

Commission communication in the framework of the implementation of 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 ⁽¹⁾

(Text with EEA relevance)

(2013/C 95/02)

The present Commission Communication fulfils Point 6 of the Introduction of the Annex to Regulation (EU) No 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 and will be updated regularly.

Reference to Part A of the Annex to Regulation (EU) No 284/2013	Test methods ⁽¹⁾	Guidance documents ⁽²⁾
1. IDENTITY OF THE PLANT PROTECTION PRODUCT	—	WHO/FAO. 2010. Manual on development and use of FAO and WHO specifications for pesticides. Second revision of the first edition. Rome, 2010 ⁽³⁾ EU Guidance Document on the assessment of the equivalence of technical materials of substances regulated under Regulation (EC) No 1107/2009 ⁽⁴⁾ (SANCO/10597/2003 rev. 10.1)
2. PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF THE PLANT PROTECTION PRODUCT	—	WHO/FAO. 2010. Manual on development and use of FAO and WHO specifications for pesticides. Second revision of the first edition. Rome, 2010
2.1. Appearance	—	—
2.2. Explosive and oxidising properties	<u>Explosive properties:</u> Method A.14 Explosive properties (Annex of Regulation (EC) No 440/2008). United Nations Recommendations on the Transport of Dangerous Goods (UN RTDG) Manual of Tests and Criteria ST/SG/AC.10/11/Rev. 5 – Part I (Test series), section 11. <u>Oxidising properties:</u> Solids: Method A.17 Oxidising properties (solids) (Annex of Regulation (EC) No 440/2008) Liquids: Method A.21 Oxidising properties (liquids) (Annex of Regulation (EC) No 440/2008) Test O.1: Test for oxidizing solids (UN RTDG Manual of Tests and Criteria ST/SG/AC.10/11/Rev. 5 – Part III, section 34.4.1)	—

⁽¹⁾ OJ L 93, 3.4.2013, p. 85.

Reference to Part A of the Annex to Regulation (EU) No 284/2013	Test methods (1)	Guidance documents (2)
	Test O.2: Test for oxidizing liquids (UN RTDG Manual of Tests and Criteria ST/SG/AC.10/11/Rev. 5 – Part III, section 34.4.2)	
2.3. Flammability and self-heating	<p><u>Flammability:</u></p> <p>Method A.9 Flash-point (liquids) (Annex of Regulation (EC) No 440/2008)</p> <p>Methods A.10 Flammability (solids), A.11 Flammability (gases), A.12 Flammability (contact with water) (Annex of Regulation (EC) No 440/2008), as appropriate.</p> <p>Test N.1: Test method for readily combustible solids (UN RTDG Manual of Tests and Criteria ST/SG/AC.10/11/Rev. 5 – Part III, section 33.2.1.4)</p> <p><u>Self-heating:</u></p> <p>Methods A.15 Auto-ignition temperature (liquids and gases) and A.16 Relative self-ignition temperature for solids (Annex of Regulation (EC) No 440/2008)</p> <p>Test N.4: test method for self-heating substances (UN RTDG Manual of Tests and Criteria ST/SG/AC.10/11/Rev. 5 – Part III, section 33.3.1.6)</p>	—
2.4. Acidity/alkalinity and pH value	<p>CIPAC Method MT 75.3: Determination of pH values (revised method)</p> <p><u>Acidic or alkaline preparations:</u></p> <p>CIPAC Method MT 31: free acidity or alkalinity</p> <p>CIPAC Method MT 191: Acidity or alkalinity of formulations</p>	—
2.5. Viscosity and surface tension	<p><u>Newtonian liquids:</u></p> <p>OECD Test Guideline 114</p> <p><u>Non Newtonian liquids:</u></p> <p>CIPAC method MT 192: Viscosity of liquids by rotational viscosimetry or</p> <p>OECD Test Guideline 114</p> <p><u>Surface tension:</u></p> <p>Method A.5 Surface tension (Annex of Regulation (EC) No 440/2008)</p>	—

Reference to Part A of the Annex to Regulation (EU) No 284/2013	Test methods (1)	Guidance documents (2)
	<p>Method A.5 is written only for solutions in water however the principles contained in it can be used for other formulation types e.g. EC</p> <p>or</p> <p>OECD Test Guideline 115</p>	
2.6. Relative density and bulk density	<p><u>Relative density:</u></p> <p>Method A.3 Relative density (Annex of Regulation (EC) No 440/2008).</p> <p>or</p> <p>OECD Test Guideline 109</p> <p><u>Bulk density:</u></p> <p>CIPAC method MT 186: Bulk density</p>	—
2.7. Storage stability and shelf-life: effects of temperature on technical characteristics of the plant protection product	<p><u>Stability:</u></p> <p>CIPAC MT 46.3: Accelerated storage procedure (combined method)</p> <p><u>Effect of low temperature on liquid preparations:</u></p> <p>CIPAC Method MT 39.3: Low temperature stability of liquid formulations</p>	CropLife International, 2009. Technical Monograph N° 17. Guidelines for Specifying the Shelf Life of Plant Protection Products.
2.8. Technical characteristics of the plant protection product	—	—
2.8.1. Wettability	CIPAC Method MT 53.3: Evaluation of wettability, wetting of dispersible powders	—
2.8.2. Persistent foaming	CIPAC Method MT 47.2 Determination of the foaming of suspension concentrates	—
2.8.3. Suspensibility, spontaneity of dispersion and dispersion stability	<p><u>Suspensibility:</u></p> <p>CIPAC Method MT 184: Suspensibility of formulations forming suspensions on dilution with water</p> <p><u>Spontaneity of dispersion:</u></p> <p>CIPAC Method MT 160: Spontaneity of dispersion of suspension concentrates</p> <p>or</p>	—

Reference to Part A of the Annex to Regulation (EU) No 284/2013	Test methods (1)	Guidance documents (2)
	CIPAC Method MT 174: Dispersibility of water dispersible granules <u>Dispersion stability:</u> CIPAC Method MT 180: Suspo-emulsions, dispersion stability	
2.8.4. Degree of dissolution and dilution stability	CIPAC Method MT 41.1: Dilution stability of aqueous solutions or CIPAC Method MT 179: Water soluble granules, degree of dissolution and solution stability or CIPAC Method MT: Solution properties of ST formulations (3)	—
2.8.5. Particle size distribution, dust content, attrition and mechanical stability	—	—
2.8.5.1. Particle size distribution	<u>Water dispersible products:</u> CIPAC Method MT 185: Wet sieve test <u>Size distribution (powders):</u> CIPAC Method MT 187: Particle size analysis by laser diffraction <u>Nominal size range (granules):</u> CIPAC Method MT 170: Dry sieve analysis of water dispersible granules CIPAC Method MT 187: Particle size analysis by laser diffraction	—
2.8.5.2. Dust content	CIPAC Method MT 171: Dustiness of granular products	—
2.8.5.3. Attrition	<u>Applicable for granules or tablets:</u> CIPAC Method MT 178: Attrition resistance of granules CIPAC Method MT 178.2: Attrition resistance of dispersible granules	—
2.8.5.4. Hardness and integrity	CIPAC Method MT 193: Friability of tablets	—
2.8.6. Emulsifiability, re-emulsifiability, emulsion stability	CIPAC Method MT 36.3: Emulsion characteristics of emulsifiable concentrates, emulsion characteristics and re-emulsification properties	—

Reference to Part A of the Annex to Regulation (EU) No 284/2013	Test methods (1)	Guidance documents (2)
2.8.7. Flowability, pourability and dustability	<p><u>Flowability:</u></p> <p>CIPAC Method MT 172.1: Flowability of granular preparations after accelerated storage under pressure</p> <p><u>Pourability:</u></p> <p>CIPAC Method MT 148: Pourability of suspension concentrates</p> <p>CIPAC Method MT 148.1: Pourability of suspension concentrates, revised method</p>	—
2.9. Physical and chemical compatibility with other products including plant protection products with which its use is to be authorized	ASTM E1518 – 05: Standard Practice for Evaluation of Physical Compatibility of Pesticides in Aqueous Tank Mixtures by the Dynamic Shaker Method	
2.10. Adherence and distribution to seeds	<p><u>Distribution:</u></p> <p>CIPAC Method MT 175: Seed treatment formulations, liquid, determination of seed-seed uniformity of distribution</p> <p><u>Adhesion:</u></p> <p>CIPAC Method MT 194: Adhesion to Treated Seed</p> <p>or</p> <p>European Seed Association, 2011. Assessment of free floating dust and abrasion particles of treated seeds as a parameter of the quality of treated seeds: Heubach test. ESA STAT Dust Working Group. (6)</p>	—
2.11. Other studies	Test methods reported in Annex I, Part II to Regulation (EC) No 1272/2008 (7)	—
3. DATA ON APPLICATION	<p>EPPO Standard PP1/239: Dose expression of plant protection products</p> <p>EPPO Standard PP1/240: Harmonized basic information for databases on plant protection products</p>	—
4. FURTHER INFORMATION ON THE PLANT PROTECTION PRODUCT	—	<p>FAO. Guidelines for the packaging and storage of pesticides</p> <p><u>Resistance of the packaging material to its contents:</u></p> <p>CroLife International Technical Monograph No 17, 2nd Edition</p>

Reference to Part A of the Annex to Regulation (EU) No 284/2013	Test methods (1)	Guidance documents (2)
5. ANALYTICAL METHODS	—	<p><u>Technical material and preparations:</u></p> <p>EU guidance document on analytical methods for the analysis of technical material and preparation (SANCO/3030/99 rev. 4)</p> <p><u>Residues:</u></p> <p>EU guidance document on analytical methods for the determination of residues (Post-registration monitoring and control) (SANCO/825/00 rev. 8.1, 2010)</p> <p>EU guidance document for generating and reporting methods of analysis in support of pre-registration data requirements (SANCO/3029/99 rev. 4).</p> <p>OECD (2007). Guidance Document on Pesticide Residue Analytical Methods. Environment, Health and Safety Publications. Series on Testing and Assessment No. 72 and Series on Pesticides No. 39.</p>
6. EFFICACY DATA	EPPO standard series PP1 (8) (Efficacy evaluation of plant protection products)	EPPO standard series PP1 (8) (Efficacy evaluation of plant protection products)
6.1. Preliminary tests	—	—
6.2. Testing effectiveness	—	—
6.3. Information on the occurrence or possible occurrence of the development of resistance	—	—
6.4. Adverse effects on treated crops	—	—
6.4.1. Phytotoxicity to target plants (including different cultivars), or to target plant products	—	—
6.4.2. Effects on the yield of treated plants or plant products	—	—
6.4.3. Effects on the quality of plants or plant product	—	—
6.4.4. Effects on transformation processes	—	—
6.4.5. Impact on treated plants or plant products to be used for propagation	Seeds harvested from treated plants: ISTA Methods - International Rules for Seed Testing (9)	—

Reference to Part A of the Annex to Regulation (EU) No 284/2013	Test methods (1)	Guidance documents (2)
6.5. Observations on other undesirable or unintended side-effects	—	—
6.5.1. Impact on succeeding crops	—	—
6.5.2. Impact on other plants, including adjacent crops	—	—
6.5.3. Effects on beneficial and other non-target organisms	—	—
7. TOXICOLOGICAL STUDIES	—	—
7.1. Acute toxicity	—	—
7.1.1. Oral toxicity	<p>Method B.1 bis Acute oral toxicity - fixed dose procedure (Annex of Regulation (EC) No 440/2008).</p> <p>Method B.1 tris Acute oral toxicity - Acute toxic class method (Annex of Regulation (EC) No 440/2008).</p> <p>OECD Test Guideline 420: Acute oral toxicity: fixed dose procedure</p> <p>OECD Test Guideline 423: Acute oral toxicity: acute toxic class method</p> <p>OECD Test Guideline 425: Acute oral toxicity: up-and-down procedure</p> <p>OECD Test Guideline 401: Acute oral toxicity (only acceptable, if performed before December 2002)</p>	—
7.1.2. Dermal toxicity	<p>Method B.3 Acute toxicity (dermal) (Annex of Regulation (EC) No 440/2008)</p> <p>OECD Test Guideline 402: Acute Dermal Toxicity</p>	—
7.1.3. Inhalation toxicity	<p>Method B.2 Acute toxicity (inhalation) (Annex of Regulation (EC) No 440/2008).</p> <p>OECD Test Guideline 403: Acute Inhalation Toxicity</p> <p>OECD Test Guideline 436: Acute Inhalation Toxicity – Acute Toxic Class Method</p>	—
7.1.4. Skin irritation	<p>Method B.4 Acute toxicity: dermal irritation/corrosion (Annex of Regulation (EC) No 440/2008).</p> <p>Method B.40 <i>In vitro</i> skin corrosion: transcutaneous electrical resistance test (TER) (Annex of Regulation (EC) No 440/2008).</p>	—

Reference to Part A of the Annex to Regulation (EU) No 284/2013	Test methods (1)	Guidance documents (2)
	<p>Method B.40 bis <i>In vitro</i> skin corrosion: human skin model test (Annex of Regulation (EC) No 440/2008).</p> <p>OECD Test Guideline 404: Acute Dermal Irritation/Corrosion</p> <p>OECD Test Guideline 431: <i>In vitro</i> Skin Corrosion: Human Skin Model Test</p> <p>OECD Test Guideline 430: <i>In vitro</i> Skin Corrosion: Transcutaneous Electrical Resistance Test</p> <p>OECD Test Guideline 435: <i>In vitro</i> Membrane Barrier Test Method for Skin Corrosion</p> <p>Method B.46 <i>In vitro</i> skin irritation: reconstructed human epidermis model test (Annex of Regulation (EC) No 440/2008).</p> <p>OECD Test Guideline 439: <i>In vitro</i> Skin Irritation: Reconstructed Human Epidermis Test Method</p>	
7.1.5. Eye irritation	<p>Method B.5 Acute toxicity: eye irritation/corrosion (Annex of Regulation (EC) No 440/2008).</p> <p>OECD Test Guideline 405: Acute eye irritation/corrosion</p> <p>OECD Test Guideline 437: Bovine Corneal Opacity and Permeability Test Method for Identifying Ocular Corrosives and Severe Irritants</p> <p>OECD Test Guideline 438: Isolated Chicken Eye Test Method for Identifying Ocular Corrosives and Severe Irritants</p> <p>Method B.47 Bovine corneal opacity and permeability test method for identifying ocular corrosives and severe irritants (Annex of Regulation (EC) No 1152/2010 (10))</p> <p>Method B.48 Isolated chicken eye test method for identifying ocular corrosives and severe irritants (Annex of Regulation (EC) No 1152/2010)</p>	—
7.1.6. Skin sensitisation	<p>Method B.42 Skin sensitisation: Local lymph node assay (Annex of Regulation (EC) No 440/2008).</p> <p>Method B.6 Skin sensitisation (Annex of Regulation (EC) No 440/2008).</p>	—

Reference to Part A of the Annex to Regulation (EU) No 284/2013	Test methods (1)	Guidance documents (2)
	OECD Test Guideline 429: Skin Sensitisation – Local Lymph Node Assay OECD Test Guideline 406: Skin sensitisation OECD Test Guideline 442A: Skin Sensitisation – Local Lymph Node Assay: DA OECD Test Guideline 442B: Skin Sensitisation – Local Lymph Node Assay: BrdU-ELISA	
7.1.7. Supplementary studies on the plant protection product	—	—
7.1.8. Supplementary studies for combinations of plant protection products	—	—
7.2. Data on exposure	—	
7.2.1. Operator exposure	—	OECD Guidance Document for the Conduct of Studies of Occupational Exposure to Pesticides During Agricultural Application, Series on Testing and Assessment No. 9, ECDE/GD(97)148.
7.2.1.1. Estimation of operator exposure	—	—
7.2.1.2. Measurement of operator exposure	—	—
7.2.2. Bystander and resident exposure	—	—
7.2.2.1. Estimation of bystander and resident exposure	—	—
7.2.2.2. Measurement of bystander and resident exposure	—	—
7.2.3. Worker exposure	—	—
7.2.3.1. Estimation of worker exposure	—	—
7.2.3.2. Measurement of worker exposure	—	—
7.3. Dermal absorption	OECD Test Guideline 428: Skin absorption: <i>in vitro</i> method OECD Test Guideline 427: Skin absorption: <i>in vivo</i> method Method B.44 Skin absorption: <i>in vivo</i> method. (Annex of Regulation (EC) No 440/2008). Method B.45 Skin absorption: <i>in vitro</i> method. (Annex of Regulation (EC) No 440/2008).	OECD Guidance notes on dermal absorption, Series on Testing and Assessment No. 156, ENV/JM/MONO (2011)36. WHO, 2006. Environmental Health Criteria, 235. Dermal Absorption. (11) EFSA Scientific Opinion of PPR Panel - Guidance on Dermal Absorption EFSA Journal 2012; 10 (4):2665.

Reference to Part A of the Annex to Regulation (EU) No 284/2013	Test methods (1)	Guidance documents (2)
7.4. Available toxicological data relating to co-formulants	—	—
8. RESIDUES IN OR ON TREATED PRODUCTS, FOOD AND FEED	Test methods reported in Section 6 of the Annex to Regulation (EU) No 283/2013 (12) apply.	Guidance documents reported in Section 6 of the Annex to Regulation (EU) No 283/2013 apply.
9. FATE AND BEHAVIOUR IN THE ENVIRONMENT	—	—
9.1. Fate and behaviour in soil	OECD Test Guideline 307: Aerobic and anaerobic transformation in soil. ISO 10381-6:2009 Soil quality. Sampling. Guidance on the collection, handling and storage of soil under aerobic conditions for the assessment of microbiological processes, biomass and diversity in the laboratory	EFSA Panel on Plant Protection Products; Guidance for evaluating laboratory and field dissipation studies to obtain DegT ₅₀ values of plant protection products in soil. EFSA Journal 2010;8(12):1936.
9.1.1. Rate of degradation in soil	—	—
9.1.1.1. Laboratory studies	OECD Test Guideline 307: Aerobic and anaerobic transformation in soil.	FOCUS Ground Water FOCUS Degradation Kinetics
9.1.1.1.2. Field studies	—	<u>Technical aspects to determine degradation rates in soil in field studies can be found in:</u> EPA Fate, Transport and Transformation Test Guideline OCSPP 835.6100 Terrestrial Field Dissipation. Regulatory Directive DIR2006-01: Harmonization of Guidance for Terrestrial Field Studies of Pesticide Dissipation under the North American Free Trade Agreement. Pest Management Regulatory Agency (PMRA). Health Canada (13) FOCUS Ground Water FOCUS Degradation Kinetics
9.1.2. Mobility in the soil	—	—
9.1.2.1. Laboratory studies	OECD Test Guideline 106: Adsorption - Desorption Using a Batch Equilibrium Method OECD Test Guideline 121: Estimation of the Adsorption Coefficient (K _{oc}) on Soil and on Sewage Sludge using High Performance Liquid Chromatography (HPLC) OECD Test Guideline 312: Leaching in Soil Columns OECD Test Guideline 307: Aerobic and anaerobic transformation in soil.	FOCUS Ground Water

Reference to Part A of the Annex to Regulation (EU) No 284/2013	Test methods (1)	Guidance documents (2)
9.1.2.2. Lysimeter studies	OECD Guidance Document 22: Guidance Document for the Performance Of Out-door Monolith Lysimeter Studies	FOCUS Ground Water
9.1.2.3. Field leaching studies	—	FOCUS Ground Water
9.1.3. Estimation of concentrations in soil	—	<u>Guidance on PEC calculation:</u> FOCUS soil persistence models FOCUS Ground Water (source of crop canopy interception values for different crop growth stages). <u>Guidance on degradation parameters and PEC calculation:</u> FOCUS Degradation Kinetics
9.2. Fate and behaviour in water and sediment	—	—
9.2.1. Aerobic mineralisation in surface water	OECD Test Guideline 309: Aerobic Mineralisation in Surface Water - Simulation Biodegradation Test	ECHA Guidance on information requirements and chemical safety assessment Chapter R 11: PBT Assessment
9.2.2. Water/sediment study	OECD Test Guideline 308: Aerobic and Anaerobic Transformation in Aquatic Sediment Systems	FOCUS Surface Water FOCUS Degradation Kinetics
9.2.3. Irradiated water/sediment study	OECD Test Guideline 308: Aerobic and Anaerobic Transformation in Aquatic Sediment Systems	—
9.2.4. Estimation of concentrations in groundwater	—	FOCUS Ground Water FOCUS Degradation Kinetics
9.2.4.1. Calculation of concentrations in groundwater	—	—
9.2.4.2. Additional field tests	—	—
9.2.5. Estimation of concentrations in surface water and sediment.	—	<u>Estimation of concentrations in surface water and sediment:</u> FOCUS Surface Water FOCUS Degradation Kinetics EU Guidance on aquatic ecotoxicology (SANCO/3268/2001 rev.4) <u>Mitigating of exposure levels and higher tier assessment on landscape level:</u> FOCUS Landscape and Mitigation FOCUS Air

Reference to Part A of the Annex to Regulation (EU) No 284/2013	Test methods (1)	Guidance documents (2)
9.3. Fate and behaviour in air	—	—
9.3.1. Route and rate of degradation in air and transport via air	—	FOCUS Air
9.4. Estimation of concentrations for other routes of exposure	—	—
10. ECOTOXICOLOGICAL STUDIES	—	OECD series of testing and assessment Number 54. "Current approaches in the statistical analysis of ecotoxicity data: a guidance to application"
10.1 Effects on birds and other terrestrial vertebrates	—	EFSA (2009) Guidance of EFSA - Risk assessment for birds and mammals. EFSA Journal 2009; 7(12):1438.
10.1.1. Effects on birds	—	—
10.1.1.1. Acute oral toxicity to birds	OECD Test Guideline 223: Avian Acute oral toxicity study or US EPA OCSPP 850.2100: Avian Acute Oral Toxicity Test (14)	—
10.1.1.2. Higher tier data on birds	—	—
10.1.2. Effects on terrestrial vertebrates other than birds	—	—
10.1.2.1. Acute oral toxicity to mammals	—	—
10.1.2.2. Higher tier data on mammals	—	—
10.1.3. Effects on other terrestrial vertebrate wildlife (reptiles and amphibians)	OECD Test Guideline 231: Amphibian Metamorphosis Assay	—
10.2. Effects on aquatic organisms	—	EU Guidance Document on Aquatic Ecotoxicology (SANCO/3268/2001 rev.4) (15)
10.2.1. Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes	<u>Fish:</u> OECD Test Guideline 203: Fish, Acute Toxicity Test <u>Invertebrates:</u> OECD Test Guideline 202: <i>Daphnia</i> sp. Acute Immobilisation Test US EPA OCSPP 850.1035 Mysid Acute Toxicity Test <u>Algae and macrophytes:</u> OECD Test Guideline 201: Freshwater Alga and Cyanobacteria, Growth Inhibition Test	OECD. Series on testing and assessment No 126. Short guidance on the threshold approach for acute fish toxicity. ENV/JM/MONO(2010)17.

Reference to Part A of the Annex to Regulation (EU) No 284/2013	Test methods (1)	Guidance documents (2)
	<p>OECD Test Guideline 221: <i>Lemma</i> sp. Growth Inhibition Test</p> <p>ASTM E1913-04: Standard Guide for Conducting Static, Axenic, 14-Day Phytotoxicity Tests in Test Tubes with the Submersed Aquatic Macrophyte, <i>Myriophyllum sibiricum</i> Komarov</p> <p>Development of a proposed test method for the rooted aquatic macrophyte <i>Myriophyllum</i> sp. In: Maltby L, Arnold D, Arts G, et al (2010). Aquatic Macrophyte Risk Assessment for pesticides (AMRAP). SETAC Press & CRC Press, Taylor & Francis Group, Boca Raton, London, New York., p. 46-56</p>	
<p>10.2.2. Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms</p>	<p><u>Fish:</u></p> <p>OECD Test Guideline 229: Fish Short Term Reproduction Assay</p> <p>OECD Test Guideline 230: 21-day Fish Assay: A Short-Term Screening for Oestrogenic and Androgenic Activity, and Aromatase Inhibition</p> <p>OECD Test Guideline 210: Fish, Early-Life Stage Toxicity Test</p> <p>OECD Test Guideline 234: Fish Sexual Development Test</p> <p>US EPA protocol OCSPP 850.1500 Fish life cycle toxicity</p> <p><u>Invertebrates:</u></p> <p>OECD Test Guideline 211: <i>Daphnia magna</i> Reproduction Test</p> <p>US EPA OCSPP 850.1350 Mysid Chronic Toxicity Test</p> <p><u>Sediment dwelling organisms:</u></p> <p>OECD Test Guideline 218: Sediment-Water Chironomid Toxicity Using Spiked Sediment</p> <p>OECD Test Guideline 219: Sediment-Water Chironomid Toxicity Using Spiked Water</p> <p>[In general a water-spiked system (i.e. OECD 219) better covers the exposure routes typical for plant protection products]</p>	<p>Further recommendations may be found in:</p> <p>Brock TCM, Alix A, Brown CD, et al (2009). Linking Aquatic Exposure and Effects: Risk Assessment of Pesticides (E-LINK). SETAC Press</p> <p>Maltby L, Arnold D, Arts G, et al (2010). Aquatic Macrophyte Risk Assessment for pesticides (AMRAP). SETAC Press & CRC Press, Taylor & Francis Group, Boca Raton, London, New York</p>
<p>10.2.3. Further testing on aquatic organisms</p>	<p>—</p>	<p>EU Guidance Document on Aquatic Ecotoxicology (SANCO/3268/2001 rev.4)</p>

Reference to Part A of the Annex to Regulation (EU) No 284/2013	Test methods (1)	Guidance documents (2)
10.3. Effects on arthropods	—	EU Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002 rev 2)
10.3.1. Effects on bees	—	EPPO Standard PP 3/10 (3) Environmental Risk Assessment Scheme for Plant Protection Products - Chapter 10: honey bees
10.3.1.1. Acute toxicity to bees	—	
10.3.1.1.1. Acute oral toxicity	EPPO Standard PP1/170 (4): Test methods for evaluating the side-effects of plant protection products on honeybees. OECD Test Guideline 213: Honeybees, Acute Oral Toxicity Test	
10.3.1.1.2. Acute contact toxicity	EPPO Standard PP1/170 (4): Test methods for evaluating the side-effects of plant protection products on honeybees. OECD Test Guideline 214: Honeybees, Acute Contact Toxicity Test	
10.3.1.2. Chronic toxicity to bees	Aupinel et al (2007): A new larval <i>in vitro</i> rearing method to test effects of pesticides on honey bee brood. <i>Redia</i> XC: 87-90 Oomen PA, de Ruijter A and van der Steen J, 1992. Method for honeybee brood feeding tests with insect growth - regulating insecticides. Bulletin OEPP/EPPO Bulletin 22, 613-616.	
10.3.1.3. Effects on honey bee development and other honey bee life stages	Aupinel P <i>et al.</i> (2007): A new larval <i>in vitro</i> rearing method to test effects of pesticides on honey bee brood. <i>Redia</i> XC: 87-90	EPPO Standard PP 3/10 (3) Environmental Risk Assessment Scheme for Plant Protection Products - Chapter 10: honey bees.
10.3.1.4. Sub-lethal effects	Oomen PA, de Ruijter A and van der Steen J, 1992. Method for honeybee brood feeding tests with insect growth - regulating insecticides. Bulletin OEPP/EPPO Bulletin 22, 613-616.	OECD Guidance Document 75 on the honeybee (<i>Apis mellifera</i> L) brood test under semi-field conditions
10.3.1.5. Cage and tunnel tests	EPPO Standard PP1/170 (4): Test methods for evaluating the side-effects of plant protection products on honeybees.	
10.3.1.6. Field tests with honeybees	EPPO Standard PP1/170 (4): Test methods for evaluating the side-effects of plant protection products on honeybees	—
10.3.2. Effects on non-target arthropods other than bees		EU guidance document on terrestrial ecotoxicology (SANCO/10329/2002 rev 2).

Reference to Part A of the Annex to Regulation (EU) No 284/2013	Test methods (1)	Guidance documents (2)
		Candolfi et al (2001). Guidance Document on Regulatory Testing and Risk Assessment Procedures for Plant Protection Products With Non-Target Arthropods: From the Escort 2 Workshop (European Standard Characteristics of Non-Target Arthropod Regulatory Testing). SETAC press, pp 46. ISBN 1-880611-52-x
10.3.2.1. Standard laboratory testing for non-target arthropods	M.P. Candolfi, S. Blümel, R. Forster et al. (2000): Guidelines to evaluate side-effects of plant protection products to non-target arthropods. IOBC, BART and EPPO Joint Initiative. ISBN: 92-9067-129-7.	
10.3.2.2. Extended laboratory testing, aged residue studies with non-target arthropods	M.P. Candolfi, S. Blümel, R. Forster et al. (2000): Guidelines to evaluate side-effects of plant protection products to non-target arthropods. IOBC, BART and EPPO Joint Initiative. ISBN: 92-9067-129-7. Mead-Briggs, M.A., Moll, M., Grimm, et al (2010). An extended laboratory test for evaluating the effects of plant protection products on the parasitic wasp, <i>Aphidius rhopalosiphii</i> (Hymenoptera, Braconidae). BioControl 55:329-338.	
10.3.2.3. Semi-field studies with non-target arthropods	M.P. Candolfi, S. Blümel, R. Forster et al. (2000): Guidelines to evaluate side-effects of plant protection products to non-target arthropods. IOBC, BART and EPPO Joint Initiative. ISBN: 92-9067-129-7.	
10.3.2.4. Field studies with non-target arthropods	M.P. Candolfi, S. Blümel, R. Forster et al. (2000): Guidelines to evaluate side-effects of plant protection products to non-target arthropods. IOBC, BART and EPPO Joint Initiative. ISBN: 92-9067-129-7.	
10.3.2.5. Other routes of exposure for non-target arthropods	—	
10.4. Effects on non-target soil meso- and macrofauna	—	EU Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002 rev 2)
10.4.1. Earthworms	—	
10.4.1.1. Earthworms - sub-lethal effects	OECD Test Guideline 222: Earthworm Reproduction Test (<i>Eisenia fetida</i> / <i>Eisenia andrei</i>)	
10.4.1.2. Earthworms - field studies	ISO 11268-3:1999: Soil quality – Effects of pollutants on earthworms – Part 3: Guidance on the determination of effects in field situations	

Reference to Part A of the Annex to Regulation (EU) No 284/2013	Test methods (1)	Guidance documents (2)
10.4.2. Effects on non-target soil meso- and macrofauna (other than earthworms)	—	
10.4.2.1. Species level testing	<p><u>For Collembola:</u></p> <p>OECD Test Guideline 232: Collembolan Reproduction Test in Soil</p> <p><u>For predatory mites:</u></p> <p>OECD Test Guideline 226: Predatory mite (<i>Hypoaspis (Geolaelaps) aculeifer</i>) reproduction test in soil</p>	
10.4.2.2. Higher tier testing	—	
10.5. Effects on soil nitrogen transformation	OECD Test Guideline 216: Soil Microorganisms: Nitrogen Transformation Test	EU Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002 rev 2)
10.6. Effects on terrestrial non-target higher plants		EU Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002 rev 2)
10.6.1. Summary of screening data	—	—
10.6.2. Testing on non-target plants	<p><u>Seedling emergence and seedling growth:</u></p> <p>OECD Test Guideline 208: Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test</p> <p><u>Terrestrial plant vegetative vigour testing:</u></p> <p>OECD Test Guideline 227: Terrestrial Plant Test: Vegetative Vigour Test</p>	—
10.6.3. Extended laboratory studies on non-target plants	—	—
10.6.4. Semi-field and field tests on non-target plants	—	—
10.7. Effects on other terrestrial organisms (flora and fauna)	—	EU Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002 rev 2)
10.8. Monitoring data	—	—
11. LITERATURE DATA		EFSA (2011). Guidance of EFSA - 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):209

Reference to Part A of the Annex to Regulation (EU) No 284/2013	Test methods ⁽¹⁾	Guidance documents ⁽²⁾
12. CLASSIFICATION AND LABELLING		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.

⁽¹⁾ 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>
- US EPA OCSPP <http://www.epa.gov/ocspp/pubs/frs/home/testmeth.htm>

⁽²⁾ Most of the guidance documents cited are available only in English. Detailed information about the guidance documents:

- European Commission: http://ec.europa.eu/food/plant/pesticides/approval_active_substances/guideline_documents_en.htm
- 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: <http://focus.jrc.ec.europa.eu/index.html>

⁽³⁾ <http://www.fao.org/agriculture/crops/core-themes/theme/pests/jmps/manual/en/>

⁽⁴⁾ OJ L 309, 24.11.2009, p. 1.

⁽⁵⁾ Prepublished method on www.cipac.org/cipacpub.htm

⁽⁶⁾ http://www.euroseeds.org/esta-european-seed-treatment-assurance/esa_11.0387

⁽⁷⁾ OJ L 353, 31.12.2008, p. 1.

⁽⁸⁾ 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.

⁽⁹⁾ ISTA rules are available at: <http://www.seedtest.org/en/productrubric.html>

⁽¹⁰⁾ OJ L 324, 9.12.2010, p. 13.

⁽¹¹⁾ http://www.who.int/ipcs/publications/ehc/ehc_numerical/en/index.html

⁽¹²⁾ OJ L 93, 3.4.2013, p. 1.

⁽¹³⁾ http://www.hc-sc.gc.ca/cps-spc/pubs/pest/_pol-guide/dir2006-01/index-eng.php

⁽¹⁴⁾ <http://www.epa.gov/ocspp/pubs/frs/home/guidelin.htm>

⁽¹⁵⁾ http://ec.europa.eu/food/plant/protection/resources/publications_en.htm