Communication from the Commission concerning Part B of the Annex to Commission Regulation (EU) No 283/2013 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)

(2023/C 202/03)

This guidance has been developed in consultation with the Member States. It does not intend to produce any legally-binding effects and, by its nature, cannot prejudice any measure taken by a Member State in the implementation of Regulation (EC) No 1107/2009, nor any case law developed with regard to this provision. Only the Court of Justice is empowered to authoritatively interpret and apply Union law.

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 must be published in the *Official Journal of the European Union*. The list below represents this list for Part B of the Annex to Regulation (EU) 283/2013, as amended by Commission Regulation (EU) 2022/1439 ([1]), and will be updated regularly.

Where provisions of Part B of the Annex to Regulation (EU) No 283/2013 require generation of data based on requirements laid down in Part A of the Annex to Regulation (EU) No 283/2013, the relevant test methods and guidance are listed in the Commission Communication relevant to the implementation of Part A of the Annex to Regulation (EU) No 283/2013 (i.e. regarding chemical active substances).

Listing of a document for a section means that it is relevant for all the sub-sections. In case there is no document listed for a section, no agreed test method or guidance document is currently available. In these cases, potential applicants should discuss proposals during the pre-submission meeting with the Rapporteur Member State and the European Food Safety Authority (EFSA), e.g. based on draft test methods.

Test methods

Only test methods that have been validated (i.e. ring-tested by the OECD or equivalent international organisations) are listed. Test methods only described in scientific publications have not been included.

The listing of a test method should be read as referring to the most updated version of that test method available 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 phase ([2]), applicants, the Rapporteur Member State, and EFSA may discuss this kind of ad-hoc test protocols, in particular if test protocols listed in the Commission Communication relevant to the implementation of Part A of the Annex to Regulation (EU) No 283/2013 can be used as surrogates or whether they can be adapted to be more suitable for active substances that are micro-organisms.

In view of minimising testing on vertebrate animals, tests already carried out based on older test methods should be considered as part of the risk assessment, as provided for in Article 62 of Regulation (EC) No 1107/2009. However, during the pre-submission meeting, applicants, the Rapporteur Member State and EFSA may consider whether new test according to newer test methods are needed, if scientifically justified.

([1]) Commission Regulation (EU) 2022/1439 of 31 August 2022 amending Regulation (EU) No 283/2013 as regards the information to be submitted for active substances and the specific data requirements for micro-organisms (OJ L 227, 1.9.2022, p. 8).

([2]) Article 32a of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

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 ([3]), Regulation (EC) No 1107/2009 (Recitals 11 and 40, Articles 8.1(d), 18(b), 33.3(c) and 62.1) and Commission Regulation (EU) No 283/2013 ([4]), unnecessary animal testing must be avoided. More specifically, 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 products shall be undertaken only where no other methods are available. Alternative methods include *in-vitro* testing, *in-silico* methods or other approaches such as read-across, as described for instance in the EURL ECVAM Status Report on the Development, Validation and Regulatory Acceptance of Alternative Methods and Approaches and the EURL ECVAM Status Report on Non-animal Methods in Science and Regulation ([5]). Furthermore, availability of guidance documents on non-animal testing and 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 to Regulation (EU) No 283/2013.

If several test methods are available to fulfil a data requirement, the order of test methods listed indicates a preference in case a new test is needed. The order prioritises 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 scientifically justified (e.g. due to limitations of the applicability domain of some methods) in order to ensure the scientific quality of the assessment.

Guidance documents

Guidance documents qualify to be listed when they:

— have been endorsed by the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF) before the publication of this Communication,

— have been developed under the auspices of an official body (e.g. EFSA, the Commission, national authorities) with the aim to address a certain area of risk assessment or procedural issues, and were consulted with relevant stakeholders, or

— have been endorsed by an intergovernmental organisation (such as OECD, FAO, WHO, or EPPO) where the Member States take part in the endorsement process.

The following types of guidance documents have been considered for listing:

— Technical guidance documents, including guidance documents that are of horizontal nature that are relevant for several or all sections of the data requirements, including implementation of point 1.5 of the Introduction of the Annex to 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 have been listed following a consideration on a case by case basis, if they are relevant for the implementation of specific data requirements.

Documents such as zonal guidance documents, EFSA statements, peer reviewed publications, technical reports, scientific reports, strategies are generally not included in the list below, except for some which were subject to a public consultation.

The listing of a guidance document should be read as referring to the most updated version of that guidance document available at the time of the initiation of the study.

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

([3]) OJ L 276, 20.10.2010, p. 33.
([4]) OJ L 93, 3.4.2013, p. 1.
([5]) Available at https://publications.jrc.ec.europa.eu/repository/

Reference to Part B of the Annex to Regulation (EU) No 283/2013	Test methods ([1])	Guidance documents ([2])
General test methods and guidance documents		EFSA 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 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		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)
General test methods and guidance documents		EFSA Statement on the requirements for whole genome sequence analysis of microorganisms intentionally used in the food chain (EFSA Journal 2021;19(7):6506)
General test methods and guidance documents		OECD Guidance Document on Good In Vitro Method Practices (GIVIMP)
General test methods and guidance documents		OECD Guidance Document for the Regulatory Framework for the Microorganism Group: Bacteriophages Series on Pesticides No. 108
1. Identity of the applicant, identity of the active substance and manufacturing information		EU Guidance Document for the assessment of the equivalence of technical grade active ingredients for identical microbial strains or isolates approved under Regulation (EC) No 1107/2009 (SANCO/12823/2012)
1.4.2.2. Identity and content of relevant contaminating micro-organisms		OECD Issue Paper on Microbial Contaminants Limits for Microbial Pest Control Products No. 65
2.7. Genetic stability and factors affecting it		EFSA Statement on the requirements for whole genome sequence analysis of microorganisms intentionally used in the food chain (EFSA Journal 2021;19(7):6506)
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 Statement on the requirements for whole genome sequence analysis of microorganisms intentionally used in the food chain (EFSA Journal 2021;19(7):6506)
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)
3.1 Function and target organism		EPPO PP1/248 Harmonized classification and coding of the uses of plant protection products ([3])

3.3. Crops or products protected or treated		EPPO Global database ([4])
3.3. Crops or products protected or treated		EPPO PP1/248 Harmonized classification and coding of the uses of plant protection product ([5])
3.4. Information on possible development of resistance in the target organism(s)		EPPO PP1/213: Resistance risk analysis
3.5 Literature data		EFSA 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]))
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 Issue Paper on Microbial Contaminants Limits for Microbial Pest Control Products No. 65
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	

5.4. Specific infectivity and pathogenicity studies on the micro-organism	US EPA OPPTS 885.3600 Subchronic Toxicity/ Pathogenicity	
5.4. Specific infectivity and pathogenicity studies on the micro-organism	US EPA OPPTS 885.3650 Reproductive/fertility effects	
5.5 Information and toxicity studies on metabolites		European Commission 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 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 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 Series on Testing and Assessment No. 124, Guidance for the Derivation of an Acute Reference Dose. (ENV/JM/MONO(2010)15)
6.1. Estimation of consumer exposure to residues		EFSA Guidance on the use of the Threshold of Toxicological Concern approach in food safety assessment (EFSA Journal 2019;17(6):5708)
7.1.1. Predicted environmental density of the micro-organism		EFSA 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, Section 2 (EFSA Journal 2014;12(3):3615)
7.1.1.1. Soil		EU Working document to the Environmental Safety Evaluation of Microbial Biocontrol Agents, section 3.1.2 (SANCO/12117/2012)
7.1.1.1. Soil		EFSA Guidance document for predicting environmental concentrations of active substances of plant protection products and transformation products of these active substances in soil, section 2.7 'Applicability of the tiered assessment scheme for microbial actives substances' (EFSA Journal 2017;15(10):4982)
7.1.1.2. Water		EU Working document to the Environmental Safety Evaluation of Microbial Biocontrol Agents, section 3.2.1 (SANCO/12117/2012)
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 environmental concentration		Generic guidance for Tier 1 FOCUS Ground water assessments (based on –among others-the European Commission (2014) Assessing Potential for Movement of Active Substances and their Metabolites to 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 studies	The relevant methods indicated under this Section may need to be adapted on a case-by-case basis. Hence the applicability of the methods selected, or adaptations of them, must be justified in light of the biological and ecological characteristcs of the active substance to be assessed and it may be discussed in pre-submission meetings.	
8. Ecotoxicological studies		EU Working document to the Environmental Safety Evaluation of Microbial Biocontrol Agents (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 terrestrial vertebrates	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), 14.1 Birds	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), 14.1 Birds

8.1. Effects on terrestrial vertebrates	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), 14.2 Small Mammals	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), 14.2 Small Mammals
8.2. Effects on aquatic organisms		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), 11.1 Freshwater Fish
8.2.1. Effects on fish	OECD Test No. 203 (2019) Fish, Acute Toxicity Test	
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 Canada (2016) Guidance document for testing the pathogenicity and toxicity of new microbial substances to aquatic and terrestrial organisms (EPS 1/RM/44), 11.1 Freshwater Fish	
8.2.2. Effects on aquatic invertebrates	OECD Test No. 233 (2010) Sediment-Water Chironomid Life-Cycle Toxicity Test Using Spiked Water or Spiked Sediment	
8.2.2. Effects on aquatic invertebrates	US EPA OCSPP 885.4240 Freshwater invertebrate Tier I	

8.2.2. Effects on aquatic 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), 10.1 Freshwater 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), 10.1 Freshwater Invertebrates
8.2.3. Effects on algae	OECD Test No. 201 (2011) Freshwater Alga and Cyanobacteria, Growth Inhibition Test	
8.2.3. Effects on algae	US EPA OCSPP 885.4300 Non target plant studies Tier I	
8.2.3. Effects on algae	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 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), 9.1 Freshwater plants
8.2.4. Effects on aquatic macrophytes	OECD Test No. 221 (2006): Lemna sp. Growth Inhibition Test	
8.2.4. Effects on aquatic macrophytes	OECD Test No. 239 (2014): Water-Sediment Myriophyllum Spicatum Toxicity Test	
8.2.4. Effects on aquatic macrophytes	OECD Test No. 238 (2014): Sediment-Free Myriophyllum Spicatum Toxicity Test	
8.3. Effects on bees	OECD Test Guideline 213 Honeybees, Acute Oral Toxicity Test	

8.3. Effects on bees	OECD Test Guideline 214 Honeybees, Acute Contact Toxicity Test.	
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

([1]) Most of the test methods cited are only available in English. Detailed information about the test methods:
- ISO http://www.iso.org/iso/home/store/catalogue_ics.htm
- OECD http://www.oecd.org/env/chemicalsafetyandbiosafety/testingofchemicals/
- EPPO http://www.eppo.int/STANDARDS/standards.htm
- US EPA OCSPP https://www.epa.gov/

([2]) Most of the guidance documents cited are available only in English. Detailed information about the guidance documents:
- European Commission: https://food.ec.europa.eu/plants/pesticides/approval-active-substances/guidelines-active-substances-and-plant-protection-products_en
- OECD http://www.oecd.org/env/chemicalsafetyandbiosafety/testingofchemicals/
- EPPO: http://www.eppo.int/STANDARDS/standards.htm
- ECHA: http://echa.europa.eu/support/guidance-on-reach-and-clp-implementation
- EFSA: http://www.efsa.europa.eu/en/publications.htm

([3]) Please consider only those uses which are deemed relevant under the scope of Reg (EC) No 1107/2009, and not those in EPPO PP 1/248 which refer to biostimulant claims as defined both under the scope of Reg (EU) No 2019/1009 and under the technical specifications CEN/TS 17724, CEN/TS 17700-1, CEN/TS 17700-2, CEN/TS 17700-3, CEN/TS 17700-4, CEN/TS 17700-5, even if these biostimulants are identified as plant growth regulators in EPPO PP 1/248.

([4]) https://gd.eppo.int/

([5]) Please consider only those uses which are demeed relevant under the scope of Reg (EC) No 1107/2009, and not those in EPPO PP 1/248 which refer to biostimulant claims as defined under the scope of Reg (EU) No 2019/1009 and the technical specifications CEN/TS 17724, CEN/TS 17700-1, CEN/TS 17700-2, CEN/TS 17700-3, CEN/TS 17700-4, CEN/TS 17700-5, even if they are identified as plant growth regulators in EPPO PP1/248.

([6]) https://efsa.onlinelibrary.wiley.com/action/downloadSupplement?doi=10.2903/j.efsa.2011.2092&file=efs22092-sup-0001-Appendix.pdf

([7]) if relevant for residues of metabolites of concern.