 0,02
< 0,05	MRL × 0,5

2.7. **Physical and chemical properties**

2.7.1 Where an appropriate FAO specification exists, that specification must be met.

2.7.2. Where no appropriate FAO specification exists, the physical and chemical properties of the product must meet the following requirements

(a) Chemical properties:

Throughout the shelf-life period, the difference between the stated and the actual content of the active substance in the plant protection product must not exceed the following values:

Declared content in g/kg or g/l at 20 °C	Tolerance
up to 25	±15 % homogeneous formulation
	±25 % non-homogeneous formulation
more than 25 up to 100	±10 %
more than 100 up to 250	±6 %
more than 250 up to 500	±5 %
more than 500	±25 g/kg or ±25 g/l

(b) Physical properties:

The plant protection product must fulfil the physical criteria (including storage stability) specified for the relevant formulation type in the 'Manual on the development and use of FAO and WHO specifications for plant protection products'.

2.7.3. Where the proposed label claims include requirements or recommendations for use of the preparation with other plant protection products or adjuvants as a tank mix and/or where the proposed label includes indications on the compatibility of the preparation with other plant protection products as a tank mix, those products or adjuvants must be physically and chemically compatible in the tank mix.

PART B

UNIFORM PRINCIPLES FOR EVALUATION AND AUTHORISATION OF PLANT PROTECTION PRODUCTS CONTAINING AN ACTIVE SUBSTANCE THAT IS A MICRO-ORGANISM

Definitions

For the purposes of Part B, in addition to general introduction, 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) **'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;

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

(4) **'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;

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

(6) **'ecological niche'** means an ecological function and actual physical spaces occupied by a particular species within the community or ecosystem;

(7) **'host range'** means the range of different biological host-species that can be infected by a microbial species or strain;

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

(9) **'infection'** means the non-opportunistic introduction or entry of a 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 it causes pathological effects or disease;

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

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

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

(13) **'virulence'** means the degree of pathogenicity that a pathogenic micro-organism is able to exert in the host;

(14) **'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;

(15) **'background level of a metabolite'** means a level of a metabolite that is likely to occur in relevant European environments (including also sources different than those of plant protection) and/or in food and feed (e.g. edible plant parts), when the micro-organisms are in conditions to grow, reproduce and to produce such metabolite in presence of a host or availability of carbon and nutrient sources, under consideration of high host densities and nutrients;

(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) **'antibiosis'** means a relationship between two or more species in which one species is actively harmed (as by the production of toxins by the harming species);

(18) **'antimicrobial resistance' ('AMR')** means the intrinsic or acquired ability of a micro-organism to multiply in the presence of an antimicrobial agent at concentrations which are relevant for therapeutic measures in human or veterinary medicine, making that substance therapeutically ineffective;

(19) **'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;

(20) **'acquired antimicrobial resistance'** means a non-intrinsic and acquired novel resistance enabling a micro-organism to survive or multiply in the presence of an antimicrobial agent at concentrations higher than that which inhibits wild type strains of the same species;

(21) **'intrinsic antimicrobial resistance'** means all inherent properties of a microbial species that limit the action of antimicrobial agents thereby allowing it to survive and multiply in presence of the antimicrobial agents at concentrations that are relevant for their therapeutic uses. Inherent properties of micro-organisms are considered not transferable and can include structural characteristics such as lack of drug targets, the impermeability of cellular envelopes, activity of multidrug efflux pumps, or metabolic enzymes. An antimicrobial resistance gene is considered intrinsic if it is located on a chromosome in the absence of mobile genetic element and shared by the majority of wild type strains of the same species;

(22) **'relevant antimicrobial activity'** means the antimicrobial activity caused by relevant antimicrobial agents;

(23) **'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 ([11]) in accordance with Article 37(5) of Regulation (EU) 2019/6 of the European Parliament and of the Council ([12]), or

— by the World Health Organisation ([13]) in the lists of Critically Important Antimicrobials, Highly Important Antimicrobials and Important Antimicrobials for Human Medicine.

([11]) 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).

([12]) 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).

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

1. **EVALUATION**

Member States shall consider during the evaluations that:

— micro-organisms are living organisms capable of replication that may be naturally present in high numbers in the environment, and the specific micro-organism under assessment may already be occurring in relevant European environments at a relevant taxonomic level,

— the biological properties and the mode of action of a micro-organism are the first and crucial step in the evaluation process, because they define which are the relevant aspects and elements on which the evaluation should focus, and also which aspects are not relevant for a robust informed decision making,

— extensive information on the micro-organism under assessment (at the relevant taxonomic level) may be available in the public domain (e.g. history of use, peer-reviewed scientific literature). Best use of this information shall be made. Where applicable, regulatory experimental studies may be needed to determine the specific properties of the micro-organism under evaluation.

Metabolism is inherent of all living organisms. If secondary metabolites that are known to be hazardous to humans or other non-target organisms have been identified during the assessment of the micro-organism, the evaluation of a plant protection product containing this micro-organism shall include an assessment of the risk due to exposures to such metabolites expected from the intended use.

Member States shall implement the following principles in the evaluation of the data and information submitted in support of applications, without prejudice to the general principles prescribed in Section 2 of the general introduction.

1.1. **Identity and manufacturing information**

An overall assessment is necessary for those data on the identity and manufacturing information required according to Section 1 of Part B of the Annex to Regulation (EU) No 283/2013 and Section 1 of Part B of the Annex to Regulation (EU) No 284/2013.

1.1.1. Identity of the micro-organism contained in the plant protection product

Member States shall verify the identity of the micro-organism that is the active substance based on information provided under point 1.3 of Part B of the Annex to Regulation (EU) No 283/2013.

Furthermore, Member States shall evaluate if the MPCA as manufactured used for manufacturing of the plant protection product complies with specification of the MPCA as manufactured characterised and quantified as required in point 1.4 of Part B of the Annex to Regulation (EU) No 283/2013 (e.g. in terms of content and identity of the micro-organism(s), metabolites of concern, additives, relevant contaminating micro-organisms, and relevant impurities).

1.1.2. Quality control of the production of the micro-organism contained in the plant protection product

Member States shall evaluate the quality assurance criteria proposed for the production of the active substance. Process control, good manufacturing practice, operational practices, process flows, cleaning practices, microbial monitoring and hygiene conditions shall be present and ensure stable quality of the MPCA as manufactured.

1.1.3. Identity of the plant protection product

Member States shall evaluate the detailed quantitative and qualitative information provided on the composition of the plant protection product as required in point 1.4 of Part B of the Annex to Regulation (EU) No 284/2013, e.g. micro-organism (active substance), metabolites of concern, relevant impurities, relevant contaminating micro-organisms, co-formulants, safeners and synergists.

1.1.4. Quality control of the plant protection product

Member States shall evaluate the quality assurance criteria proposed, in particular whether strict maintenance of environmental conditions and quality control analysis during the manufacturing process have been assured by the producer, in order to ensure compliance with the limits for relevant contaminating micro-organisms, relevant impurities and metabolites of concern.

1.2. **Biological, physical, chemical and technical properties**

Member States shall carry out an overall assessment of the information on biological, physical, chemical, and technical properties of the plant protection product provided under Section 2 of Part B of the Annex to Regulation (EU) No 283/2013 and Section 2 of Part B of the Annex to Regulation (EU) No 284/2013.

1.2.1. Biological properties of the micro-organism in the plant protection product

1.2.1.1. Member States shall evaluate information on the origin, occurrence and history of use of the micro-organism contained the plant protection product, giving particular relevance to both the location from which the strain was isolated, and the geographical distribution of the micro-organism at the relevant highest taxonomic level in relevant European environments.

1.2.1.2. Member States shall evaluate information on the ecology and the life cycle of the micro-organism, taking also into consideration the population densities of the micro-organism in relation to host densities as provided for in point 2.3 of Part B of the Annex to Regulation (EU) No 283/2013. In particular, for bacteriophages, the lysogenic and lytic properties of the virus shall be evaluated.

1.2.1.3. Member States shall evaluate information on the mode of action on the target organisms for the plant protection product to identify potential risks and function of the active substance that is a micro-organism according to the proposed conditions of use. In particular, Member States shall evaluate the role of possible infectivity, pathogenicity, toxicity and relevant antimicrobial activity in the mode of action against the target organism. If applicable, factors that enhance the pathogenicity/virulence of a micro-organism and environmental factors affecting a pathogenic mode of action shall be described.

Information on the mode of action can be a very valuable tool in identifying potential risks and purpose of the micro-organism in the plant protection product.

Aspects to be considered in the evaluation are, for instance:

(a) invertebrate pathogenicity;

(b) parasitisation;

(c) competition for the ecological niche (e.g. nutrients, habitats);

(d) endophytic growth;

(e) interference with the virulence of a pathogenic target organism;

(f) induction of plant defence;

(g) antibiosis.

1.2.1.4. Member States shall evaluate data provided on the host range of the micro-organism, taking into account any available information on the relationship of the micro-organism to known pathogens to humans, animals, plants and other non-target species, at the most appropriate taxonomic level.

1.2.1.5. Member States shall evaluate information on growth requirements, by defining limiting factors e.g. UV light, humidity, pH, temperatures and other relevant agro-environmental conditions influencing the growth of the micro-organism.

1.2.1.6. Member States shall evaluate the genetic stability of a micro-organism that is a non-virulent variant of a plant pathogen virus, taking into consideration the likelihood of the micro-organisms to regain virulence, and the risk that could be caused by this occurrence.

1.2.1.7. In order to determine whether the micro-organism produces metabolites of concern, Member States shall take into account the information on production, toxicity and exposure concerning metabolites as provided for in points 2.8, 6.1, 6.2, 5.5, 7.2 and 8.8 of Part B of the Annex to Regulation (EU) No 283/2013.

1.2.1.8. For bacteria, Member States shall evaluate information on phenotypical resistance to relevant antimicrobial agents. Member States shall evaluate, taking into consideration that resistance genes in bacteria can be horizontally transmitted, and that this may potentially interfere with the effectiveness of relevant antimicrobial agents, information on the presence and transferability of genes coding for resistance to such antimicrobial agents.

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

1.2.2.1. Member States shall evaluate shelf-life and storage stability of the plant protection product, taking into account the packaging, optimal (recommended) storage temperature, and light conditions. Possible changes in composition due to growth or decline of the micro-organism or of relevant contaminating micro-organisms, or the production of metabolites of concern during storage, etc., shall be considered.

1.2.2.2. Member States shall evaluate the physical and chemical properties of the plant protection product and the retention of these characteristics after storage and take into consideration, unless a suitable FAO specification exists, all relevant physical and chemical properties of the plant protection product.

1.2.2.3. Where the proposed label includes requirements or recommendations for use of the plant protection product in combination with other plant protection products or adjuvants as a tank mix, Member states shall evaluate whether the plant protection product is physically and chemically compatible with those other plant protection products or adjuvants in the tank mix.

1.3. **Efficacy**

Member States shall evaluate the efficacy of the plant protection product based on those data submitted in accordance with Section 6 of Part B of the Annex to Regulation (EU) No 284/2013.

1.3.1. Where the proposed use concerns the control of or protection against an organism, Member States shall evaluate if the target organism could be a danger to plant health under the agricultural and environmental (including climatic) conditions in the area of the proposed use.

1.3.2. Member States shall evaluate whether significant damage to plants or plant products or loss in yields could occur under the agricultural and environmental (including climatic) conditions in the area of proposed use, if the plant protection product was not used.

1.3.3. Member States shall evaluate the efficacy data provided for in Part B of the Annex to Regulation (EU) No 284/2013 for the plant protection product, having regard to the degree of control or the extent of the effect desired and to relevant experimental conditions such as:

(a) the choice of the crop or cultivar;

(b) the agricultural and environmental (including climatic) conditions (if necessary for a specific use such data/information shall also be given for the time before and after application);

(c) the presence and density of the target organism;

(d) the development stage of crop and target organism;

(e) the application rate of the plant protection product;

(f) if required on the label, the application rate of adjuvant to be added;

(g) the frequency and timing of the applications;

(h) the type of application equipment to be used;

(i) the need for any special cleaning measures for the application equipment before and after use.

1.3.4. Member States shall evaluate the efficacy of the plant protection product under the range of agricultural, plant health and environmental (including climatic) conditions likely to be encountered in practice in the area of proposed use. The evaluation shall include the compatibility with integrated pest management. In particular, consideration shall be paid to:

(a) the level, consistency and duration of the effect sought in relation to the proposed dose;

(b) the comparison of the proposed dose with a suitable reference product or products, where they exist, and an untreated control;

(c) where relevant, the effect on yield or reduction of loss in storage, in terms of quantity and/or quality, in comparison with a suitable reference product or products, where they exist, and an untreated control;

(d) the risk of occurrence and development of resistance or cross-resistance in populations of target organism.

Where no suitable reference product exists, Member States shall evaluate the efficacy of the plant protection product to determine whether there is a consistent and defined benefit under the agricultural, plant health and environmental (including climatic) conditions likely to be encountered in practice in the area of proposed use.

1.3.5. Member States shall evaluate possible occurrence of adverse effects and their degree, on the treated crop after use of the plant protection product in accordance with the proposed conditions of use in comparison, where relevant, with a suitable reference product or products, where they exist, and/or an untreated control.

(a) This evaluation shall take into consideration the following information:

(i) efficacy data;

(ii) other relevant information on the plant protection product such as nature of the plant protection product, dose, method of application, number and timing of applications, incompatibility with other crop treatments;

(iii) all relevant information on the micro-organism, including biological properties e.g. mode of action, survival, host range specificity.

(b) This evaluation shall include:

(i) the nature, frequency, level and duration of observed phytotoxic/phytopathogenic effects and the agricultural, plant health and environmental (including climatic) conditions that affect them;

(ii) differences between main cultivars with regard to their sensitivity to phytotoxic/phytopathogenic effects;

(iii) the part of the treated crop or plant products where phytotoxic/phytopathogenic effects are observed;

(iv) adverse impact on the yield of the treated crop or plant products in terms of quantity and/or quality, and on transformation processes;

(v) adverse impact on treated plants or plant products to be used for propagation, in terms of viability, germination, sprouting, rooting and establishment;

(vi) where micro-organisms are disseminated, in particular for weed control, any adverse impact on adjacent crops.

1.3.6. Where the proposed label of the plant protection product includes recommendations or requirements for the use of the plant protection product with other plant protection products and/or adjuvants as a tank mix, Member States shall make the evaluations referred to in points 1.3.3 to 1.3.5 with regard to the information supplied for the tank mix, and shall evaluate the appropriateness of the mix and of its conditions of use.

1.3.7. Member States shall evaluate potential effects (e.g. antagonism, fungicidal effects) on the activity of the micro-organism after mixing or spraying in sequence (or employing other relevant types of applications) with other plant protection products in accordance with the instructions proposed by the applicant on the label.

1.3.8. Where the available data indicate that the micro-organism has adverse effects on plants, or that metabolites of concern that have adverse effects on plants can persist in soil, and/or persist in/on plants in significant quantities after use of the plant protection product in accordance with the proposed conditions of use, Member States shall evaluate the degree of adverse effects on succeeding crops, taking into consideration the relevant information provided for under point 6.6 of Part B of the Annex to Regulation (EU) No 284/2013.

1.3.9. Member States shall evaluate potential negative effects of the micro-organism on beneficial organisms, either deliberately released, or as part of other practices (e.g. conservation biological control), taking into consideration the relevant information provided for under point 6.7 of Part B of the Annex to Regulation (EU) No 284/2013.

1.3.10. Where the proposed use of a plant protection product is intended to have an effect on vertebrates, Member States shall evaluate the mechanism by which this effect is obtained and the observed effects on the behaviour and health of the target animals. When the intended effect is to kill the target animal they shall evaluate the time necessary to obtain the death of the animal and the conditions under which death occurs.

This evaluation shall take into consideration the following information:

(a) all relevant information as provided for under Part B of the Annex to Regulation (EU) No 283/2013 and the results of the evaluation thereof, including the toxicological studies;

(b) all relevant information on the plant protection product as provided for under Part B of the Annex to Regulation (EU) No 284/2013, including toxicological studies and efficacy data.

1.3.11. If there is evidence of development of resistance of the target organism towards the plant protection product requiring a resistance management strategy, the Member State shall evaluate if the submitted resistance management strategy, required according to point 6.4 of Part B of the Annex to Regulation (EU) No 284/2013, addresses this adequately and sufficiently.

1.4. **Identification/detection and quantification methods**

Member States shall assess data on the identification/detection and quantification methods submitted in accordance with Section 4 of Part B of the Annex to Regulation (EU) No 283/2013 and Section 5 of Part B of the Annex to Regulation (EU) No 284/2013.

Member States shall evaluate the analytical methods proposed for control and monitoring purposes, of the micro-organism both in the plant protection product and, where relevant, in or on edible parts of treated crops. In addition, where relevant, the analytical methods relating to metabolites of concern and relevant impurities present in the plant protection product shall also be evaluated. Appropriate validation data shall be provided by the applicant as regards the pre-authorisation analytical methods and post-authorisation monitoring methods. Methods that are considered suitably validated for post-authorisation monitoring shall be clearly identified.

1.4.1. Analytical methods for the plant protection product

The evaluation concerning analytical methods for the plant protection product shall take into consideration the relevant information provided for under point 4.1 of Part B of the Annex to Regulation (EU) No 283/2013 and under point 5.1 of Part B of the Annex to Regulation (EU) No 284/2013.

1.4.1.1. Analytical methods for micro-organisms

Member States shall evaluate the methods proposed to identify and quantify the micro-organism, and especially methods that discriminate that micro-organism from closely related strains. These methods shall include the most appropriate molecular analytical and phenotypic methods, to allow unequivocal distinction between the micro-organism under assessment, and other strains belonging to the same species. Member States shall also evaluate the methods proposed to identify and quantify relevant contaminating micro-organisms.

1.4.1.2. Analytical methods for metabolites of concern, relevant impurities, additives, co-formulants, safeners and synergist

Where applicable, Member States shall evaluate the analytical methods proposed to identify and quantify metabolites of concern identified according to point 2.8 of Part B of the Annex to Regulation (EU) No 283/2013, relevant impurities, co-formulants, safeners and synergists.

1.4.2. Analytical methods for the determination of residues and density of the micro-organism

Member States shall take into consideration the relevant information provided for under point 4.2 of Part B of the Annex to Regulation (EU) No 283/2013 and under point 5.2 of Part B of the Annex to Regulation (EU) No 284/2013.

1.4.2.1. Density of the micro-organism

Member States shall evaluate the methods proposed to identify and quantify the density of the micro-organism, where relevant, on and/or in crops, in foodstuffs and feeding stuffs, in animal and human body tissues and fluids, in relevant environmental compartment.

1.4.2.2. Residues of metabolites of concern

Member States shall evaluate the analytical methods proposed to identify and quantify residues of metabolites of concern, where relevant, on and/or in crops, in foodstuffs and feeding stuffs, in animal and human body tissues and fluids, in relevant environmental compartment.

1.5. **Impact on human and animal health**

Member States shall evaluate data on human and animal (i.e. species normally fed and kept by humans or food-producing animals) health submitted in accordance with Sections 5 and 6 of Part B of the Annex to Regulation (EU) No 283/2013 and Sections 7 and 8 of Part B of the Annex to Regulation (EU) No 284/2013.

The most important aspects that shall be assessed are:

— infectivity and pathogenicity;

— toxicity of metabolites of concern, safeners, synergists, and relevant impurities;

— relevant antimicrobial activity of metabolites present in the plant protection product;

— susceptibility to relevant antimicrobial agents to ensure the availability of sufficient treatment options in case of an opportunistic infection.

These aspects comprise a complex set of interactions between micro-organisms and the hosts, and need to be assessed in an integrated way and applying a weight of evidence approach.

An assessment of infectivity and pathogenicity is always necessary.

1.5.1. Effects on human or animal health arising from the plant protection product

1.5.1.1. Availability of sufficient treatment options against the micro-organism contained in the plant protection product shall be evaluated.

1.5.1.2. Member States shall evaluate infectivity and pathogenicity of the micro-organism and toxicity of metabolites of concern and relevant impurities. This evaluation shall take into consideration the following information:

(a) the available information on infectivity and pathogenicity (e.g. based on biological properties, peer-reviewed literature, animal studies performed by the applicant) as provided for in Part B of the Annex to Regulation (EU) No 283/2013. For micro-organisms, infectivity and pathogenicity tests on animals may not always be suitable for extrapolation to humans due to differences between humans and test animals (e.g. immune system, microbiome). Micro-organisms might have a narrow host range, hence it cannot always be assumed

that a micro-organism that does cause disease in the animals tested has the same result in humans, and vice-versa. Information available and provided by the applicant, as required in points 2.1, 2.3, 2.4, 2.6 and 5.1 of Part B of the Annex to Regulation (EU) No 283/2013, and/or retrieved from any other reliable sources (e.g. Qualified Presumption of Safety, peer-reviewed literature) may provide robust and reliable scientific indication on infectivity and pathogenicity of the micro-organism. Where an applicant provides a summary of information already available on infectivity and pathogenicity of the micro-organism, as described in point 5.2 of Part B of the Annex to Regulation (EU) No 283/2013, Member States shall assess such scientific evidence provided by the applicant using a weight of evidence approach, in order to evaluate whether the possible non-submission of certain studies required in points 5.3.1 and 5.4 of Part B of the Annex to Regulation (EU) No 283/2013 is justified. The evaluation shall take into consideration the following principles:

— to avoid unnecessary animal testing, in a first instance infectivity and pathogenicity shall be assessed on the basis of existing information as provided for under point 5.2 of Part B of the Annex to Regulation (EU) No 283/2013;

— infectivity and pathogenicity studies described in point 5.3.1 of Part B of the Annex to Regulation (EU) No 283/2013 may be necessary;

— further specific studies may be required, as indicated in point 5.4 of Part B of the Annex to Regulation (EU) No 283/2013. For instance, if there are indications of infectivity, or any adverse effects, further testing shall be conducted, taking into account the exposure scenario and an observation period suitable for the micro-organisms, to allow observing a clearance in the host. The choice of appropriate timing of the observational period may be based on available information such as biological properties of the micro-organism or other relevant available information.

The evaluation of available information and possible animal studies performed by the applicant, shall take into consideration the ability of the micro-organism to infect, persist or grow in the mammalian host, and its ability to cause effects or reactions in the host. Parameters that indicate the absence of ability to persist and multiply in the host, and the absence of ability to produce adverse effects in a host, include clearance from the body, if relevant. Replication temperatures may be different from mammalian body temperature, possibly indicating low likelihood of persistence and multiplication in the host. However, temperature adaptation may occur, and this parameter alone shall not be considered sufficient to conclude on persistence and multiplication of the micro-organism in the host. Evaluation based on relevant parameters of study results and available information shall lead to an assessment of the possible effects of occupational exposure.

(b) the available information on toxicity (e.g. based on biological properties, peer-reviewed literature, animal studies performed by the applicant) as described in points 2.8 and 5.5 of Part B of the Annex to Regulation (EU) No 283/2013, and Section 7 of Part B of the Annex to Regulation (EU) No 284/2013. Information available on toxicity, such as from published literature, medical information, Integrated Approach to Testing and Assessment (IATA), results of CLP calculation rules in accordance with Regulation (EC) No 1272/2008, or bridging data from similar plant protection products, may provide robust and reliable scientific indication on the toxicity of relevant chemical substances contained in the plant protection product, and be used for classification and labelling. Where an applicant provides information available on human and animal toxicity of (chemical substances present in) the plant protection product (including *in vitro* and *ex vivo* data), Member States shall assess such scientific evidence provided by the applicant using a weight of evidence approach, in order to evaluate whether the possible non-submission of certain studies required in points 7.3.1 to 7.3.6 of Part B of the Annex to Regulation (EU) No 284/2013 is justified. The evaluation shall take into consideration the following principles:

— to avoid unnecessary animal testing, in a first instance toxicity shall be assessed on the basis of existing information as provided for in point 7.2 of Part B of the Annex to Regulation (EU) No 284/2013;

— toxicity studies may be necessary;

— further specific studies may be required taking into consideration the intended use, according to the provisions of points 2.8 and 5.5 of Part B of the Annex to Regulation (EU) No 283/2013, and of points 7.4 and 7.7 of Part B of the Annex to Regulation (EU) No 284/2013.

The evaluation of available information and possible animal studies performed by the applicant, shall take into consideration the ability of metabolites of concern, safeners, synergists, and relevant impurities to cause adverse effects on humans or animals. Evaluation based on relevant parameters of the tests shall lead to an assessment of the possible effects of non-dietary exposure, taking into account the intensity and duration of exposure under the proposed conditions of use.

(c) other relevant information provided for under Part B of the Annex to Regulation (EU) No 284/2013, such as:

— composition of the plant protection product,

— nature of the plant protection product,

— size, design and type of packaging.

1.5.1.3. Member States shall evaluate the effects to human and animal health related to non-dietary exposure of operators, workers, bystanders and residents to the micro-organism which is contained in the plant protection product, and the components which may be toxicologically relevant (e.g. metabolites of concern, relevant impurities), and which are likely to occur under the proposed conditions of use (including, in particular, dose, application method and climatic conditions). Realistic data on exposure levels to the plant protection product shall be used. If such data is not available, a suitable, and if possible validated, calculation model for plant protection products containing a micro-organism shall be employed. This evaluation shall take into consideration the following aspects:

(a) on the basis of the information referred to in point 1.5.1.2 the following overall end-points shall be established for single or repeated operator, worker, bystanders and residents exposure following the intended use, as regards:

— observed or expected infectivity and pathogenicity of the micro-organism(s) in the plant protection product,

— observed or expected adverse toxicological effects of the plant protection product due to metabolites of concern safeners, synergists, and/or relevant impurities.

(b) the evaluation of the exposure of the operator shall be made for each type of application method and application equipment proposed for the use of the plant protection product as well as for the different types and sizes of packaging containers to be used, taking into account mixing, loading operations, application of the plant protection product and cleaning and routine maintenance of application equipment. Where relevant, other authorised uses of the plant protection product in the area of envisaged use, concerning the same active substance or which give rise to the same residues, shall also be taken into account.

(c) the possibility of adverse effects in humans shall be assessed with regard to measured or estimated levels of human exposure as compared to the tested dose levels, as provided for under Section 7 of Part B of the Annex to Regulation (EU) No 284/2013. This risk assessment shall include consideration of e.g. mode of action, physical and chemical properties of the micro-organism and other components in the plant protection product, such as metabolites of concern, safeners, synergists and relevant impurities.

(d) other relevant information provided for under Part B of the Annex to Regulation (EU) No 284/2013, such as:

— field of use and nature of the crop or target,

— method of application including handling, mixing and loading of the plant protection product,

— exposure reduction measures recommended,

— protective clothing recommendations,

— maximum application rate,

— cleaning and routine maintenance of application equipment, , taking into account also seed treatment and good occupational practice,

— recommendation to be followed after application, such as re-entry period and working duration,

— minimum (spray) application volume stated on the label,

— number and timing of applications, including intervals between applications,

— re-entry periods, necessary waiting periods or other precautions to protect humans and animals,

— dried residues of the plant protection products on plants and plant products after treatment, taking into account the capacity of the micro-organism to grow *in situ*, and the influence of factors such as temperature, UV light, pH and the presence of certain substances,

— further information on exposure (e.g. operator/worker/bystander/resident exposure study, further activities whereby workers are exposed).

1.5.1.4. Member States shall evaluate information relating to the nature and characteristics of the packaging proposed, in particular the following aspects:

(a) the type of packaging;

(b) its dimensions and capacity;

(c) the size of the opening;

(d) the type of closure;

(e) its strength, leak proofness and resistance to normal transport and handling;

(f) its resistance to and compatibility with the contents.

1.5.1.5. Member States shall evaluate the nature and characteristics of the protective clothing and equipment proposed, in particular the following aspects:

(a) obtainability and suitability;

(b) effectiveness;

(c) ease of wearing taking into account physical stress and climatic conditions;

(d) resistance to and compatibility with the plant protection product.

1.5.1.6. Micro-organisms approved as active substances of plant protection product are not expected to be infective for humans. However, in order to ensure the availability of sufficient therapeutic measures in the event of opportunistic infections, Member States shall, where relevant based on biological properties of the micro-organism, evaluate the susceptibility of the micro-organism (except viruses) to antimicrobial agents.

1.5.2. Effects on human or animal health arising from residues of metabolites of concern

The evaluation of consumer exposure to residues of metabolites, for which a hazard to human and animal health was identified, is based either on the applicant's substantiated estimation or, in case where the substantiated estimation does not demonstrate an acceptable risk to consumers, on residue trials for metabolites of concern.

In cases provided for in point 6.1 of Part B of the Annex to Regulation (EU) No 283/2013, also information on viable micro-organisms may be required and assessed with the information on residues of metabolites of concern.

1.5.2.1. Member States shall evaluate the potential residue levels of metabolites of concern for which a hazard was identified to human or animal health in points 2.8 and 5.5 of Part B of Annex to Regulation (EU) No 283/2013. This evaluation shall be performed for each proposed use and shall take into account the following information:

— the intended use, including data on application and proposed pre-harvest intervals for envisaged uses or withholding periods or storage periods in the case of post-harvest uses;

— analytical methods as provided for under point 5.2 of Part B of the Annex to Regulation (EU) No 284/2013;

— the specific information on residues in/on treated plants, plant products, food and feed as provided for in Section 8 of Part B of the Annex to Regulation (EU) No 284/2013;

— realistic possibilities for extrapolating data from one crop to another.

Member States shall evaluate the potential exposure of consumers to metabolites of concern through diet using a suitable calculation model. This evaluation shall take into account, where relevant, other sources of the same metabolite of concern for which either maximum residue levels have been set in accordance with Regulation (EC) No 396/2005, or maximum tolerances have been set in accordance with Council Regulation (EEC) No 315/93 ([14]) on contaminants in food.

In cases where the estimation of residue levels does not demonstrate acceptable risk to consumers, Member States shall refine the evaluation, either based on data generated through residues trials, or on toxicity of metabolites of concern through determination of a toxicological endpoint, such as the acceptable daily intake (ADI), or, where appropriate, the Threshold of Toxicological Concern (TTC) value having regard to the specific information provided in accordance with point 6.2 of Part B of the Annex to Regulation (EU) No 283/2013.

1.5.2.2. Member States shall, where relevant, estimate the exposure of animals to residues of metabolites of concern, taking into account the residue levels estimated or measured in treated plants or plant products intended to be fed to animals.

1.5.2.3. Member States shall, where relevant, evaluate the residues of metabolites of concern estimated or measured in products of animal origin and their toxicity, taking into consideration the information provided for under points 2.8 and 5.5 and Section 6 of Part B of the Annex to Regulation (EU) No 283/2013.

1.5.2.4. Member States shall, where relevant, estimate the potential exposure of consumers to metabolites of concern through diet via the products of animal origin mentioned in point 1.5.2.3, using a suitable calculation model. This evaluation shall take account, where relevant, of other sources of the same metabolite of concern for which either maximum residue levels had been set in accordance with Regulation (EC) No 396/2005 (in case of authorised uses of the micro-organism producing it in biocidal or veterinary products), or maximum tolerances have been set in accordance with Regulation (EEC) No 315/93, where relevant.

1.5.2.5. Member States shall assess data on density of micro-organisms on edible parts of treated crops, if those are provided to support the estimation of residues of metabolites of concern produced *in-situ*. Data on density of micro-organisms on edible parts of treated crops is required only in few circumstances, as provided for in point 6.1 of Part B of Annex to Regulation (EU) No 283/2013, since micro-organisms which are infective or pathogenic to humans or other vertebrate animals will not be eligible for approval, and non-pathogenic micro-organisms are not expected to cause adverse effects to consumers, apart from possible production of metabolites of concern to be assessed in accordance with the points 1.5.2.1 to 1.5.2.4. Absence of viable micro-organisms on edible parts excludes the risk of *in-situ* production of metabolites of concern.

1.6. **Environmental occurrence of the micro-organism, including fate and behaviour of metabolites of concern**

Member States shall assess data on the environmental occurrence of the micro-organism, including fate and behaviour of metabolites of concern, submitted in accordance with Section 7 of Part B of the Annex to Regulation (EU) No 283/2013 and Section 9 of Part B of the Annex to Regulation (EU) No 284/2013.

The evaluation of the environmental occurrence of an active substance that is a micro-organism needs to take into account that micro-organisms may be already occurring in relevant European environments, have the ability to replicate and have the ability to become dormant allowing for the formation of seed banks of micro-organisms.

([14]) Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food (OJ L 37, 13.2.1993, p. 1).

The evaluation of the environmental exposure to the relevant components of the plant protection product, i.e. the micro-organism and metabolites of concern, shall be considered in order to conduct risk assessments as regards:

— non-target organisms (concerning the exposure to the micro-organism and to the metabolites of concern);

— humans via the environment (concerning the exposure to the metabolites of concern).

The evaluation of environmental exposure shall be based either on a substantiated estimation or, in case where this substantiated estimation does not demonstrate an acceptable risk, on experimental data. This experimental data may include measurements concerning the population dynamics of the micro-organism in specific environmental compartments upon use of the plant protection product, and the fate and behaviour of metabolites of concern.

1.6.1. Environmental occurrence of the micro-organism

Member States shall evaluate the possibility of exposure of soil and/or surface water to the micro-organism based on the intended use and the biological properties of the micro-organism. If the possibility of exposure cannot be excluded, Member States shall evaluate the estimated exposure of soil and/or surface water after the use of the plant protection product in accordance with the intended conditions of use.

For non-target organisms for which a hazard is identified, for instance based on the calculation of the predicted environmental density as provided for under point 7.1.1 of Part B of the Annex to Regulation (EU) No 283/2013, Member States shall evaluate the estimation of the exposure of the relevant non-target organisms to the micro-organism. This estimation shall be performed for each intended use and shall take into account the following information:

— the data on the proposed good agricultural practice, including data on application;

— nature of the plant protection product;

— analytical methods, as provided for under point 4.2 of Part B of the Annex to Regulation (EU) No 283/2013, and under point 5.2 of Part B of the Annex to Regulation (EU) No 284/2013;

— the specific information on occurrence of the micro-organism, e.g. possible increase of microbial density in the relevant environmental compartment compared to the occurrence at the relevant highest taxonomic level in European environments, as provided for under point 7.1 of Part B of the Annex to Regulation (EU) No 283/2013, and, where relevant, Section 9 of Part B of the Annex to Regulation (EU) No 284/2013;

— data extrapolated from one crop to another, if considered realistic by Member States;

— in addition, for micro-organisms not occurring in the relevant European environments at the relevant highest taxonomic level, and which are known to be pathogenic either for plants or for other organisms, the exposure of non-target organisms through colonised host organisms shall be evaluated taking into account also the information on the population density of the micro-organism in host organisms, and the exposure of non-target organisms to colonised host organisms.

1.6.2. Environmental fate and behaviour of the metabolites of concern

In case a hazard has been identified for humans and/or non-target organisms due to a metabolite of concern, as provided for under points 2.8, 5.5 and 8.8 of Part B of the Annex to Regulation (EU) No 283/2013, and Sections 7 and 10 of Part B of the Annex to Regulation (EU) No 284/2013, Member States shall estimate the concentrations in the relevant environmental compartments that lead to exposure of humans and non-target organisms for which the hazard has been identified. This estimation shall be performed for each intended use and shall take into account the following information:

— the data on the proposed good agricultural practice, including data on application;

— nature of the plant protection product;

— analytical methods, as provided for under point 4.2 of Part B of the Annex to Regulation (EU) No 283/2013, and under point 5.2 of Part B of the Annex to Regulation (EU) No 284/2013;

— the specific information on environmental fate and behaviour of the metabolite of concern present in the plant protection product, as provided for under point 7.2 of Part B of the Annex to Regulation (EU) No 283/2013, and, if relevant, Section 9 of Part B of the Annex to Regulation (EU) No 284/2013;

— if available and if submitted by the applicant to perform a qualitative exposure assessment as provided for under point 7.2.2 of Part B of the Annex to Regulation (EU) No 283/2013, on background level of the same metabolite of concern in the relevant environmental compartments;

— realistic possibilities of extrapolating data from one crop to another.

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

Member States shall assess data on the risks to non-target organisms that the plant protection product may cause submitted in accordance with Section 8 Part B of the Annex to Regulation (EU) No 283/2013 and Section 10 Part B of the Annex to Regulation (EU) No 284/2013.

This assessment shall take into consideration the biology of the micro-organism, the exposure of non-target organisms under field condition according to the proposed conditions of use, and shall take into consideration possible increase of microbial density in the relevant environmental compartment compared to the occurrence of the micro-organism in European environments at the relevant highest taxonomic level.

To assess the possibility of exposure the following information shall be taken into consideration:

(a) conditions of use;

(b) information on fate and behaviour as provided in Section 9 of Part B of the Annex to Regulation (EU) No 284/2013.

Where an applicant does not perform certain studies required in Section 8 of Part B of the Annex to Regulation (EU) No 283/2013 and Section 10 of Part B of the Annex to Regulation (EU) No 284/2013, Member States shall assess if the scientific evidence provided by the applicant using a weight of evidence approach justifies the non-submission of these data.

1.7.1. Member States shall evaluate the risks to terrestrial vertebrates after the use of the plant protection product in accordance with the proposed conditions of use and taking into account the evaluation criteria provided for in point 1.6.

(a) Member States shall evaluate the risks to terrestrial vertebrates due to the micro-organism and its potential to infect and multiply in the host, taking into account the following information on the micro-organism:

— mode of action;

— other biological properties;

— studies on mammalian infectivity and pathogenicity;

— studies on avian infectivity and pathogenicity;

— other relevant information on terrestrial vertebrate infectivity and pathogenicity.

(b) Member States shall evaluate the risk to terrestrial vertebrates due to toxic effects of the plant protection product in accordance with relevant provisions referred to in point 1.5.2.1 of Part A.

1.7.2. Member States shall evaluate the risks to aquatic organisms after the use of the plant protection product in accordance with the proposed conditions of use and taking into account the evaluation criteria provided for in point 1.6.

(a) Member States shall evaluate the risks to aquatic organisms due to the micro-organism and its potential to infect and multiply the host, taking into account the following information on the micro-organism:

— its mode of action;

— other biological properties;

— studies on infectivity and pathogenicity to aquatic organisms and/or other existing relevant information.

(b) Member States shall evaluate the risk to aquatic organisms due to toxic effects of the plant protection product in accordance with relevant provisions referred to in point 1.5.2.2 of Part A.

1.7.3. Member States shall evaluate the risks to bees after the use of the plant protection product in accordance with the proposed conditions of use and taking into account the evaluation criteria provided for in point 1.6.

(a) Member States shall evaluate the risks to bees due to the micro-organism and its potential to infect and multiply the host, taking into account the following information on the micro-organism:

— its mode of action;

— other biological properties;

— studies on infectivity and pathogenicity to bees and/or other existing relevant information.

(b) Member States shall evaluate the risk to bees due to toxic effects of the plant protection product, in accordance with relevant provisions referred to in point 1.5.2.3 of Part A.

1.7.4. Member States shall evaluate the risks to non-target arthropods other than bees after the use of the plant protection product in accordance with the proposed conditions of use and taking into account the evaluation criteria provided for in point 1.6. Member States shall pay particular attention to the risks to beneficial organisms deliberately released for biocontrol purposes.

(a) Member States shall evaluate the risks to arthropods other than bees due to the micro-organism and its potential to infect and multiply the host, taking into account the following information on the micro-organism:

— its mode of action;

— other biological properties;

— studies on infectivity and pathogenicity to honeybees and other arthropods and/or other existing relevant information.

(b) Member States shall evaluate the risk to arthropods other than bees due to toxic effects of the plant protection product in accordance with relevant provisions referred to in point 1.5.2.4 of Part A.

1.7.5. Member States shall evaluate the risks to non-target meso- and macro-organisms in soil after the use of the plant protection product in accordance with the proposed conditions of use and taking into account the evaluation criteria provided for in point 1.6.

(a) Member States shall evaluate the risks to meso- and macroorganisms in soil due to the micro-organism and its potential to infect and multiply the host, taking into account the following information on the micro-organism:

— its mode of action;

— other biological properties;

— studies on infectivity and pathogenicity to meso- and macro-organisms and/or other existing relevant information.

(b) Member States shall evaluate the risk to meso- and macro-organisms in soil due to toxic effects of the plant protection product in accordance with relevant provisions referred to in point 1.5.2.5 of part A.

1.7.6. Member States shall evaluate the risks to non-target terrestrial plants after the use of the plant protection product in accordance with the proposed conditions of use and taking into account the evaluation criteria provided for in point 1.6.

(a) Member States shall evaluate the risks to terrestrial plants due to the micro-organism and its potential to infect and multiply the host, taking into account the following information on the micro-organism:

— its mode of action;

— other biological properties;

— studies on infectivity and pathogenicity to terrestrial plants;

— relatedness to known plant-pathogens.

(b) Member States shall evaluate the risk to terrestrial plants due to toxic effects of the plant protection product.

1.8. **Conclusions and proposals**

Member States shall draw conclusions on the need for further information and/or testing and the need for measures to limit the risks arising. Member States shall justify proposals for the classification and labelling of plant protection products.

2. **DECISION-MAKING**

The following principles shall apply without prejudice to the general principles referred to in Section 3 of the general introduction.

2.1. **Identity**

2.1.1. For each authorisation granted the Member States shall ensure that the active substance concerned has been approved in accordance with Regulation (EC) No 1107/2009.

2.1.2. For each authorisation granted the Member States shall set the specification as regards the composition of the plant protection product. The minimum and maximum content of the micro-organism that is the active substance contained in the plant protection product shall be defined. The content of metabolites of concern, relevant impurities, co-formulants, safeners and synergists in the plant protection product, and relevant contaminating micro-organisms derived from the production process shall to the extent possible be defined. Member States shall verify, based on the information provided in the dossier, that quality assurance on the manufacturing process allows levels of metabolites of concern, relevant impurities, and relevant contaminating micro-organisms to be controlled to an acceptable level.

2.1.3. No authorisation shall be granted unless the manufacturing processes of the MPCA as manufactured and the plant protection product ensure that the production of MPCA as manufactured and plant protection product is of consistent quality, as set out in the specification set out in point 2.1.2.

2.1.4. In accordance with Article 48 of Regulation (EC) No 1107/2009 and Directive 2001/18/EC of the European Parliament and of the Council ([15]), where the micro-organism has been genetically modified no authorisation shall be granted unless:

— the evaluation conducted in accordance with Directive 2001/18/EC as well as the relevant decision taken by the Member States has been provided by the applicant in the dossier, and

— an authorisation is granted in accordance with Part C of Directive 2001/18/EC under which that organism can be released into the environment, or placed on the market in a plant protection product.

2.1.5. Member States shall ensure that adequate quality control measures are applied to ensure the identity of the micro-organism and of the other components of the plant protection product.

([15]) Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

2.2. **Biological and technical properties**

2.2.1. No authorisation shall be granted for a plant protection product containing a micro-organism, if the micro-organism that is the active substance is a non-virulent variant of a plant pathogen virus, and the likelihood of regaining virulence and causing adverse effects in target and non-target plants through mutation, after application under the proposed conditions of use (including possible risk mitigation measures), is not negligible.

2.3. **Efficacy and absence of unacceptable effects on plants and plant products**

2.3.1. Efficacy

2.3.1.1. No authorisation shall be granted where, on the basis of experience acquired or scientific evidence under normal agricultural, plant health and environmental (including climatic) conditions, the proposed uses include:

— recommendations for the control of or protection against target organisms, or any other effects, which are not considered to cause adverse effects on crops, plants, or plant products; or,

— effects which are not considered to be beneficial under those conditions.

2.3.1.2. No authorisation shall be granted when the proposed minimum dose, or a range of minimum doses, necessary to achieve sufficient efficacy against a target pest or any other relevant benefit across the proposed use, i.e. the minimum effective dose, is not justified based on available information or efficacy trials.

2.3.1.3. The level, consistency and duration of control or protection or other intended effects shall be at least higher than those observed in the untreated control, and if possible similar to a suitable reference product. Where relevant, yield response when the plant protection product is used, or reduction of loss in storage, shall be quantitatively and/or qualitatively at least higher than those observed for the untreated control, and if possible similar to a suitable reference product. The plant protection product shall be shown to give a defined benefit under the agricultural, plant health and environmental (including climatic) conditions in the area of proposed use.

2.3.1.4. Conclusions as to the efficacy of the plant protection product shall be valid for all areas and conditions in which it is to be authorised.

2.3.1.5. Where the proposed label includes recommendations or requirements for use of the plant protection product with other specified plant protection products and/or adjuvants in a tank mix, spray sequences, or employing other relevant types of applications, or any other recommendations (e.g. weather conditions, soil conditions, irrigation application), Member States shall not accept the recommendations or requirements unless they are justified, if applicable, by supporting information and comply with the principles referred to in points 2.3.1.1 to 2.3.1.4.

2.3.1.6. Where negative interactions are expected between the plant protection product containing the micro-organism(s) and other plant protection products, which the label requires to use in tank mix, spray sequences, or employing other relevant types of applications, or other common practices (e.g. conservation biological control), affecting the efficacy of one or the others, Member States shall set appropriate conditions in the authorisation of the plant protection product containing the micro-organism(s), and they shall ensure that a warning labelling phrase is indicating such negative interaction.

2.3.2. Absence of unacceptable effects on plants and plant products

2.3.2.1. There shall be no relevant phytotoxic or pathogenic effects on treated plants or plant products, except where the proposed label indicates appropriate limitations of use.

2.3.2.2. There shall be no reduction of yield at harvest below that which could be obtained without the use of the plant protection product, unless this reduction is compensated for by other advantages beside the plant protection action, such as an enhancement of the quality of the treated plants or plant products.

2.3.2.3. There shall be no unacceptable adverse effects on the quality of treated plants or plant products, except in the case of adverse effects on food and feed transformation processes (e.g. wine making, brewing, bread making, or silage productions as feed) where proposed label specifies that the plant protection product shall not be applied to crops to be used in transformation processes.

2.3.2.4. There shall be no unacceptable adverse effects on treated plants or plant products used for propagation or reproduction, such as effects on viability, germination, sprouting, rooting and establishment, except where proposed label specifies that the plant protection product shall not be applied to plants or plant products to be used for propagation or reproduction.

2.3.2.5. There shall be no unacceptable impact on succeeding crops, except where proposed label specifies that particular crops, which would be affected, shall not be grown following the treated crop.

2.3.2.6. There shall be no unacceptable impact on adjacent crops, except where proposed label specifies that the plant protection product should not be applied when particular sensitive adjacent crops are present.

2.3.2.7. Where the proposed label of the plant protection product includes recommendations or requirements for the use with other plant protection products and/or adjuvants as a tank mix, the same criteria referred to in points 2.3.2.1 to 2.3.2.6 apply in relation to the information supplied for the tank mix.

2.3.2.8. The proposed instructions for cleaning the application equipment shall be both practical and effective so that they can be applied with ease so as to ensure the removal of residual traces of the plant protection product which could subsequently cause damage.

2.4 **Identification/detection and quantification methods**

The methods proposed shall reflect the most appropriate techniques. The following conditions shall be met in order to permit validation of the pre-authorisation analytical methods and, where relevant, the analytical methods proposed for post-authorisation control and monitoring purposes.

2.4.1. No authorisation shall be granted unless there is an adequate method of sufficient quality to identify and quantify the micro-organism in appropriate microbial unit, and any other components of the plant protection product, such as metabolites of concern, relevant impurities and co-formulants, which are relevant for human and animal health and/or the environment. For a plant protection product containing more than one micro-organism as active substance, the recommended methods should be capable of identifying and determining the content of each micro-organism independently of the others.

2.4.2. No authorisation shall be granted unless there is an adequate method for control and monitoring to identify and quantify residues of metabolites of concern for which MRL have been set. These methods shall involve the use of commonly available reagents and equipment. Methods shall be available for analysis of:

(a) plants, plant products, foodstuffs of plant and animal origin and feeding stuffs if relevant residues occur. Residues are considered relevant if a MRL or a waiting or re-entry safety period or other such precaution is required;

(b) soil, water, air and/or body fluids and tissues, in those compartments where toxicologically, ecotoxicologically or environmentally relevant residues occur.

2.5. **Impact on human and animal health**

2.5.1. Effects on human and animal health arising from the plant protection product

When making a decision on the authorisation of the plant protection product containing (a) micro-organism(s), Member States shall consider possible effects on all human populations, namely professional users, non-professional users and humans exposed directly or indirectly through the diet or the environment, and on animals.

2.5.1.1. No authorisation shall be granted if it is concluded that the micro-organism is infective or causes unacceptable adverse health effects in humans or animals under the recommended conditions of use, including in a realistic worst case exposure scenario.

2.5.1.2. No authorisation shall be granted if, where relevant based on biological properties of the micro-organism, there are no sufficient treatment options which are effective against the micro-organism.

2.5.1.3. No authorisation shall be granted if the plant protection product has unacceptable toxic effects on humans or animals under the proposed conditions of use, including in a realistic worst-case exposure scenario.

2.5.1.4. All micro-organisms shall be regarded as potential sensitisers until a test method is validated and unless it is established by means of relevant information that there is no risk of sensitisation. Authorisations granted shall therefore specify, as a non-specific risk mitigation measure, that personal protective equipment (e.g. masks) shall be worn, taking into account the conditions of use, and that the exposure via inhalation to the plant protection product containing a micro-organism shall be minimised. In addition, the proposed conditions of use may require that specific risk mitigation measures are applied as envisaged by Article 6 of Regulation (EC) No 1107/2009.

Where the proposed conditions of use require personal protective equipment, no authorisation shall be granted unless those are:

— effective and in accordance with Regulation (EU) 2016/425 of the European Parliament and of the Council ([16]),

— readily obtainable by the user,

— feasibly usable under the claimed conditions of use of the plant protection product, taking into account climatic conditions in particular.

2.5.1.5. Plant protection products which, because of particular properties, or which, if mishandled or misused, could lead to unacceptable risk, shall be subject to particular restrictions such as restrictions on the size of packaging, preparation type, distribution, use or manner of use. In addition, plant protection products, which are classified as very toxic, shall not be authorised for use by non-professional users.

2.5.1.6. Waiting and re-entry safety periods or other precautions shall be established in such a way that no infection of or other adverse effects on bystanders, workers, or residents or animals exposed after application of the plant protection product are expected.

2.5.1.7. Waiting and re-entry periods or other precautions to ensure that no infection or adverse effects are expected shall be realistic; if necessary, special precautionary measures shall be prescribed.

2.5.1.8. The conditions of authorisation shall be in compliance with Council Directives 98/24/EC ([17]) and 89/656/EEC ([18]), and Directives 2000/54/EC ([19]) and 2004/37/EC of the European Parliament and of the Council. The experimental data and information relevant to the recognition of the symptoms of infection and on the effectiveness of first aid and therapeutic measures provided shall be considered.

([16]) Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51).

([17]) Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11).

([18]) Council Directive 89/656/EEC of 30 November 1989 on the minimum health and safety requirements for the use by workers of personal protective equipment at the workplace (third individual directive within the meaning of Article 16 (1) of Directive 89/391/EEC) (OJ L 393, 30.12.1989, p. 18).

([19]) Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 262, 17.10.2000, p. 21).

2.5.2. Effects on human and animal health arising from residues

2.5.2.1. No authorisation shall be granted unless there is sufficient information for plant protection products containing an active substance that is a micro-organism, to decide that there is no harmful effect on human or animal health arising from exposure to the micro-organism and metabolites of concern remaining in or on plants or plant products.

2.5.2.2. No authorisation shall be granted where the treated plants or plant products are intended to be fed to animals and residues occurring have adverse effect on animal health.

2.6. **Fate and behaviour in the environment**

2.6.1. No authorisation shall be granted if, as a result of the use of the plant protection product under the proposed conditions, a contamination of surface water is expected by metabolites of concern, and:

— the surface water in or from the area of envisaged use is intended for the abstraction of drinking water; and

— this contamination exceeds the parameters or values established in accordance with Directive 2000/60/EC.

2.6.2 No authorisation shall be granted unless the proposed instruction for use of the plant protection product, including procedures for cleaning application equipment, are clearly described, and reduce to the minimum the likelihood of accidental contamination of surface water.

2.6.3. No authorisation shall be granted if, as a result of the use of the plant protection product under the proposed conditions, contamination of groundwater is expected by metabolites of concern, and this contamination exceeds the lower of the following limit values:

(i) the maximum permissible concentration laid down by Council Directive 98/83/EC ([20]); or

(ii) the maximum concentration laid down when approving the active substance in accordance with Regulation (EC) No 1107/2009, based on appropriate data, in particular toxicological data, or, where that concentration has not been laid down, the concentration corresponding to one tenth of the ADI laid down when the active substance was approved ([21]) in accordance with Regulation (EC) No 1107/2009,

unless a consumer risk assessment demonstrates no unacceptable risk or it is scientifically demonstrated that under relevant field conditions the parameters or maximum concentrations is not contravened or exceeded.

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

Member States shall ensure that the available information is sufficient to permit a decision to be taken as to whether there may be unacceptable effects on non-target organism groups indicated in Section 10 of Part B to the Annex of Regulation (EU) No 284/2013, due to exposure to the plant protection product containing a micro-organism following its intended use.

2.7.1. Where there is a possibility of terrestrial vertebrates being exposed according to the consideration done under point 1.6, no authorisation shall be granted:

(a) if the micro-organism is pathogenic to terrestrial vertebrates,

(b) in case of toxic effects of the plant protection product, if the acute and short-term toxicity/exposure ratio for terrestrial vertebrates is less than 10 on the basis of LD_{50} (acute dietary risk assessment) or the long-term toxicity/exposure ratio is less than 5, unless it is clearly established through an appropriate risk assessment that under field conditions no unacceptable impact occurs, directly or indirectly, after use of the plant protection product in accordance with the proposed conditions of use.

([20]) Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption (OJ L 330, 5.12.1998, p. 32).

([21]) Where the ADI is not available for a metabolite of concern, the default value of 0.1 μg/l applies.

2.7.2. Where there is a possibility of aquatic organisms being exposed according to the consideration done under point 1.6, no authorisation shall be granted:

(a) if the micro-organism is pathogenic to aquatic organisms, unless it is clearly established through an appropriate risk assessment that under field conditions no unacceptable impact on aquatic organism populations would occur after use of the plant protection product in accordance with the proposed conditions of use; or

(b) in case of toxic effects of the plant protection product if the:

— toxicity/exposure ratio for fish and Daphnia is less than 100 for acute exposure and less than 10 for long-term exposure, or

— algal growth inhibition/exposure ratio is less than 10,

unless it is clearly established through an appropriate risk assessment that under field conditions no unacceptable impact on exposed species occurs, directly or indirectly, after use of the plant protection product in accordance with the proposed conditions of use.

2.7.3. Where the possibility of bees to be exposed cannot be excluded according to the consideration done under point 1.6, no authorisation shall be granted:

(a) if the micro-organism is pathogenic to bees under the proposed conditions of use, unless it is clearly established through an appropriate risk assessment that under field conditions no unacceptable impact is expected to occur to the populations of bees after use of the plant protection product in accordance with the proposed conditions of use; or

(b) in case of toxic effects of the plant protection product, as defined in the decision-making principles of point 2.5.2.3 of Part A.

2.7.4. Where there is a possibility of arthropods other than bees being exposed according to the consideration done under point 1.6, no authorisation shall be granted:

(a) if the micro-organism is pathogenic to arthropods other than bees, unless it is clearly established through an appropriate risk assessment that under field conditions no unacceptable impact is expected to occur to the populations of arthropods other than bees after use of the plant protection product in accordance with the proposed conditions of use; or

(b) in case of toxic effects of the plant protection product, as defined in the decision-making principles of point 2.5.2.4 of Part A, unless it is clearly established through an appropriate risk assessment that under field conditions there is no unacceptable impact on arthropods other than bees after use of the plant protection product in accordance with the proposed conditions of use. Any claims for selectivity and proposals for use in integrated pest management systems shall be substantiated by appropriate data.

2.7.5. Where the micro-organism was not isolated from the soil and there is a possibility of meso- and macro-organisms in soil being exposed according to the consideration done under point 1.6, no authorisation shall be granted:

(a) if the micro-organism is pathogenic to meso- and macro-organisms in soil, unless it is clearly established through an appropriate risk assessment that under field conditions no unacceptable impact on soil meso- and macro-organism populations occurs after use of the plant protection product in accordance with the proposed conditions of use; or

(b) in the case of toxic effects of the plant protection product, if the acute toxicity/exposure ratio for meso- and macro-organisms in soil is less than 10 or the long-term toxicity/exposure ratio is less than 5, unless it is clearly established through an appropriate risk assessment that under field conditions no unacceptable impact on soil meso- and macro-organism populations occur after use of the plant protection product in accordance with the proposed conditions of use.

2.7.6. If the micro-organism has an herbicidal mode of action or it is closely related to a known plant pathogen, and there is a possibility of terrestrial plants being exposed to the micro-organism according to the consideration done under point 1.6, no authorisation shall be granted if the micro-organism is pathogenic to, or the plant protection product has toxic effects on, terrestrial plants. This criterion applies unless it is clearly established through an appropriate risk assessment that, under field conditions, no unacceptable impact on non-target terrestrial plant populations occurs after use of the plant protection product in accordance with the proposed conditions of use.'