

# **Evaluation Manual**

**for the Authorisation of Biopesticides  
according to Reg. (EC) No 1107/2009**

## **Part I: Micro-organisms**

**Version 3.0, August 2024**

## Document history

Version	Date	Amended paragraph(s)	General description of changes
<b>Pre-separation history of the Micro-organism section</b>			
Not considered relevant to keep a change log of the pre-separation version, because the document has been completely revised in the process.			
<b>Post-separation history of the Micro-organism section</b>			
2.0	December 2022	-	Initial version of the separated EM Biopesticides – Part I, dedicated to the assessment of micro-organisms, in accordance with Part B of Regulations (EU) No 283/2013 and (EU) No 284/2013 as amended.
2.1	April 2023	Update of references to Overview table in Appendix I. Occurrences: A.2.8, A.4.1	Addition of 'Appendix I to EM Biopesticides Part 1: Microorganisms – Roadmap for SANCO/2020/12258' (separate document).
2.2	September 2023	A.7.1.1.1, A.8, P.2.7, P.10	Update of references to new Communications from the Commission concerning Part B of the Annex to (EU) No 283/2013 and (EU) No 284/2013.
<b>History of the Micro-organism section, post-into force date of the Explanatory Notes for the implementation of the data requirements on micro-organisms (PAFF-PPL-October 2023-Doc.A.07.01, d.d. 12 October 2023)</b>			
3.0	August 2024	The following sections contain content that is not covered by the Explanatory Notes: A.1.4 Specification A.2.8 Metabolites of concern A.7.1 Environmental occurrence A.7.2 Fate of metabolites A.8. Ecotoxicological studies A.8.8 Information on metabolites P.3 Data on application P.9 Fate and behaviour P.10. Effects on non-target organisms P.10.2 Effects on aquatic organisms P.10.4 Effects on NTAs other than bees P.10.5 Effects on non-target meso -and macrofauna in soil P.10.6 Effects on non-target terrestrial plants	Full revision toward a document that only covers (i) Dutch national elements in the assessment of micro-organisms, and (ii) re-interpretations of the Framework due to progressive insight. Main changes: <ul style="list-style-type: none"> <li>- Removal of all sections that are covered by the Explanatory Notes;</li> <li>- Correction of errata that involuntarily ended up in the Explanatory Notes;</li> <li>- Preservation and update of content relating to Dutch national elements.</li> </ul>

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## Purpose of this document

As a principle, the Explanatory Notes (PAFF-PPL-October 2023-Doc.A.07.01, d.d. 12 October 2023) represent the main body of EU-agreed, interpretative text on the data requirements related to micro-organisms, as laid down in the recently amended Regulations (EU) No 283/2013 and (EU) No 284/2013. They should be used as primary resource when preparing the data package for a registration or authorization dossier for a micro-organism, or when drafting a DAR or RR.

However, this does not imply that Ctgb's Evaluation Manual for the Authorisation of Biopesticides, Part I: Micro-organisms, i.e., the document that is at the root of the Explanatory Notes, has been made redundant.

First, the Evaluation Manual still serves to provide information on a small number of remaining elements in the assessment of micro-organisms for which a Dutch-specific approach is still in place. Secondly, the Evaluation Manual was always intended as a flexible repository of new insights that should contribute to making assessments of micro-organisms ever more efficient and purposeful. Both roles cannot be fulfilled by the Explanatory Notes.

As a consequence of the shift in its position from standalone document to supplement (to the Explanatory Notes), Ctgb needed to substantially revise the Evaluation Manual. Its structure and appearance is the same as that of the Notes, except that it is for the largest part left blank; where the main text in the Notes already provides all that is now considered relevant regarding a given Annex point, the Evaluation Manual generically states that '*Currently, there are no relevant amendments to the Explanatory Notes regarding this point*'. These placeholders are an implicit testament to our belief that the vision of how an MO-assessment should ultimately be performed is never truly complete, be it in a scientific, regulatory, or economical sense.

Where substantial amendments are available, a description under the corresponding Annex point is provided. Readers are advised to use the Version history (starting at version 3.0) to conveniently keep track of all amendments.

As a mandatory disclaimer, it must be explicitly stated that the amendments contained in this Evaluation Manual purely reflect Ctgb's viewpoints.

## **Glossary of abbreviations and acronyms**

DRT75	Drift Reducing Technique that achieves a drift reduction of 75 %
GAP	Good Agricultural Practice (colloquially refers to GAP-table)
GEP	Good Experimental Practice
NTO	Non-Target Organism
PED	Predicted Environmental Density
PED <sub>SOIL</sub>	Predicted Environmental Density in soil
PED <sub>SW</sub>	Predicted Environmental Density in surface water
PPP	Plant Protection Product
WG	Wettelijk Gebruiksvoorschrift

## **Definitions used in this document**

Below, definitions are included other than those provided in the Regulations.

**'Claimed active metabolite'** means a secondary metabolite present in the MPCA-AM that is claimed to be part of the plant protection action and whose quantitative presence in the final product is considered indispensable to the effect (see A.1.4.1 of the Explanatory Notes for further explanation). Claimed active metabolites are included in the specification.

**'Specification element'** means a component, either an active (component), additive, contaminating micro-organism, relevant impurity, or MoC, that has been included in the specification.

## A.1 IDENTITY OF THE APPLICANT, IDENTITY OF THE ACTIVE SUBSTANCE AND MANUFACTURING INFORMATION

### A.1.1 Applicant

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

### A.1.2 Producer

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

### A.1.3 Identity, taxonomy and phylogeny of the micro-organism

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

### A.1.4 Specification of the microbial pest control agent as manufactured

#### Amending framework available

In the Explanatory Notes, the grey box on 'Claimed active metabolites' erroneously suggests that a secondary metabolite may be a claimed active metabolite while also being considered a metabolite of concern.

This is not possible from a regulatory perspective; a given component can never be more than one type of specification element at the same time, so as to avoid illogical situations in which a component would end up in two potentially conflicting assessment routes (in this case: the 'active substance-route' and the 'metabolite of concern-route').

### A.1.5 Information on manufacturing process and control measures for the active substance

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

## A.2 BIOLOGICAL PROPERTIES OF THE MICRO-ORGANISM

### A.2.1 Origin, occurrence and history of use

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

### A.2.2 Ecology and life cycle of the micro-organism

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

### A.2.3 Mode of action on the target organism and host range

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

### A.2.4 Growth requirements

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

### A.2.5 Infectivity to the target organism

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

### A.2.6 Relationship to known human pathogens and to pathogens to non-target organisms

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

### A.2.7 Genetic stability and factors affecting it

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

### A.2.8 Information on metabolites of concern

#### Amending framework available

Ctgb has prepared a [Roadmap for SANCO/2020/12258](#), as an Appendix 1 to this Evaluation Manual Biopesticides Part 1: Micro-organisms.

This Roadmap intends to help users of the main guidance by:

- adding a more complete and detailed decision scheme to SANCO/2020/12258;
- providing a set of instructions for the use of the Overview table that can be found in Annex III of SANCO/2020/12258.

Furthermore, the Roadmap may serve as an adaptable platform to record hands-on experience gained in the assessment of secondary metabolites and as a tool that potentially facilitates harmonization of this particular part of registration dossiers.

### A.2.9 Presence of transferable antimicrobial resistance genes

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

### **A.3 FURTHER INFORMATION**

#### **A.3.1 Function and target organism**

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

#### **A.3.2 Field of use envisaged**

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

#### **A.3.3 Crops or products protected or treated**

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

#### **A.3.4 Information on possible development of resistance in the target organism(s)**

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

#### **A.3.5 Literature data**

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

#### **A.4 ANALYTICAL METHODS**

##### **A.4.1 Methods for the analysis of the MPCA as manufactured**

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

##### **A.4.2 Methods to determine the density of the micro-organism and quantify residues**

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

**A.5 EFFECTS ON HUMAN HEALTH****A.5.1 Medical data**

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

**A.5.2 Assessment on potential infectivity and pathogenicity of the micro-organism to humans**

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

**A.5.3 Infectivity and pathogenicity studies on the micro-organism**

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

**A.5.4 Specific infectivity and pathogenicity studies on the micro-organism**

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

**A.5.5 Information and toxicity studies on metabolites**

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

## **A.6 RESIDUES IN OR ON TREATED PRODUCTS, FOOD AND FEED**

### **A.6.1 Estimation of consumer exposure to residues**

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

### **A.6.2 Data generation on residues**

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

## A.7 ENVIRONMENTAL OCCURRENCE OF THE MICRO-ORGANISM, INCLUDING FATE AND BEHAVIOUR OF METABOLITES OF CONCERN

### A.7.1 Environmental occurrence of the micro-organism

#### Amending framework available

#### A.7.1.1 Predicted environmental density

The methodology on how to calculate the  $PED_{SOIL}$  or  $PED_{SW}$  is similar to the explanatory notes. It should be noted that for the Netherlands no specific guidelines or methodology for environmental exposure prediction are in place, but as some aspects of the assessment are not fully harmonized across the member states, several issues may arise that could influence the critical worst-case risk envelope that is selected for PEDs. As an example, the explanatory notes mention that the worst-case scenario applications per annum should be considered, but it is not further explained where the applicant should get the underlying information on crop cycles to determine this. Currently, the Netherlands has its own sheet with farming practices concerning crop cycles found [here](#) on the Ctgb website.

Another example for unharmonized working practices is the density of seeds sown, or seedlings transplanted where an indoor application on soil might be carried over to the outdoors, releasing plant protection product in the process. The specifics for the seed density and transplanting density can be found [in a summary table](#) published on the Ctgb website.

The Ctgb is aware of the discrepancy between the evaluation manual for chemical substances (Part A of (EU) No 283/2013 and (EU) No 284/2013) and the biopesticide evaluation manual for micro-organisms regarding drift mitigation of DRT75, which is mandatory in the Netherlands for outdoor crops, but is not incorporated for the micro-organism assessment. Currently, the only accepted value for drift are the ones found in the Rautmann tables<sup>1</sup> that are mentioned in the explanatory notes. These values do not account for a possible drift reduction that is obtained by using the drift reducing techniques that are mandatory in practice via the national policies for the Netherlands. Until (more) information (e.g. experimental data) becomes available on the applicability of the Dutch-specific drift values on in-practice drift values for products containing micro-organisms, the Rautmann tables are used. This also extends to PPPs where a relevant metabolite is present in the product next to a micro-organism. The issues for the possibility for mitigation measures for surface water exposure have been discussed recently in the EFSA Pesticides Peer review meeting 28<sup>2</sup>. The Rautmann tables do have drift values based on a distance from the edge-of-field (crop free zone) which can be used zonally, but these have a practical upper limit for the Netherlands (e.g., the maximum allowable crop free zone for downward sprayed arable crops is 4 meters, as wider zones will not be applied in Dutch agriculture).

### A.7.2 Fate and behaviour of metabolite(s) of concern

#### Amending framework available

#### A.7.2.1 Predicted environmental concentration

<sup>1</sup> Rautmann D, Strelake M, Winkler R. (2001), New basic drift values in the authorisation procedure for plant protection products, In: Forster R, Strelake M. Workshop on Risk Assessment and Risk Mitigation Measures in the Context of the Authorisation of Plant Protection Products (WORMM), Mitt. Biol. Bundesamt. Land-Forstwirtschaft. Berlin-Dahlem, Heft 381 pp.

<sup>2</sup> See [minutes](#) of the EFSA Pesticides Peer Review (PREV) Meeting 28, held from 23-25 October 2023, Agenda cluster 4.

Please consult the points that are explained under the PED under A 7.1.1, as these are similarly applicable to the situation for metabolites of concern that are present in the product.

## **A.8 ECOTOXICOLOGICAL STUDIES**

Apart from the Explanatory Notes, also refer to the agreements made at the EFSA Pesticides Peer Review meeting 28, held from 23-25 October 2023. Currently, [the minutes](#) from this meeting have been made available and a meeting report containing more details is anticipated.

Please note the remarks in section A.7 Environmental occurrence of the microorganism, including fate and behavior of metabolites of concern, have impact on possible mitigation measures in the risk assessment of the proposed use(s). This is addressed under the section P.10, if relevant.

### **A.8.1 Effects on terrestrial vertebrates**

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

### **A.8.2 Effects on aquatic organisms**

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

### **A.8.3 Effects on bees**

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

### **A.8.4 Effects on non-target arthropods other than bees**

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

### **A.8.5 Effects on non-target meso- and macro-organisms in soil**

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

### **A.8.6 Effects on non-target terrestrial plants**

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

### **A.8.7 Additional studies on the micro-organism**

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

### **A.8.8 Information and toxicity studies on metabolites**

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#### **Amending framework available**

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Please refer to the Explanatory Notes and account for the information provided under point 7.1.1 and 7.2.1 regarding the limited possibilities for the use of drift reduction techniques in the current national risk assessment.

## **Assessment principles – Product**

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

#### **P.1.1 Applicant**

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

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

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

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

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

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

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

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

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

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

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

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

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

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

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

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

### **P.2.2 Explosivity and oxidising properties**

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

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

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

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

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

### **P.2.5 Viscosity and surface tension**

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

### **P.2.6 Storage stability and shelf life**

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

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

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

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

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

### **P.2.9 Adherence and distribution to seeds**

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

## P.3 DATA ON APPLICATION

### Amending framework available

The information provided in this section is essential for the risk assessment as they indicate both qualitative and quantitative information on the proposed uses (in accordance with Good Agricultural Practice). In addition to the information in the Explanatory Notes regarding the point in this section, reference is made to the efficacy chapter of the Evaluation Manual for conventional plant protection products (to be found here: [Evaluation Manuals | Plant Protection Products | Board for the Authorisation of Plant Protection Products and Biocides \(ctgb.nl\)](#)). In the Evaluation Manual, the information on Dutch agricultural practice and terminology for the legal conditions for use can be found, which are equally applicable for plant protection products based on micro-organisms. This includes information regarding definitions of terminology, crop definitions, crop cycles, seed sowing rates and planting density, Dutch water spray volumes, dipping fluid absorbed by flower bulbs or flower tubers during a dipping treatment, extrapolation tables, legal conditions for use in the Netherlands (i.e., the WG), and information on GEP certification, including links to relevant appendices. The information on Dutch agricultural practice and relevant appendices are essential for drafting the NL-GAP table and WG. For drafting the WG, also the following information is of relevance: [Opstellen wettelijk gebruiksvoorschrift | Instructie gewasbeschermingsmiddelen | College voor de toelating van gewasbeschermingsmiddelen en biociden \(ctgb.nl\)](#), as this document provides guidance on how to draft the WG. As the WG should be drafted in Dutch, this document is (unfortunately) also only available in Dutch.

For more information on application for minor uses (article 51) including an overview of which crops are considered minor uses in the Netherlands is referred to [Minor uses | Plant Protection Products | Board for the Authorisation of Plant Protection Products and Biocides \(ctgb.nl\)](#).

As the Dutch agricultural practices may also have an impact for mutual recognition, the consideration for mutual recognition regarding the aspect efficacy that have been drafted for conventional PPPs are likewise applicable for PPPs based on micro-organisms. Therefore, for this information is also referred to the efficacy chapter of the Evaluation Manual for conventional plant protection products, accessible via the link provided above.

#### P.3.1 Field of use envisaged

Currently, there are no relevant amendments to the Explanatory Notes regarding this point, other than stated in the general introduction of this section.

#### P.3.2 Mode of action on the target organism

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

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

Currently, there are no relevant amendments to the Explanatory Notes regarding this point, other than stated in the general introduction of this section.

#### P.3.4 Application rate

Currently, there are no relevant amendments to the Explanatory Notes regarding this point, other than stated in the general introduction of this section.

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

Currently, there are no relevant amendments to the Explanatory Notes regarding this point, other than stated in the general introduction of this section.

**P.3.6 Method of application**

Currently, there are no relevant amendments to the Explanatory Notes regarding this point, other than stated in the general introduction of this section.

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

Currently, there are no relevant amendments to the Explanatory Notes regarding this point, other than stated in the general introduction of this section.

**P.3.8 Proposed instructions for use**

Currently, there are no relevant amendments to the Explanatory Notes regarding this point, other than stated in the general introduction of this section.

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

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

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

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

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

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

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

##### **P.4.3 Measures in case of accident**

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

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

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

## **P.5 ANALYTICAL METHODS**

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

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

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

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

**P.6 EFFICACY DATA****P.6.1 Preliminary tests**

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

**P.6.2 Minimum effective dose**

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

**P.6.3 Testing effectiveness**

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

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

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

**P.6.5 Adverse effects on treated crops**

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

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

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

**P.6.7 Compatibility in plant protection programmes**

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

**P.7 EFFECT ON HUMAN HEALTH****P.7.1 Medical data**

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

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

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

**P.7.3 Acute toxicity**

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

**P.7.4 Additional toxicity information**

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

**P.7.5 Data on exposure**

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

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

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

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

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

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

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

**P.9 FATE AND BEHAVIOUR IN THE ENVIRONMENT****Amending framework available**

Please consult the points that are explained under the PED under A 7.1.1, as these are similarly applicable to the situation for metabolites of concern that are present in the product.

## **P.10 EFFECT ON NON-TARGET ORGANISMS**

Apart from the Explanatory Notes, also refer to the agreements made at the EFSA Pesticides Peer Review meeting 28, held from 23-25 October 2023. Currently, [the minutes](#) from this meeting have been made available and a meeting report containing more details is anticipated.

### **P.10.1 Effects on terrestrial vertebrates**

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

### **P.10.2 Effects on aquatic organisms**

#### **Amending framework available**

Please refer to the Explanatory Notes and account for the information provided under point 7.1.1 and 7.2.1 regarding the limited possibilities for the use of drift reduction techniques in the current national risk assessment.

### **P.10.3 Effects on bees**

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.

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

#### **Amending framework available**

Please refer to the Explanatory Notes and account for the information provided under point 7.1.1 and 7.2.1 regarding the limited possibilities for the use of drift reduction techniques in the current national risk assessment.

### **P.10.5 Effects on non-target meso- and macro-organisms in soil**

#### **Amending framework available**

Please refer to the Explanatory Notes and account for the information provided under point 7.1.1 and 7.2.1 regarding the limited possibilities for the use of drift reduction techniques in the current national risk assessment.

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

#### **Amending framework available**

Please refer to the Explanatory Notes and account for the information provided under point 7.1.1 and 7.2.1 regarding the limited possibilities for the use of drift reduction techniques in the current national risk assessment.

### **P.10.7 Additional toxicity studies**

Currently, there are no relevant amendments to the Explanatory Notes regarding this point.