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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 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

Draft Communication from the Commission in the framework of the implementation of Part B of the Annex of the 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

(Text with EEA relevance)

The present Commission Communication fulfils Point 6 of the Introduction of the Annex to Regulation (EU) 284/2013 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) 284/2013 as amended by Regulation **YYYY**[1], and will be updated regularly.

Where provisions of Part B of the Annex to the Commission Regulation (EU) No 284/2013 require generation of data based on requirements laid down in Part A of the Annex to the Commission Regulation (EU) No 284/2013, 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 284/2013 (i.e. regarding plant protection products containing chemical active substances). The latest version of this Communication shall apply.

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

Test guidelines

If the Commission Regulation (EC) No 440/2008[2] provides for cross reference to an OECD test guidelines (by indicating that a test method is replicate, analogous to or equivalent to, an OECD test method) only the OECD method is listed to avoid duplication.

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.

For plant protection products containing an active substance that is a micro-organisms, during the pre-submission phase, applicants, EFSA and/or the Rapporteur Member State can agree on employing methods indicated in the Commission Communication regarding the Commission Regulation setting out the data requirements for plant

[1] [reference of the amending Regulation]

[2] Commission Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

protection products containing chemical active substances, or adaptation of these protocols in order to make the assessment suitable for micro-organisms.

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 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.

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.

Tests already carried 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 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 SCoPAFF 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 implementation of 1.5 point 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 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 General EPPO standard series PP1 is also cited in the list.

Reference to Part B of the Annex to Regulation (EU) No 284/2013	Test methods[3]	Guidance documents[4]
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)
1. Identity of the applicant, identity of the plant protection product 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 Detailed quantitative and qualitative information on the composition of the preparation		EU guidance document on the risk assessment of metabolites produced by microorganisms used as plant protection active substances (SANCO/2020/12258)
1.4 Detailed quantitative and qualitative information on the composition of the preparation		OECD (2014) Issue Paper on Microbial Contaminants Limits for Microbial Pest Control Products No. 65
1.4 Detailed quantitative and qualitative information on the composition of the preparation		WHO/FAO (2018). Amendment of the "Manual on development and use of FAO and WHO specifications for pesticides", Section 9 "Specification guidelines for microbial pesticides"

[3] With exception of methods described in Regulation (EC) No 440/2008 (OJ L 142, 31.5.2008, p. 1), most of the test methods cited are only available in English (some also in French). Detailed information about the test methods:

— CIPAC http://www.cipac.org/
— ASTM http://www.astm.org/Standard/index.shtml
— 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

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

— European Commission:
— 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
— FOCUS: https://esdac.jrc.ec.europa.eu/projects/focus-dg-sante

1.4 Detailed quantitative and qualitative information on the composition of the preparation		EU guidance document on significant and non-significant changes of the chemical composition of authorised plant protection products under Regulation (EC) No 1107/2009 of the EU Parliament and Council on placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (SANCO/12638/2011)
1.5 Physical state and nature of the preparation		WHO/FAO (2018). Amendment of the "Manual on development and use of FAO and WHO specifications for pesticides", Section 9 "Specification guidelines for microbial pesticides"
2. Physical, chemical and technical properties of the plant protection product		WHO/FAO. (2018). Amendment of the "Manual on development and use of FAO and WHO specifications for pesticides", Section 9 "Specification guidelines for microbial pesticides"
2.6 Storage stability and shelf-life		OECD (2014) Issue Paper on Microbial Contaminants Limits for Microbial Pest Control Products No. 65.
2.6 Storage stability and shelf-life		OECD (2016). Guidance document on storage stability of microbial pest control products. Series on Pesticides No. 85 (ENV/JM/MONO(2016)54)
2.6.2 Effects of temperature and packaging	CIPAC MT 39 Stability of liquid formulations at 0˚C	
2.6.2 Effects of temperature and packaging	CIPAC MT 46.3 Accelerated storage procedure	
2.7.1 Wettability	CIPAC MT 53.3 Evaluation of wettability, wetting of dispersible powders	
2.7.2 Persistent foaming	CIPAC MT 47.2 Determination of the foaming of suspension concentrates	
2.7.2 Persistent foaming	CIPAC MT 47.3 Persistent foaming	
2.7.3 Suspensibility, spontaneity of dispersion and dispersion stability	CIPAC MT 15 Suspensibility of wettable powders in water	

2.7.3 Suspensibility, spontaneity of dispersion and dispersion stability	CIPAC MT 161 Suspensibility of aqueous suspension concentrates	
2.7.3 Suspensibility, spontaneity of dispersion and dispersion stability	CIPAC MT 184 Suspensibility of formulations forming suspensions on dilution with water	
2.7.3 Suspensibility, spontaneity of dispersion and dispersion stability	CIPAC MT 160 Spontaneity of dispersion of suspension concentrates	
2.7.3 Suspensibility, spontaneity of dispersion and dispersion stability	CIPAC MT 174 Dispersibility of water dispersible granules	
2.7.3 Suspensibility, spontaneity of dispersion and dispersion stability	CIPAC MT 180 Suspo-emulsions, dispersion stability.	
2.7.4 Dry sieve test and wet sieve test	CIPAC MT 59.1 Dry sieving – dust	
2.7.4 Dry sieve test and wet sieve test	CIPAC MT 59.3 Wet sieving	
2.7.4 Dry sieve test and wet sieve test	CIPAC MT 167 Wet sieving after dispersion of water dispersible granules	
2.7.5 Particle size distribution (dustable and wettable powders, granules), content of dust/fines (granules), attrition and friability (granules)	OECD test n. 110 Particle Size Distribution/ Fibre Length and Diameter Distributions	
2.7.5 Particle size distribution	CIPAC MT 170 Dry sieve analysis of water dispersible granules	

(dustable and wettable powders, granules), content of dust/fines (granules), attrition and friability (granules)		
2.7.5 Particle size distribution (dustable and wettable powders, granules), content of dust/fines (granules), attrition and friability (granules)	CIPAC MT 171 Dustiness of granular products	
2.7.5 Particle size distribution (dustable and wettable powders, granules), content of dust/fines (granules), attrition and friability (granules)	CIPAC MT 185 Wet sieve test	
2.7.5 Particle size distribution (dustable and wettable powders, granules), content of dust/fines (granules), attrition and friability (granules)	CIPAC MT 187 Particle size analysis by laser diffraction	
2.7.6 Emulsifiability, re-emulsifiability and emulsion stability	CIPAC MT 36 Emulsion characteristics of emulsifiable concentrates	
2.7.6 Emulsifiability, re-emulsifiability and emulsion stability	CIPAC MT 36.3 Emulsion characteristics and re-emulsification properties	
2.7.6 Emulsifiability, re-emulsifiability and emulsion stability	CIPAC MT 173 Colorimetric method for determination of the stability of dilute emulsions	
2.7.7 Flowability, pourability (rinsability) and dustability	CIPAC MT 148 Pourability of suspension concentrates	

2.7.7 Flowability, pourability (rinsability) and dustability	CIPAC MT 171.1 Dustiness of granular formulation – revised method	
2.7.7 Flowability, pourability (rinsability) and dustability	CIPAC MT 172 Flowability of water dispersible granules after heat test under pressure	
2.7.7 Flowability, pourability (rinsability) and dustability	CIPAC Method MT 172.1 Flowability of granular preparations after accelerated storage under pressure	
2.7.7 Flowability, pourability (rinsability) and dustability	CIPAC MT 172.2 Flowability of granular formulations after accelerated storage under pressure	
2.8 Physical, chemical and biological compatibility with other products including plant protection products with which its use is to be authorised	ASTM E1518 – 05 Standard Practice for Evaluation of Physical Compatibility of Pesticides in Aqueous Tank Mixtures by the Dynamic Shaker Method	
2.9 Adherence and distribution to seeds	CIPAC MT 194 Adhesion to Treated Seed	
2.9 Adherence and distribution to seeds	CIPAC MT 175 Seed treatment formulations, liquid, determination of seed-seed uniformity of distribution	
3. Data on application		EPPO Global Database[5]
3.3. Function, target organisms, plants or plants products to be protected and possible risk mitigation measures		EPPO PP 1/248 Harmonized classification and coding of the uses of plant protection products
3.4. Application rate		EPPO PP1/239: Dose expression of plant protection products

[5] https://gd.eppo.int.

4.1. Procedures for cleaning and decontaminating of application equipment		EPPO PP1/292 (Cleaning pesticide application equipment (PAE) – efficacy aspects)
5.1. Methods for the analysis of the preparation		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)
5.1. Methods for the analysis of the preparation		OECD (2014) Issue Paper on Microbial Contaminants Limits for Microbial Pest Control Products No. 65
5.1. Methods for the analysis of the preparation		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
5.2. Methods to determine and quantify residues		Residues Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes (SANTE/2020/12830)
6. Efficacy data	Specific standards of the EPPO standard series PP1[9]	
6. Efficacy data		EU guidance document on data requirements on efficacy for the dossier to be submitted for the approval of new active substances contained in plant protection products. (SANCO/10054/2013)
		EU Guidance document on the efficacy composition of core dossier and national addenda submitted to support the authorization of plant protection products under regulation (EC) No 1107/2009 of the EU parliament and council on placing of plant protection products on the market. (SANCO/10055/2013)
6. Efficacy data		General EPPO standard series PP1[6] (Efficacy evaluation of plant protection products)
6. Efficacy data		EPPO PP1/319 General principles for efficacy evaluation of plant protection products with a mode of action as plant defence inducers

[6] EPPO standards are available at http://pp1.eppo.org/ - EPPO standards of series PP1 describe how to evaluate the efficacy of plant protection products. The series contain general standards and specific standards. Specific standards should be used together with relevant general standards and vice versa.

6.2. Minimum effective dose		EPPO PP1/152 Design and analysis of efficacy evaluation trials
6.2. Minimum effective dose		EPPO PP1/181 Conduct and reporting of efficacy evaluation trials including good experimental practice
6.2. Minimum effective dose		EPPO PP1/214 Principles of acceptable efficacy
6.2. Minimum effective dose		EPPO PP1/225 Minimum effective dose
6.2. Minimum effective dose		EPPO PP1/276 Principles of efficacy evaluation for microbial plant protection products
6.2. Minimum effective dose		EPPO PP1/296 principles of efficacy evaluation for low-risk plant protection products
6.3. Testing effectiveness		EPPO PP1/152 Design and analysis of efficacy evaluation trials
6.3. Testing effectiveness		EPPO PP1/181 Conduct and reporting of efficacy evaluation trials including good experimental practice
6.3. Testing effectiveness		EPPO PP1/214 Principles of acceptable efficacy
6.3. Testing effectiveness		EPPO PP1/223 Introduction to the efficacy evaluation of plant protection products
6.3. Testing effectiveness		EPPO PP1/226 Number of efficacy trials
6.3. Testing effectiveness		EPPO PP1/239 Dose expression for plant protection products
6.3. Testing effectiveness		EPPO PP1/241 Guidance on comparable climates
6.3. Testing effectiveness		EPPO PP1/257 Efficacy and crop safety extrapolations for minor uses
6.3. Testing effectiveness		EPPO PP1/269 Comparable climates on global level
6.3. Testing effectiveness		EPPO PP1/271 Guidance on comparative assessment
6.3. Testing effectiveness		EPPO PP1/276 Principles of efficacy evaluation for microbial plant protection products

6.3. Testing effectiveness		EPPO PP1/278 Principles of zonal data production and evaluation
6.3. Testing effectiveness		EPPO PP1/296 Principles of efficacy evaluation for low-risk plant protection products
6.4. Information on possible development of resistance in target organisms		EPPO PP1/213 Resistance risk analysis
6.5. Adverse effects on treated crops		EPPO PP1/135 Phytotoxicity assessment
6.5.3. Effects on the quality of plants or plant products		EPPO PP1/242 Taint tests
6.5.4. Effects on transformation processes		EPPO PP1/243 Effects of plant protection products on transformation processes
6.5.4. Effects on transformation processes		EPPO PP1/268 Study of unintentional effects of plant protection products on fermentation processes and characteristics of wine
6.6.1. Impact on succeeding crops	OECD Guidelines for the Testing of Chemicals No. 227 “Terrestrial Plant Test: Vegetative Vigour Test” (2006)	
6.6.1. Impact on succeeding crops	OECD Guidelines for Testing of Chemicals No. 208 “Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test” (2006)	
6.6.1. Impact on succeeding crops		EPPO PP1/207 Effects on succeeding crops
6.6.2. Impact on other plants, including adjacent crops		EPPO PP1/256 Effects on adjacent crops
7.2. Assessment of potential toxicity of the plant protection product		EFSA (2014) Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (EFSA Journal 2014;12(10):3874)

7.3.1 Acute oral toxicity	Method B1 bis Acute Toxicity (Oral) of Commission Regulation (EC) No. 440/2008	
7.3.1 Acute oral toxicity	Method B1 tris Acute Toxicity (Oral) of Commission Regulation (EC) No. 440/2008	
7.3.2. Acute dermal toxicity	Method B3 of Commission Regulation (EC) No. 440/2008	
7.3.3. Acute inhalation toxicity	Method B2 of Commission Regulation (EC) No. 440/2008	
7.3.4. Skin irritation	Method B4 of Commission Regulation (EC) No. 440/2008, method B.40, method B.40 bis, addition of in vitro tests acc. to OECD TG 430, 431, 435, 439	
7.3.5. Eye irritation	Method B5 of Commission Regulation (EC) No. 440/2008, addition of in vitro tests acc. to OECD TG 437, 438, 460, 491, 492	
7.3.5. Eye irritation	Method B.47 of Commission Regulation (EC) No. 440/2008	
7.3.5. Eye irritation	Method B.48 of Commission Regulation (EC) No. 440/2008	
7.3.6. Skin sensitisation	Method B6 of Commission Regulation (EC) No. 440/2008	
7.3.6. Skin sensitisation	Method B.42 of Commission Regulation (EC) No. 440/2008 (LLNA acc. to OECD 429)	
7.3.6. Skin sensitisation	Method B.50 of Commission Regulation (EC) No. 440/2008 (442A)	
7.3.6. Skin sensitisation	Method B.59 of Commission Regulation (EC) No. 440/2008 (442C)	
7.3.6. Skin sensitisation	Method B.60 of Commission Regulation (EC) No. 440/2008 (442D)	
7.3.6. Skin sensitisation	Method B.71 of Commission Regulation (EC) No. 440/2008 (442E)	
7.5. Data on exposure	Method B44 of Commission Regulation (EC) No. 440/2008	
7.5. Data on exposure	Method B45 of Commission Regulation (EC) No. 440/2008	

7.5. Data on exposure		EU (2018) Guidance on dermal adsorption (SANTE/2018/10591)
7.5. Data on exposure		EU guidance document on the risk assessment of metabolites produced by microorganisms used as plant protection active substances (SANCO/2020/12258)
7.5. Data on exposure		EFSA (2014) Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (EFSA Journal 2014;12(10):3874)
7.5. Data on exposure		EFSA (2017) Guidance on dermal absorption (EFSA Journal 2017;15(6):4873)
7.5. Data on exposure		FAO Operator exposure models and local risk assessment[7]
8. 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)
8. Residues in or on treated products, food and feed		EFSA guidance (2016) Guidance on the establishment of the residue definition for dietary risk assessment (EFSA Journal 2016;14(12):4549)
8. Residues in or on treated products, food and feed		EFSA guidance (2019) Reporting data on pesticide residues in food and feed according to Regulation (EC) No 396/2005 (2018 data collection) (EFSA Journal 2019;17(4):5655)
10. Effects on non-target organisms	Relevant methods discussed in pre-submission meetings, which may include methods indicated in the Commission Communication regarding the Commission Regulation setting out the data requirements for for plant protection products containing chemical active substances	
10. Effects on non-target organisms		EU guidance document on the risk assessment of metabolites produced by microorganisms used as plant protection active substances (SANCO/2020/12258)

[7] http://www.fao.org/pesticide-registration-toolkit/registration-tools/assessment-methods/method-detail/en/c/1187029/

10. Effects on non-target organisms		OECD (2012) guidance to the environmental safety evaluation of microbial biocontrol agents, Series on Pesticides No. 67 (ENV/JM/MONO(2012)1)