

IV

(Notices)

NOTICES FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES

EUROPEAN COMMISSION

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

(Text with EEA relevance)

(2013/C 95/01)

The present Commission Communication fulfils Point 6 of the Introduction of the Annex to Regulation 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 and will be updated regularly.

Reference to Part A of the Annex to Regulation (EU) No 283/2013	Test methods ⁽¹⁾	Guidance documents ⁽²⁾
1. IDENTITY OF THE ACTIVE SUBSTANCE	—	WHO/FAO. 2002. Pesticide Specifications. Manual on development and use of FAO and WHO specifications for pesticides. Series FAO Plant Production and Protection Papers, Rome, 2002 ⁽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 AND CHEMICAL PROPERTIES OF THE ACTIVE SUBSTANCE	—	
2.1. Melting point and boiling point	Method A.1 Melting/Freezing temperature (Annex to Regulation (EC) No 440/2008). OECD Test Guideline 102: Melting Point/ Melting Range Method A.2 Boiling temperature (Annex to Regulation (EC) No 440/2008). OECD Test Guideline 103: Boiling point	—

⁽¹⁾ OJ L 93, 3.4.2013, p. 1.

Reference to Part A of the Annex to Regulation (EU) No 283/2013	Test methods ⁽¹⁾	Guidance documents ⁽²⁾
2.2. Vapour pressure, volatility	Method A.4 Vapour pressure (Annex to Regulation (EC) No 440/2008). OECD Test Guideline 104: Vapour Pressure	—
2.3. Appearance (physical state, colour)	—	—
2.4. Spectra (UV/VIS, IR, NMR, MS), molar extinction at relevant wavelengths, optical purity	OECD Test Guideline 101: UV-VIS Absorption Spectra	—
2.5. Solubility in water	Method A.6 Water solubility (Annex to Regulation (EC) No 440/2008). OECD Test Guideline 105: Water Solubility	—
2.6. Solubility in organic solvents	CIPAC Method MT 181: Solubility in organic solvents	—
2.7. Partition coefficient n-octanol/water	Method A.8 Partition coefficient (Annex to Regulation (EC) No 440/2008). OECD Test Guideline 107: Partition coefficient, shake-flask method <i>If a compound is surface active (as defined by Method A.5 Surface tension) the shake-flask method described in method A.8 can be applicable if in the report it is clear that no problems occurred (e.g. phase separations). The HPLC method described in Method A.8 is not applicable to surface active compounds.</i>	—
2.8. Dissociation in water	OECD Test Guideline 112: Dissociation Constants in Water.	—
2.9. Flammability and self-heating	<u>Flammability:</u> Methods A.10 Flammability (solids), A.11 Flammability (gases), A.12 Flammability (contact with water) (Annex to Regulation (EC) No 440/2008), as appropriate; 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) <u>Self-heating:</u> Methods A.15 Auto-ignition temperature (liquids and gases), A16 Relative self-ignition temperature for solids, (Annex to Regulation (EC) No 440/2008), as appropriate. 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)	—

Reference to Part A of the Annex to Regulation (EU) No 283/2013	Test methods ⁽¹⁾	Guidance documents ⁽²⁾
2.10. Flash point	Method A.9 Flash-point (Annex to Regulation (EC) No 440/2008) - only closed cup methods should be used. Test methods according to table 2.6.3 of Annex I, Part 2 of Regulation (EC) No 1272/2008 ⁽³⁾ (liquids);	—
2.11. Explosive properties	Method A.14 Explosive properties (Annex to 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.	—
2.12. Surface tension	Method A.5 Surface tension (Annex to Regulation (EC) No 440/2008). OECD Test Guideline 115: Surface tension of aqueous solutions	—
2.13. Oxidising properties	Solids: Method A.17 Oxidising properties (solids) (Annex to Regulation (EC) No 440/2008) Liquids: Method A.21 Oxidising properties (liquids) (Annex to 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. 4 - Part I (Test series). 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) 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)	—
2.14. Other studies	Test methods reported in Annex I, Part II to Regulation (EC) No 1272/2008	—
3. FURTHER INFORMATION ON THE ACTIVE SUBSTANCE	EPPO standard series PP1: Efficacy evaluation of plant protection products ⁽⁶⁾	—
3.1. Use of the active substance	—	—
3.2. Function	—	—
3.3. Effects on harmful organisms	—	—
3.4. Field of use envisaged	—	—

Reference to Part A of the Annex to Regulation (EU) No 283/2013	Test methods ⁽¹⁾	Guidance documents ⁽²⁾
3.5. Harmful organisms controlled and crops or products protected or treated	—	—
3.6. Mode of action	—	—
3.7. Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies	EPPO standard PP 1/213: Resistance risk analysis	—
3.8. Methods and precautions concerning handling, storage, transport or fire	—	—
3.9. Procedures for destruction or decontamination	—	—
3.10. Emergency measures in case of an accident	—	—
4. 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>
5. TOXICOLOGICAL AND METABOLISM STUDIES	—	—
5.1. Studies on absorption, distribution, metabolism and excretion in mammals	—	<p>EU Working Document. Draft Guidance for the Setting and Application of Acceptable Operator Exposure Levels (AOEL's) (SANCO 7531 rev. 10, 10.07.2006)</p> <p>OECD (2010) Guidance for the Derivation of an Acute Reference Dose" OECD Series on testing and assessment, No. 124, 08-Jun-2010</p>

Reference to Part A of the Annex to Regulation (EU) No 283/2013	Test methods ⁽¹⁾	Guidance documents ⁽²⁾
5.1.1. Absorption, distribution, metabolism and excretion after exposure by oral route	Method B.36 Toxicokinetics (Annex to Regulation (EC) No 440/2008). OECD Test Guideline 417: Toxicokinetics	—
5.1.2. Absorption, distribution, metabolism and excretion after exposure by other routes	Method B.36 Toxicokinetics (Annex to Regulation (EC) No 440/2008). OECD Test Guideline 417: Toxicokinetics	—
5.2. Acute toxicity	—	—
5.2.1. Oral	Method B.1 bis Acute oral toxicity - fixed dose procedure (Annex to Regulation (EC) No 440/2008). Method B.1 tris Acute oral toxicity - Acute toxic class method (Annex to Regulation (EC) No 440/2008). OECD Test Guideline 420: Acute oral toxicity: fixed dose procedure OECD Test Guideline 423: Acute oral toxicity: acute toxic class method OECD Test Guideline 425: Acute oral toxicity: up-and-down procedure OECD Test Guideline No 401: Acute oral toxicity (only acceptable, if performed before December 2002)	—
5.2.2. Dermal	Method B.3 Acute toxicity (dermal) (Annex to Regulation (EC) No 440/2008). OECD Test Guideline 402: Acute Dermal Toxicity	—
5.2.3. Inhalation	Method B.2 Acute toxicity (inhalation) (Annex to Regulation (EC) No 440/2008). OECD Test Guideline 403: Acute Inhalation Toxicity OECD Test Guideline 436: Acute Inhalation Toxicity – Acute Toxic Class Method	—
5.2.4. Skin irritation	Method B.4 Acute toxicity: dermal irritation/corrosion (Annex to Regulation (EC) No 440/2008). Method B.40 <i>In vitro</i> skin corrosion: transcutaneous electrical resistance test (TER) (Annex to Regulation (EC) No 440/2008). Method B.40 bis <i>In vitro</i> skin corrosion: human skin model test (Annex to Regulation (EC) No 440/2008). OECD Test Guideline 404: Acute Dermal Irritation/Corrosion OECD Test Guideline 431: <i>In vitro</i> Skin Corrosion: Human Skin Model Test	—

Reference to Part A of the Annex to Regulation (EU) No 283/2013	Test methods ⁽¹⁾	Guidance documents ⁽²⁾
	<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>OECD Test Guideline 439: <i>In vitro</i> Skin Irritation: Reconstructed Human Epidermis Test Method</p> <p>Method B.46 <i>In vitro</i> skin irritation: reconstructed human epidermis model test (Annex III of Regulation (EC) No 761/2009 ⁽⁷⁾).</p>	
5.2.5. Eye irritation	<p>Method B.5 Acute toxicity: eye irritation/corrosion (Annex to 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 ⁽⁸⁾)</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>	—
5.2.6. Skin sensitisation	<p>Method B.42 Skin sensitisation: Local lymph node assay (Annex to Regulation (EC) No 440/2008).</p> <p>Method B.6 Skin sensitisation (Annex to Regulation (EC) No 440/2008).</p> <p>OECD Test Guideline 429: Skin Sensitisation – Local Lymph Node Assay</p> <p>OECD Test Guideline 406: Skin sensitisation</p> <p>OECD Test Guideline 442A: Skin Sensitisation – Local Lymph Node Assay: DA</p> <p>OECD Test Guideline 442B: Skin Sensitisation – Local Lymph Node Assay: BrdU-ELISA</p>	—
5.2.7. Phototoxicity	<p>Method B.41 <i>In vitro</i> 3T3 NRU phototoxicity test (Annex to Regulation (EC) No 440/2008).</p>	—

Reference to Part A of the Annex to Regulation (EU) No 283/2013	Test methods ⁽¹⁾	Guidance documents ⁽²⁾
	<p>OECD Test Guideline 432: <i>In vitro</i> 3T3 NRU Phototoxicity Test</p> <p>OECD Test Guideline 101: UV-VIS Absorption Spectra</p>	
5.3. Short-term toxicity	—	—
5.3.1. Oral 28-day study	<p>Method B.7 Repeated dose (28 days) toxicity (oral) (Annex to Regulation (EC) No 440/2008).</p> <p>OECD Test Guideline 407: Repeated dose 28-day oral toxicity study in rodents</p>	—
5.3.2. Oral 90-day study	<p>Method B.26 Sub-chronic oral toxicity test. Repeated dose 90-day oral toxicity study in rodents (Annex to Regulation (EC) No 440/2008).</p> <p>Method B.27 Sub-chronic oral toxicity test. Repeated dose 90-day oral toxicity study in non-rodents (Annex to Regulation (EC) No 440/2008).</p> <p>OECD Test Guideline 408: Repeated dose 90-day oral toxicity study in rodents</p> <p>OECD Test Guideline 409: Repeated dose 90-day oral toxicity study in non-rodents</p>	—
5.3.3. Other routes	<p>Method B8 Repeated dose (28 days) toxicity (inhalation) (Annex to Regulation (EC) No 440/2008).</p> <p>Method B.9 Repeated dose (28 days) toxicity (dermal) (Annex to Regulation (EC) No 440/2008).</p> <p>Method B.28 Sub-chronic dermal toxicity test: 90-day repeated dermal dose study using rodent species (Annex to Regulation (EC) No 440/2008).</p> <p>Method B.29 Sub-chronic inhalation toxicity study 90-day repeated inhalation dose study using rodent species (Annex to Regulation (EC) No 440/2008).</p> <p>OECD Test Guideline 410: Repeated dose dermal toxicity: 21/28-day study.</p> <p>OECD Test Guideline 411: Subchronic dermal toxicity: 90-day study.</p> <p>OECD Test Guideline 412: Subacute inhalation toxicity: 28-day study.</p> <p>OECD Test Guideline 413: Subchronic inhalation toxicity: 90-day study.</p>	—
5.4. Genotoxicity testing	—	—

Reference to Part A of the Annex to Regulation (EU) No 283/2013	Test methods ⁽¹⁾	Guidance documents ⁽²⁾
5.4.1. <i>In vitro</i> studies	<p>Method B.13/14 Mutagenicity - reverse mutation test using bacteria (Annex to Regulation (EC) No 440/2008).</p> <p>Method B.10 Mutagenicity - <i>In vitro</i> mammalian chromosome aberration test (Annex to Regulation (EC) No 440/2008).</p> <p>Method B.17 - Mutagenicity - <i>In vitro</i> mammalian cell gene mutation test (Annex to Regulation (EC) No 440/2008). - For this test mouse lymphoma assay is recommended.</p> <p>OECD Test Guideline 471: Bacterial Reverse Mutation Test</p> <p>OECD Test Guideline 473: <i>In vitro</i> Mammalian Chromosome Aberration Test</p> <p>OECD Test Guideline 476: <i>In vitro</i> Mammalian Cell Gene Mutation Test - For this test mouse lymphoma assay is recommended.</p> <p>OECD Test Guideline 487. <i>In vitro</i> Mammalian Cell Micronucleus Test.</p> <p><i>In vitro</i> Comet assay could be used when justified.</p>	—
5.4.2. <i>In vivo</i> studies in somatic cells	<p>Method B.12 - Mutagenicity - <i>In vivo</i> mammalian erythrocyte micronucleus test (Annex to Regulation (EC) No 440/2008).</p> <p>Method B.11 - Mutagenicity - <i>In vivo</i> mammalian bone-marrow chromosome aberration test (Annex to Regulation (EC) No 440/2008).</p> <p>OECD Test Guideline 474: Mammalian Erythrocyte Micronucleus Test</p> <p>OECD Test Guideline 475: Mammalian Bone Marrow Chromosome Aberration Test</p> <p>OECD Test Guideline 486: Unscheduled DNA synthesis (UDS) - Test with mammalian liver cells <i>in vivo</i>.</p> <p>OECD Test Guideline 488: Transgenic Rodent Somatic and Germ Cell Gene Mutation Assays</p> <p>Method B.39 Unscheduled DNA synthesis (UDS) - Test with mammalian liver cells <i>in vivo</i> (Annex to Regulation (EC) No 440/2008).</p> <p><i>In vivo</i> Comet assay could be used when justified and considering EFSA (2012). Minimum Criteria for the acceptance of <i>in vivo</i> alkaline Comet Assay Reports. EFSA Journal 2012;10(11):2977</p>	

Reference to Part A of the Annex to Regulation (EU) No 283/2013	Test methods ⁽¹⁾	Guidance documents ⁽²⁾
5.4.3. <i>In vivo</i> studies in germ cells	<p>Method B.23 Mammalian spermatogonial chromosome aberration test (Annex to Regulation (EC) No 440/2008).</p> <p>OECD Test Guideline 483: Mammalian Spermatogonial Chromosome Aberration Test.</p> <p>OECD Test Guideline 488: Transgenic Rodent Somatic and Germ Cell Gene Mutation Assays.</p>	—
5.5. Long term toxicity and carcinogenicity	<p>Method B.30 Chronic toxicity test (Annex to Regulation (EC) No 440/2008).</p> <p>Method B.32 Carcinogenicity test (Annex to Regulation (EC) No 440/2008).</p> <p>Method B.33 Combined chronic toxicity/carcinogenicity test (Annex to Regulation (EC) No 440/2008).</p> <p>OECD Test Guideline 451: Carcinogenicity Studies.</p> <p>OECD Test Guideline 452: Chronic Toxicity Studies.</p> <p>OECD Test Guideline 453: Combined Chronic Toxicity/Carcinogenicity Studies.</p>	—
5.6. Reproductive toxicity		—
5.6.1. Generational studies	<p>Method B.35 Two-generation reproduction toxicity study (Annex to Regulation (EC) No 440/2008).</p> <p>OECD Test Guideline 416: Two-Generation Reproduction Toxicity.</p> <p>OECD Test Guideline 443: Extended One-generation Reproduction Toxicity.</p>	—
5.6.2. Developmental toxicity studies	<p>Method B.31 Prenatal developmental toxicity study (Annex to Regulation (EC) No 440/2008).</p> <p>OECD Test Guideline 414: Prenatal developmental toxicity study.</p> <p>OECD Test Guideline 426: Developmental neurotoxicity study.</p>	—
5.7. Neurotoxicity studies		—
5.7.1. Neurotoxicity studies in rodents	<p>Method B.43 Neurotoxicity study in rodents (Annex to Regulation (EC) No 440/2008).</p> <p>OECD Test Guideline 424: Neurotoxicity study in rodents.</p>	—

Reference to Part A of the Annex to Regulation (EU) No 283/2013	Test methods ⁽¹⁾	Guidance documents ⁽²⁾
5.7.2. Delayed polyneuropathy studies	<p>Method B.37 Delayed neurotoxicity of organophosphorus substances after acute exposure (Annex to Regulation (EC) No 440/2008).</p> <p>Method B.38 Delayed neurotoxicity of organophosphorus substances 28-day repeated dose study (Annex to Regulation (EC) No 440/2008).</p> <p>OECD Test Guideline 418: Delayed Neurotoxicity of Organophosphorus Substances Following Acute Exposure.</p> <p>OECD Test Guideline 419: Delayed Neurotoxicity of Organophosphorus Substances: 28-day Repeated Dose Study.</p>	—
5.8. Other toxicological studies	—	—
5.8.1. Toxicity studies of metabolites		EU Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council Directive 91/414/EEC (SANCO/221/2000 – rev.10. final)
5.8.2. Supplementary studies on the active substance	—	OECD (2010) Guidance for conducting a single exposure toxicity study. IN: OECD (2010) Guidance for the Derivation of an Acute Reference Dose” OECD Series on testing and assessment, No. 124, 08-Jun-2010
5.8.3. Endocrine disrupting properties	<p>OECD Test Guideline 456: H295R Steroidogenesis Assay</p> <p>OECD Test Guideline 441: Hershberger Bioassay in Rats, A Short-term Screening Assay for (Anti)Androgenic Properties</p> <p>OECD Test Guideline 455: Stably Transfected Human Estrogen Receptor-alpha Transcriptional Activation Assay for Detection of Estrogenic Agonist-Activity of Chemicals</p> <p>OECD Test Guideline 440: Uterotrophic Bioassay in Rodents A short-term screening test for oestrogenic properties</p> <p>OCSPP Guideline 890.1500: Pubertal Development and Thyroid Function in Intact Juvenile/Peripubertal Male Rats Assay</p> <p>OCSPP Guideline 890.1450: Pubertal Development and Thyroid Function in Intact Juvenile/Peripubertal Female Rats Assay</p> <p>U.S. Environmental Protection Agency (2007): 15-Day Intact Adult Male Rat Assay</p>	—
5.9. Medical data	—	—

Reference to Part A of the Annex to Regulation (EU) No 283/2013	Test methods ⁽¹⁾	Guidance documents ⁽²⁾
6. RESIDUES IN OR ON TREATED PRODUCTS, FOOD AND FEED		OECD (2009). Guidance Document on Overview of Residue Chemistry Studies (as revised in 2009). Environment, Health and Safety Publications. Series on Testing and Assessment No. 64 and Series on Pesticides No. 32.
6.1 Storage stability of residues	OECD Test Guideline 506: Stability of pesticide residues in stored commodities	—
6.2 Metabolism, distribution and expression of residues	—	—
6.2.1. Plants	OECD Test Guideline 501: Metabolism in crops	—
6.2.2. Poultry	OECD Test Guideline 503: Metabolism in livestock	—
6.2.3. Lactating ruminants	OECD Test Guideline 503: Metabolism in livestock	—
6.2.4. Pigs	OECD Test Guideline 503: Metabolism in livestock	—
6.2.5. Fish	—	—
6.3. Magnitude of residue trials in plants	OECD Test Guideline 509: Crop field trials	OECD (2011) Guidance Document on Crop Field Trials (Series on Testing and Assessment No. 164 and Series on Pesticides No. 66)
6.4. Feeding studies	—	—
6.4.1. Poultry	OECD Test Guideline 505: Residues in livestock.	—
6.4.2. Ruminants	OECD Test Guideline 505: Residues in livestock.	—
6.4.3. Pigs	OECD Test Guideline 505: Residues in livestock.	—
6.4.4. Fish	—	—
6.5. Effects of processing	—	—
6.5.1. Nature of the residue	OECD Test Guideline 507: Nature of the pesticide residues in processed commodities – High temperature hydrolysis.	—
6.5.2. Distribution of the residue in inedible peel and pulp	OECD Test Guideline 508: Magnitude of the pesticide residues in processed commodities. OECD Test Guideline 509: Crop field trials.	—
6.5.3. Magnitude of residues in processed commodities	OECD Test Guideline 508: Magnitude of the pesticide residues in processed commodities.	OECD (2008). Guidance document on magnitude of pesticide residues in processed commodities. Environment, Health and Safety Publications. Series on Testing and Assessment No. 96.
6.6. Residues in rotational crops	—	—

Reference to Part A of the Annex to Regulation (EU) No 283/2013	Test methods ⁽¹⁾	Guidance documents ⁽²⁾
6.6.1. Metabolism in rotational crops	OECD Test Guideline 502: Metabolism in rotational crops.	—
6.6.2. Magnitude of residues in rotational crops	OECD Test Guideline 504: Residues in rotational crops (limited field studies). OECD Test Guideline 509: Crop field trials.	—
6.7. Proposed residue definitions and maximum residue levels	—	—
6.7.1. Proposed residue definitions	—	OECD (2009). Guidance Document on the Definition of Residues, Environment, Health and Safety Publications. Series on Testing and Assessment No. 63 and Series on Pesticides No. 31
6.7.2. Proposed maximum residue levels (MRLs) and justification of the acceptability of the levels proposed	—	EU guidance document "Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs" (SANCO 7525/VI/95 rev. 9, March 2011). OECD MRL calculator (2011)
6.7.3. Proposed maximum residue levels (MRLs) and justification of the acceptability of the levels proposed for imported products (import tolerance)	—	EU guidance document "Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs" (SANCO 7525/VI/95 rev. 9, March 2011). OECD MRL calculator (2011)
6.8. Proposed safety intervals	—	EU guidance document "Calculation of Maximum Residue Levels and Safety Intervals e.g. Pre-harvest Intervals" (SANCO 7039/VI/95, 22/7/1997)
6.9. Estimation of the potential and actual exposure through diet and other sources	—	EFSA calculation model Pesticide Residue Intake Model "PRIMo" - revision 2 ⁽⁹⁾
6.10. Other studies	—	—
6.10.1. Residue level in pollen and bee products	—	—
7. FATE AND BEHAVIOUR IN THE ENVIRONMENT	—	—
7.1. 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	—
7.1.1. Route of degradation in soil	—	—

Reference to Part A of the Annex to Regulation (EU) No 283/2013	Test methods ⁽¹⁾	Guidance documents ⁽²⁾
7.1.1.1. Aerobic degradation	OECD Test Guideline 307: Aerobic and anaerobic transformation in soil.	—
7.1.1.2. Anaerobic degradation	OECD Test Guideline 307: Aerobic and anaerobic transformation in soil.	—
7.1.1.3. Soil photolysis	—	SETAC 1995 – Procedures for assessing the environmental fate and ecotoxicity of pesticides
7.1.2. Rate of degradation in soil	—	EFSA (2010). 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.
7.1.2.1. Laboratory studies	OECD Test Guideline 307: Aerobic and anaerobic transformation in soil.	FOCUS Ground Water FOCUS Degradation Kinetics EFSA (2007). Scientific Opinion on a request from EFSA related to the default Q10 value used to describe the temperature effect on transformation rates of pesticides in soil. The EFSA Journal (2007) 622, 1-32.
7.1.2.2. Field studies	US EPA OCSPP 835.6100; Terrestrial field dissipation	FOCUS Ground Water FOCUS Degradation Kinetics FOCUS soil persistence models <u>Technical aspects to determine degradation rates in soil in field studies can be found in:</u> 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 ⁽¹⁰⁾
7.1.3. Adsorption and desorption in soil	—	—
7.1.3.1. Adsorption and desorption	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 307: Aerobic and anaerobic transformation in soil.	FOCUS Ground Water European Commission. Scientific Committee on plants SCP/KOC/002-Final. Opinion of the Scientific Committee on Plants on methods for the determination of the organic carbon adsorption coefficient (K _{oc}) for a plant protection product active substance in the context of Council Directive 91/414/EEC (18 July 2002) ⁽¹¹⁾
7.1.3.2. Aged sorption	—	FOCUS Ground Water
7.1.4. Mobility in soil	—	—

Reference to Part A of the Annex to Regulation (EU) No 283/2013	Test methods ⁽¹⁾	Guidance documents ⁽²⁾
7.1.4.1. Column leaching studies	OECD Test Guideline 312: Leaching in Soil Columns	—
7.1.4.2. Lysimeter studies	OECD Guidance Document 22: Guidance Document for the Performance Of Out-door Monolith Lysimeter Studies	FOCUS Ground Water
7.1.4.3. Field leaching studies	—	FOCUS Ground Water
7.2. Fate and behaviour in water and sediment	—	—
7.2.1. Route and rate of degradation in aquatic systems (chemical and photochemical degradation)	—	—
7.2.1.1. Hydrolytic degradation	OECD Test Guideline 111: Hydrolysis as a Function of pH	—
7.2.1.2. Direct photochemical degradation	OECD Test Guideline 316: Photo-transformation of Chemicals in Water - Direct Photolysis	—
7.2.1.3. Indirect photochemical degradation	—	—
7.2.2. Route and rate of biological degradation in aquatic systems	—	—
7.2.2.1. "Ready biodegradability"	Method C.4 Determination of "ready" biodegradability (Annex to Regulation (EC) No 440/2008). OECD Guideline Test 301: Ready Biodegradability (301 A - F)	—
7.2.2.2. 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
7.2.2.3. Water/sediment study	OECD Test Guideline 308: Aerobic and Anaerobic Transformation in Aquatic Sediment Systems	FOCUS Surface Water FOCUS Degradation Kinetics
7.2.2.4. Irradiated water/sediment study	OECD Test Guideline 308: Aerobic and Anaerobic Transformation in Aquatic Sediment Systems	—
7.2.3. Degradation in the saturated zone	—	—
7.3. Fate and behaviour in air	—	FOCUS Air
7.3.1. Route and rate of degradation in air	—	—
7.3.2. Transport via air	—	—
7.3.3. Local and global effects	—	—

Reference to Part A of the Annex to Regulation (EU) No 283/2013	Test methods ⁽¹⁾	Guidance documents ⁽²⁾
7.4. Definition of the residue	—	—
7.4.1. Definition of the residue for risk assessment	—	—
7.4.2. Definition of the residue for monitoring	—	—
7.5. Monitoring data	—	—
8. ECOTOXICOLOGICAL STUDIES	—	OECD series of testing and assessment Number 54. "Current approaches in the statistical analysis of ecotoxicity data: a guidance to application"
8.1. Effects on birds and other terrestrial vertebrates	—	EFSA (2009) Guidance of EFSA - Risk assessment for birds and mammals. EFSA Journal 2009; 7(12):1438.
8.1.1. Effects on birds	—	—
8.1.1.1. Acute oral toxicity to birds	OECD Test Guideline No 223: Avian acute oral toxicity study or US EPA OCSPP 850.2100: Avian oral toxicity test	—
8.1.1.2. Short-term dietary toxicity to birds	OECD Test Guideline 205: Avian Dietary Toxicity Test or US EPA OCSPP 850.2200: Avian dietary toxicity test.	—
8.1.1.3. Sub-chronic and reproductive toxicity to birds	OECD Test Guideline 206: Avian Reproduction Test or US EPA OCSPP 850.2300: Avian Reproduction Test	—
8.1.2. Effects on terrestrial vertebrates other than birds	—	—
8.1.2.1. Acute oral toxicity to mammals	—	—
8.1.2.2. Long-term and reproductive toxicity to mammals	—	—
8.1.3. Active substance bioconcentration in prey of birds and mammals	—	—
8.1.4. Effects on terrestrial vertebrate wildlife (birds, mammals, reptiles and amphibians)	OECD Test Guideline 231: Amphibian Metamorphosis Assay	—

Reference to Part A of the Annex to Regulation (EU) No 283/2013	Test methods ⁽¹⁾	Guidance documents ⁽²⁾
8.1.5. Endocrine disrupting properties	—	Workshop report on OECD countries activities regarding testing, assessment and management of endocrine disrupters. Series on testing and assessment No 118. 18 January 2010.
8.2. Effects on aquatic organisms	—	EU Guidance Document on Aquatic Ecotoxicology (SANCO/3268/2001 rev.4) OECD (2000). Guidance document on aquatic toxicity testing of difficult substances and mixtures. OECD series on testing and assessment Number 23.
8.2.1. Acute toxicity to fish	OECD Test Guideline 203: Fish, Acute Toxicity Test ⁽¹²⁾	OECD. Series on testing and assessment No 126. Short guidance on the threshold approach for acute fish toxicity. ENV/JM/MONO(2010)17
8.2.2. Long-term and chronic toxicity to fish	—	—
8.2.2.1. Fish early life stage toxicity test	OECD Test Guideline 210: Fish, Early-Life Stage Toxicity Test	—
8.2.2.2. Fish full life cycle test	US EPA protocol OCSPP 850.1500 Fish life cycle toxicity.	—
8.2.2.3. Bioconcentration in fish	—	—
8.2.3. Endocrine disrupting properties	OECD Test Guideline 229: Fish Short Term Reproduction Assay OECD Test Guideline 230: 21-day Fish Assay: A Short-Term Screening for Oestrogenic and Androgenic Activity, and Aromatase Inhibition OECD Test Guideline 231: Amphibian Metamorphosis Assay OECD Test Guideline 234 Fish Sexual Development Test	Workshop report on OECD countries activities regarding testing, assessment and management of endocrine disrupters. Series on testing and assessment No 118. 18 January 2010.
8.2.4. Acute toxicity to aquatic invertebrates	—	EU Guidance Document on Aquatic Ecotoxicology (SANCO/3268/2001 rev.4)
8.2.4.1. Acute toxicity to <i>Daphnia magna</i>	OECD Test Guideline 202: <i>Daphnia</i> sp. Acute Immobilisation Test	—
8.2.4.2. Acute toxicity to an additional aquatic invertebrate species	US EPA OCSPP 850.1035 Mysid Acute Toxicity Test	—
8.2.5. Long-term and chronic toxicity to aquatic invertebrates	—	—
8.2.5.1. Reproductive and development toxicity to <i>Daphnia magna</i>	OECD Test Guideline 211: <i>Daphnia magna</i> Reproduction Test	—

Reference to Part A of the Annex to Regulation (EU) No 283/2013	Test methods ⁽¹⁾	Guidance documents ⁽²⁾
8.2.5.2. Reproductive and development toxicity to an additional aquatic invertebrate species	US EPA OCSPP 850.1350 Mysid Chronic Toxicity Test	—
8.2.5.3. Development and emergence in <i>Chironomus riparius</i>	OECD Test Guideline 219: Sediment-Water Chironomid Toxicity Using Spiked Water [In general a water-spiked system (i.e. OECD 219) better covers the exposure routes typical for plant protection products]	—
8.2.5.4. Sediment dwelling organisms	OECD Test Guideline 218: Sediment-Water Chironomid Toxicity Using Spiked Sediment	—
8.2.6. Effects on algal growth	—	—
8.2.6.1. Effects on growth of green algae	OECD Test Guideline 201: Algae growth inhibition test	—
8.2.6.2. Effects on growth of an additional algal species	OECD Test Guideline 201: Algae growth inhibition test.	—
8.2.7. Effects on aquatic macrophytes	<p>OECD Test Guideline 221: <i>Lemna sp.</i> 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 Komarov</i></p> <p>Development of a proposed test method for the rooted aquatic macrophyte <i>Myriophyllum sp.</i> 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>	
8.2.8. Further testing on aquatic organisms	—	EU Guidance Document on Aquatic Ecotoxicology (SANCO/3268/2001 rev.4)
8.3. Effect on arthropods	—	EU Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002 rev 2)
8.3.1. Effects on bees	—	EPPO Standard PP 3/10 (3) Environmental risk assessment scheme for plant protection products. Chapter 10: honeybees.
8.3.1.1. Acute toxicity to bees	—	
8.3.1.1.1. Acute oral toxicity	<p>EPPO Standard PP1/170 (4): Test methods for evaluating the side-effects of plant protection products on honeybees.</p> <p>OECD Test Guideline 213: Honeybees, Acute Oral Toxicity Test</p>	

Reference to Part A of the Annex to Regulation (EU) No 283/2013	Test methods ⁽¹⁾	Guidance documents ⁽²⁾
8.3.1.1.2. 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	
8.3.1.2. Chronic toxicity to bees	Aupinel et al (2007): A new larval in vitro 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.	
8.3.1.3. Effects on honeybee development and other honeybee life stages	Aupinel et al (2007): A new larval in vitro rearing method to test effects of pesticides on honey bee brood. <i>Redia</i> XC: 87-90	
8.3.1.4. 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.	
8.3.2. Effects on non-target arthropods other than bees		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.
8.3.2.1. Effects on <i>Aphidius rhopalosiphii</i>	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.	
8.3.2.2. Effects on <i>Typhlodromus pyri</i>	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	
8.4. Effects on non-target soil meso- and macrofauna	—	EU Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002 rev 2)
8.4.1. Earthworm – sub-lethal effects	OECD Test Guideline 222: Earthworm Reproduction Test (<i>Eisenia fetida</i> / <i>Eisenia andrei</i>)	
8.4.2. Effects on non-target soil meso-and macrofauna (other than earthworms)	—	

Reference to Part A of the Annex to Regulation (EU) No 283/2013	Test methods ⁽¹⁾	Guidance documents ⁽²⁾
8.4.2.1. 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>	
8.5. 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)
8.6. Effects on terrestrial non-target higher plants	—	EU Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002 rev 2)
8.6.1. Summary of screening data	—	—
8.6.2. 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>	—
8.7. Effects on other terrestrial organisms (flora and fauna)	—	EU Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002 rev 2)
8.8. Effects on biological methods for sewage treatment	OECD Test Guideline 209: Activated Sludge, Respiration Inhibition Test	EU Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002 rev 2)
9. 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
10. 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 Commission 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/firs/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
 - http://ec.europa.eu/food/plant/pesticides/guidance_documents/mrls_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>

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- (3) http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/PestSpecsManual2010.pdf
- (4) OJ L 309, 24.11.2009, p. 1.
- (5) OJ L 353, 31.12.2008, p. 1.
- (6) EPPO standards are available at <http://pp1.eppo.int/> - 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.
- (7) OJ L 220, 24.8.2009, p. 1.
- (8) OJ L 324, 9.12.2010, p. 13.
- (9) <http://www.efsa.europa.eu/en/mrls/mrlteam.htm>
- (10) http://www.hc-sc.gc.ca/cps-spc/pubs/pest/_pol-guide/dir2006-01/index-eng.php
- (11) http://ec.europa.eu/food/fs/sc/scp/outcome_ppp_en.html
- (12) Prior to the adoption of the revised guideline, efforts to reduce the number of animals in the limit and main tests should be made as far as possible.
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