

EUROPEAN COMMISSION

> Brussels, XXX SANTE/XXXX/20XX [...](2021) XXX draft

COMMUNICATION FROM THE COMMISSION

Draft Communication from the Commission in the framework of the implementation of Part B of the Annex of the 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 This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

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Draft Communication from the Commission in the framework of the implementation of Part B of the Annex of the Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market

(Text with EEA relevance)

The present Commission Communication fulfils Point 6 of the Introduction of the Annex to Regulation (EU) 283/2013 that provides that, for purposes of information and of harmonisation, the list of test methods and guidance documents relevant to the implementation of this Regulation shall be published in the *Official Journal of the European Union*. The table below represents this list for Part B of the Annex to Regulation (EU) 283/2013 as amended by Regulation **YYYY¹**, and will be updated regularly.

Where provisions of Part B of the Annex to the Commission Regulation (EU) No 283/2013 require generation of data based on requirements laid down in Part A of the Annex to the Commission Regulation (EU) No 283/2013, the test methods and guidance documents will not be double-listed in this document, they are indicated in the Communication from the Commission in the framework of the implementation of Part A of the Annex of the Commission Regulation (EU) No 283/2013 (i.e. regarding chemical active substances). The latest version of this Communication shall apply.

Guidance documents and test guidelines (e.g. OECD) are referred by their number and not by their year or revision number.

Test guidelines

Only test methods that have been properly validated (e.g. ring tested by OECD or equivalent international organisations) are listed. Scientific publications are out of scope.

The required regulatory tests should be carried out in accordance with the most updated test guidelines at the time of the initiation of the study.

For active substances that are micro-organisms, ad-hoc test protocols may be needed to address some data requirements. During the pre-submission phase², applicants, Rapporteur Member States,

¹ [reference of the amending Regulation]

² Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No

and the Europan Food Safety Authority (EFSA) may discuss this kind of ad-hoc test protocols, in particular if test protocols listed in the Commission Communication regarding the Commission Regulation setting out the data requirements for chemical active substances can be used as surrogates or whether they can be adaptated to be more suitable for micro-organisms.

Article 62 of Regulation (EC) No 1107/2009 provides that testing on vertebrate animals for the purposes of the approval of active substances for plant protection shall be undertaken only where no other methods are available. Other methods cover *in vitro* testing, *in silico* methods or other approaches such read-across.

Tests carried already out based on older test guidelines should be considered as part of the risk assessment. However, during the pre-submission phase, applicants, EFSA and/or the Rapporteur Member State can consider whether new studies carried out according to newer test guidelines should additionally be required, if scientifically justified and in view of minimising animal testing. In all cases, in accordance with Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes, Regulation (EC) No 1107/2009 (Recitals 11 and 40, Articles 8.1(d), 18(b), 33.3(c) and 62.1) and Regulation (EU) No 283/2013, unnecessary animal testing should be avoided. Furthermore, availability of validated and reliable in–vitro study protocols should be considered as a valid scientific justification when considering point 1.5 of the Introduction of the Annex of Regulation (EU) No 283/2013.

If several test guidelines are available, the order of test guidelines listed indicates a preference in case of new test needed. The order will prioritise methods where no or fewer test animals are needed and/or this method is associated with less severe suffering of the test animals. However, during the pre-submission meeting, upon advice by EFSA and the Rapporteur Member State the order of priority can be changed when justified in order to ensure the scientific quality of the assessment.

Guidance documents

Guidance documents that qualify to be listed are stand-alone documents that have been developed under the auspices of an official body (e.g. EFSA, the European Commission, in some cases national authorities) with the aim to address a certain area of risk assessment, or procedural issues, which were consulted with relevant stakeholders, and endorsed by the Standing Committee on Plants, Animals, Food and Feed before or through the listing in the Communications. In case of guidance documents endorsed by an intergovernmental organisation such as OECD, FAO, WHO, EPPO where the EU takes part in the endorsement process, there is no need for stakeholder consultation and further consultation with Member States.

Criteria for the selection of documents to be listed as guidances:

- Technical guidance documents, including guidance documents that are of horizontal nature that are relevant for several or all sections of the data requirements, including

^{178/2002, (}EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC

implementation of point 1.5 of the Introduction of the Annex of Regulation (EU) No 283/2013

- Administrative/procedural guidance documents if they are relevant for the implementation of the data requirements
- Models or calculation tools, if they are relevant for the data requirements and can be linked to or are supportive to a guidance document
- Scientific Opinions of the EFSA Panels and guidance documents from the interzonal Steering Committee relevant for all the Member States might be considered on a case by case basis, if they are relevant for the implementation of specific data requirements.

Documents such as zonal guidance documents, statements, peer reviewed publications, technical reports, scientific reports, strategies are generally considered out of scope. However, by way of derogation and if a public consultation has been carried out, such documents may also be taken into account in the risk assessment and included in this list.

The most recent endorsed revision of a guidance document available at the time of the application should always be used.

As regards the EPPO standards series concerning the efficacy evaluation of plant protection products, the most relevant standards are indicated in this table. However, the list should be considered not exhaustive since the database is updated regularly and other standards may be needed on a case-by-case approach. Consequently, the EPPO global database is also cited in the list.

Reference to Part B of the Annex to Regulation (EU) No 283/2013	Test methods ³	Guidance documents ⁴
General test methods and guidance documents		EFSA (2011). Guidance on submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (EFSA Journal 2011;9(2):2092)
General test methods and guidance documents		EFSA (2017). Guidance on the use of the weight of evidence approach in scientific assessments (EFSA Journal 2017;15(8):4971)
General test methods and guidance documents		EFSA (2019). Administrative guidance on submission of dossiers and assessment reports for the peer- review of pesticide active substances (EFSA Journal 2019; :EN-1612. 49 pp)
1. Identity of the applicant, identity of the active substance and manufacturing information		WHO/FAO (2018). Amendment to the "Manual on development and use of FAO and WHO specifications for pesticides", Section 9 "Specification guidelines for microbial pesticides"
1.3 Identity, taxonomy and phylogeny of the micro-organism		EFSA (2021) statement on the requirements for whole genome sequence analysis of microorganisms intentionally used in the food chain (EFSA-Q-2019-00434)
1.4.1. Content of the active substance		EU guidance document on the assessment of new isolates of baculovirus species already included in Annex I of Council Directive 91/414/EEC (SANCO/0253/2008)

- OECD http://www.oecd.org/env/chemicalsafetyandbiosafety/testingofchemicals/
- EPPO http://www.eppo.int/STANDARDS/standards.htm
- US EPA OCSPP http://www.epa.gov/ocspp/pubs/frs/home/testmeth.htm

- European Commission: <u>http://ec.europa.eu/food/plant/pesticides/guidance_documents/mrls_en.htm</u>
- OECD http://www.oecd.org/env/chemicalsafetyandbiosafety/testingofchemicals/
- EPPO: <u>http://www.eppo.int/STANDARDS/standards.htm</u>
- ECHA: http://echa.europa.eu/support/guidance-on-reach-and-clp-implementation
- EFSA: <u>http://www.efsa.europa.eu/en/publications.htm</u>

³ Most of the test methods cited are only available in English. Detailed information about the test methods:

⁻ ISO <u>http://www.iso.org/iso/home/store/catalogue_ics.htm</u>

⁴ Most of the guidance documents cited are available only in English. Detailed information about the guidance documents:

1.4.2.1. Identity and quantification of additives	EU guidance document: Technical Active Substance and Plant protection products: Guidance for generating and reporting methods of analysis in support of pre- and post-registration data requirements for Annex (Section 4) of Regulation (EU) No 283/2013 and Annex (Section 5) of Regulation (EU) No 284/2013 (SANCO/3030/99)
1.4.2.2. Identity and content of relevant contaminating micro- organisms	OECD (2014) Issue Paper on Microbial Contaminants Limits for Microbial Pest Control Products No. 65
1.4.2.2. Identity and content of relevant contaminating micro- organisms	ISO 16140-3:2021 Microbiology of the food chain — Method validation — Part 3: Protocol for the verification of reference methods and validated alternative methods in a single laboratory
1.4.2.3. Identity and quantification of relevant impurities	EU guidance document on the risk assessment of metabolites produced by micro-organisms used as plant protection active substances (SANCO/2020/12258)
1.4.2.3. Identity and quantification of relevant impurities	EU guidance document: Technical Active Substance and Plant protection products: Guidance for generating and reporting methods of analysis in support of pre- and post-registration data requirements for Annex (Section 4) of Regulation (EU) No 283/2013 and Annex (Section 5) of Regulation (EU) No 284/2013 (SANCO/3030/99)
1.4.3. Analytical profile of batches	EU Guidance document on the assessment of new isolates of baculovirus species already included in Annex I of Council Directive 91/414/EEC (SANCO/0253/2008)
1.4.3. Analytical profile of batches	OECD (2014) Issue Paper on Microbial Contaminants Limits for Microbial Pest Control Products No. 65 ISO 16140-3:2021 Microbiology of the food chain — Method validation — Part 3: Protocol for the verification of reference methods and validated alternative methods in a single laboratory
1.5 Information on manufacturing process and control measure for the active substance	EU guidance document on the assessment of new isolates of baculovirus species already included in Annex I of Council Directive 91/414/EEC (SANCO/0253/2008)
2.7. Genetic stability and factors affecting it	EFSA (2021) statement on the requirements for whole genome sequence analysis of microorganisms intentionally used in the food chain (EFSA-Q-2019-00434)
2.8 Information on metabolites of concern	EU guidance document on the risk assessment of metabolites produced by microorganisms used as plant protection active substances (SANCO/2020/12258)

2.8 Information on metabolites of concern	EFSA (2021) statement on the requirements for whole genome sequence analysis of microorganisms intentionally used in the food chain (EFSA-Q-2019-00434)
2.8 Information on metabolites of concern	OECD (2018) working document on the risk assessment of secondary metabolites of microbial biocontrol agents No. 98 (ENV/JM/MONO(2018)33)
2.9. Presence of transferrable antimicrobial resistance genes	EU guidance document on the approval and low-risk criteria linked to "antimicrobial resistance" applicable to microorganisms used for plant protection in accordance with Regulation (EC) No 1107/2009 (SANTE/2020/12260)
2.9. Presence of transferrable antimicrobial resistance genes	EFSA (2021) statement on the requirements for whole genome sequence analysis of microorganisms intentionally used in the food chain (EFSA-Q-2019-00434)
3.1 Function and target organism	EPPO PP1/248 Harmonized classification and coding of the uses of plant protection products
3.3. Crops or products protected or treated	EPPO global database ⁵
3.3. Crops or products protected or treated	EPPO PP1/248 Harmonized classification and coding of the uses of plant protection product
3.4. Information on possible development of resistance of the target organism(s)	EPPO PP1/213: Resistance risk analysis
3.5 Literature data	EFSA (2011) guidance on submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (EFSA Journal 2011;9(2):2092 - including appendix ⁶)

⁵ https://gd.eppo.int/ ⁶ https://efsa.onlinelibrary.wiley.com/action/downloadSupplement?doi=10.2903/j.efsa.2011.2092&file=efs22092-sup-0001-Appendix.pdf

4.1. Methods for the analysis of the MPCA as manufactured		EU guidance document: Technical Active Substance and Plant protection products: Guidance for generating and reporting methods of analysis in support of pre- and post-registration data requirements for Annex (Section 4) of Regulation (EU) No 283/2013 and Annex (Section 5) of Regulation (EU) No 284/2013 (SANCO/3030/99)
4.1. Methods for the analysis of the MPCA as manufactured		OECD (2014) Issue Paper on Microbial Contaminants Limits for Microbial Pest Control Products No. 65
4.1. Methods for the analysis of the MPCA as manufactured		ISO 16140-3:2021 Microbiology of the food chain — Method validation — Part 3: Protocol for the verification of reference methods and validated alternative methods in a single laboratory
4.2. Methods to determine density of the micro-organism and quantify residues		Residues Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes (SANTE/2020/12830) ⁷
5.1.3. Information on sensitisation and allergenicity	US EPA OPPTS 885.3400 hypersensitivity Incidents	
5.3.1.1. Oral infectivity and pathogenicity	US EPA OPPTS 885.3050 Acute Oral Toxicity/ Pathogenicity	
5.3.1.2. Intratracheal/ intranasal infectivity and pathogenicity	US EPA OPPTS 885.3150 Acute pulmonary toxicity/ pathogenicity	
5.3.1.3. Intravenous, intraperitoneal or subcutaneous single exposure	US EPA OPPTS 885.3200 Microbial pesticide test guidelines. Acute injection toxicity/pathogenicity	
5.3.2. Cell culture study	US EPA OPPTS 885.3500 Cell culture	

⁷ if relevant for residues of metabolites of concern.

5.4. Specific infectivity and pathogenicity studies on the micro- organism	US EPA OPPTS 885.3600 Subchronic Toxicity/Pathogenicity	
and pathogenicity studies on the micro- organism	US EPA OPPTS 885.3650 Reproductive/fertility effects	
5.5 Information and toxicity studies on metabolites		EU guidance document on the risk assessment of metabolites produced by microorganisms used as plant protection active substances (SANCO/2020/12258)
5.5 Information and toxicity studies on metabolites		European Commission (2001) draft guidance document Guidance for the setting of an acute reference dose (ARfD) (7199/VI/99)
5.5 Information and toxicity studies on metabolites		ECHA (2017) guidance on the application of the CLP criteria. Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures
5.5 Information and toxicity studies on metabolites		EFSA (2019) guidance on the use of the Threshold of Toxicological Concern approach in food safety assessment (EFSA Journal 2019;17(6):5708)
5.5 Information and toxicity studies on metabolites		OECD (2010) Series on Testing and Assessment No. 124, Guidance for the Derivation of an Acute Reference Dose. (ENV/JM/MONO(2010)15)
 Residues in or on treated products, food and feed 		EU guidance document on the risk assessment of metabolites produced by microorganisms used as plant protection active substances (SANCO/2020/12258)
6.1. Estimation of consumer exposure to residues		EFSA (2019) guidance on the use of the Threshold of Toxicological Concern approach in food safety assessment (EFSA Journal 2019;17(6):5708)

7. Environmental occurrence of the micro-organism, including fate and behaviour of metabolites of concern	EU working document to the Environmental Safety Evaluation of Microbial Biocontrol Agents (SANCO/12117/2012)
of the micro-organism	protection products and transformation products of these active substances from protected crops (greenhouses and crops grown under cover) to relevant environmental compartments (EFSA Journal 2014;12(3):3615)
7.1.1.1. Soil	EFSA (2017) guidance document for predicting environmental concentrations of active substances of plant protection products and transformation products of these active substances in soil (EFSA Journal 2017;15(10):4982)
7.2. Fate and behaviour of metabolite(s) of concern	EU guidance document on the risk assessment of metabolites produced by microorganisms used as plant protection active substances (SANCO/2020/12258)
7.2. Fate and behaviour of metabolite(s) of concern	EFSA (2014) guidance document on clustering and ranking of emissions of active substances of plant protection products and transformation products of these active substances from protected crops (greenhouses and crops grown under cover) to relevant environmental compartments (EFSA Journal 2014;12(3):3615)
7.2.1. Predicted environmental concentration	Generic Guidance for Estimating Persistence and Degradation Kinetics from Environmental Fate Studies in Pesticides in EU Registration (based on –among others- Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration - Final Report of the Work Group on Degradation Kinetics of FOCUS (Sanco/10058/2005); Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil (SANCO/12117/2014))

7.2.1. Predicted	Generic guidance for Tier 1 FOCUS Ground water assessments (based on –among others-the European
environmental	Commission (2014) Assessing Potential for Movement of Active Substances and their Metabolites to
concentration	Ground Water in the EU - Final Report of the Ground Water Work Group of FOCUS (Sanco/13144/2010);
	FOCUS (2000) "FOCUS groundwater scenarios in the EU review of active substances" Report of the
	FOCUS Groundwater Scenarios Workgroup (Sanco/321/2000); Scientific Opinion of the Panel on Plant
	Protection Products and their Residues on a request from EFSA related to the default Q10 value used to
	describe the temperature effect on transformation rates of pesticides in soil.(doi:
	10.2903/j.efsa.2008.622); Generic Guidance for Estimating Persistence and Degradation Kinetics from
	Environmental Fate Studies in Pesticides in EU Registration (including Guidance Document on Estimating
	Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration -
	Final Report of the Work Group on Degradation Kinetics of FOCUS (Sanco/10058/2005); Guidance
	Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active
	substances of plant protection products and transformation products of these active substances in soil
	(SANCO/12117/2014)); section 3.3.1 of European Food Safety Authority. Guidance Document for
	predicting environmental concentrations of active substances of plant protection products and
	transformation products of these active substances in soil (doi:10.2903/j.efsa.2017.4982); section 3.3 of
	Scientific report of EFSA on the 'repair action' of the FOCUS surface water scenarios
	(doi:10.2903/j.efsa.2020.6119))
8. Ecotoxicological	EU working document to the Environmental Safety Evaluation of Microbial Biocontrol Agents
studies	(SANCO/12117/2012)
8. Ecotoxicological	
studies	US EPA 885,4000 (1996) Background for non-target organism testing of microbial pest control agents
8. Ecotoxicological	
studies	Environment and Climate Change Canada (2016), guidance document for testing the pathogenicity and
	toxicity of new microbial substances to aquatic and terrestrial organisms (EPS1/RM/44)
8.1. Effects on Environment and Climate C	hange
terrestrial vertebrates Canada (2016) Guidance docume	ent for
testing the pathogenicity and to	exicity Environment and Climate Change Canada (2016) Guidance document for testing the pathogenicity and
of new microbial substance	to toxicity of new microbial substances to aquatic and terrestrial organisms (EPS1/RM/44). 14.1 Birds
aquatic and terrestrial orga	nisms

8.1. Effects on	Environment and Climate Change	Environment and Climate Change Canada (2016) Guidance document for testing the pathogenicity and
terrestrial vertebrates	Canada (2016) Guidance document	toxicity of new microbial substances to aquatic and terrestrial organisms (EPS 1/RM/44), 14.2 Small
	for testing the pathogenicity and	Mammals
	toxicity of new microbial substances	
	to aquatic and terrestrial organisms	
	(EPS 1/RM/44), 14.2 Small Mammals	
8.2. Effects on aquatic		Environment and Climate Change Canada (2016) Guidance document for testing the pathogenicity and
organisms		toxicity of new microbial substances to aquatic and terrestrial organisms (EPS 1/RM/44), 11.1 Freshwater
		Fish
8.2.1. Effects on fish	OECD Test No. 203 (2019) Fish, Acute	
	Toxicity Test	
	Note: test duration shall be extended	
	to the maximum possible as indicated	
	by the test method	
8.2.1. Effects on fish		
	OECD Test No. 210 (2013) Fish, Early-	
	life Stage Toxicity Test	
8.2.1. Effects on fish		
	US EPA OCSPP 885.4200 freshwater	
	fish Tier I	
8 2 1 Effects on fish	Environment and Climate Change	
0.2.1. LITECIS OIT IISIT	Canada (2016) Guidance document for	
	testing the nathogenicity and toxicity	
	of new microhial substances to	
	aquatic and terrestrial organisms (FPS	
	1/RM/44), 11.1 Freshwater Fish	
8.2.2. Effects on aquatic	OECD Test No. 233 (2010) Sediment-	
invertebrates	Water Chironomid Life-Cycle Toxicity	
	Test Using Spiked Water or Spiked	
	Sediment	
8.2.2. Effects on aquatic	US FPA OCSPP 885 4240 Freshwater	
invertebrates	invertebrate Tier I	

8.2.2. Effects on aquatic	Environment and Climate Change	Environment and Climate Change Canada (2016) Guidance document for testing the pathogenicity and
invertebrates	Canada (2016) Guidance document for testing the pathogenicity and toxicity	toxicity of new microbial substances to aquatic and terrestrial organisms (EPS 1/RM/44), 10.1 Freshwater Invertebrates
	of new microbial substances to	
	aquatic and terrestrial organisms (EPS	
	1/RM/44), 10.1 Freshwater	
8.2.3. Effects on algae	OECD Test No. 201 (2011) Eresbwater	
	Alga and Cyanobacteria, Growth	
	Inhibition Test	
8.2.3. Effects on algae	LIS EPA OCSPP 885 4200 Non target	
	plant studies Tier I	
	·	Environment and Climate Change Canada (2010) Childrens desument for testing the nother priots and
8.2.3. Effects on algae	Canada (2016) Guidance document for	Environment and climate change canada (2016) Guidance document for testing the pathogenicity and toxicity of new microbial substances to aquatic and terrestrial organisms (EPS 1/RM/44), 9.1 Freshwater
	testing the pathogenicity and toxicity	plants
	of new microbial substances to	
	aquatic and terrestrial organisms (EPS	
8.2.4. Effects on aquatic		
macrophytes	OECD Test No. 221 (2006): Lemna sp.	
	Growth Inhibition Test	
8.2.4. Effects on aquatic	OECD Test No. 239 (2014): Water-	
macrophytes	Sediment Myriophyllum Spicatum	
9.2.4 Effects on equation	loxicity lest	
macrophytes	OECD Test No. 238 (2014): Sediment-	
	Test	
8.3. Effects on bees	OECD Test Guideline 213 Honeybees,	
	Acute Oral Toxicity Test	
	Note: test duration shall be extended	
	by the test method	

8.3. Effects on bees	OECD Test Guideline 214 Honeybees, Acute Contact Toxicity Test. Note: test duration shall be extended to the maximum possible as indicated by the test method	
8.3. Effects on bees	OECD Test Guideline 245 Honey Bee, Chronic Oral Toxicity Test	
8.3. Effects on bees	OECD guidance document 239 Honey Bee Larval Toxicity Test, Repeated Exposure	
8.3. Effects on bees	OECD guidance document 75: Honey Bee Brood Test Under Semi-Field Conditions	
8.3. Effects on bees	EPPO Bulletin (2019) 49 Oomen Bee Brood Feeding Test	
8.3. Effects on bees	EPPO Bulletin (2010) 40 Side-Effects On Honeybees	
8.3. Effects on bees	OECD Test No. 247 (2017) Bumblebee, Acute Oral Toxicity Test	
8.3. Effects on bees	Environment and Climate Change Canada (2016) Guidance document for testing the pathogenicity and toxicity of new microbial substances to aquatic and terrestrial organisms (EPS 1/RM/44), 13.2.1 Honey bees	Environment and Climate Change Canada (2016) Guidance document for testing the pathogenicity and toxicity of new microbial substances to aquatic and terrestrial organisms (EPS 1/RM/44), 13.2.1 Honey bees
8.3. Effects on bees	US EPA OCSPP 885.4380 Honey bee Tier I	

8.4. Effects on non- target arthropods other than bees	US EPA OCSPP 885.4340 Non-target Insect Tier I	
8.4. Effects on non- target arthropods other than bees	Environment and Climate Change Canada (2016) Guidance document for testing the pathogenicity and toxicity of new microbial substances to aquatic and terrestrial organisms (EPS 1/RM/44), 13.3.1 Tests for Plant- Dwelling Invertebrates	Environment and Climate Change Canada (2016) Guidance document for testing the pathogenicity and toxicity of new microbial substances to aquatic and terrestrial organisms (EPS 1/RM/44), 13.3.1 Tests for Plant-Dwelling Invertebrates
8.5. Effects on non- target meso- and macroorganisms in soil	OECD Test No. 222 (2016): Earthworm Reproduction Test (Eisenia fetida/Eisenia andrei)	
8.5. Effects on non- target meso- and macroorganisms in soil	OECD Test No. 232 (2016): Collembolan Reproduction Test in Soil	
8.5. Effects on non- target meso- and macroorganisms in soil	OECD Test No. 226 (2016): Predatory mite (Hypoaspis (Geolaelaps) aculeifer) reproduction test in soil	
8.5. Effects on non- target meso- and macroorganisms in soil	Environment and Climate Change Canada (2016) Guidance document for testing the pathogenicity and toxicity of new microbial substances to aquatic and terrestrial organisms (EPS 1/RM/44), 13.2.2 Springtails	Environment and Climate Change Canada (2016) Guidance document for testing the pathogenicity and toxicity of new microbial substances to aquatic and terrestrial organisms (EPS 1/RM/44), 13.2.2 Springtails
8.5. Effects on non- target meso- and macroorganisms in soil	Environment and Climate Change Canada (2016) Guidance document for testing the pathogenicity and toxicity of new microbial substances to aquatic and terrestrial organisms (EPS 1/RM/44), 13.3.2 Earthworms	Environment and Climate Change Canada (2016) Guidance document for testing the pathogenicity and toxicity of new microbial substances to aquatic and terrestrial organisms (EPS 1/RM/44), 13.3.2 Earthworms

8.6. Effects on non- target terrestrial plants	OECD Test No. 227 (2006): Terrestrial Plant Test: Vegetative Vigour Test	
8.6. Effects on non- target terrestrial plants	OECD Test No. 208 (2006): Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test	
8.6. Effects on non- target terrestrial plants	Environment and Climate Change Canada (2016) Guidance document for testing the pathogenicity and toxicity of new microbial substances to aquatic and terrestrial organisms (EPS 1/RM/44), 12.2 Terrestrial plants	Environment and Climate Change Canada (2016) Guidance document for testing the pathogenicity and toxicity of new microbial substances to aquatic and terrestrial organisms (EPS 1/RM/44), 12.2 Terrestrial plants
8.8. Information and toxicity studies on metabolites		EU guidance document on the risk assessment of metabolites produced by microorganisms used as plant protection active substances (SANCO/2020/12258)