PLANT PROTECTION

Overview recent guidance documents

Information about recent technical and procedural guidance documents and their date of entry into force

Federal Public Service **Health, Food Chain Safety and Environment**
Service Plant protection products and Fertilizers

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DOCUMENT INFORMATION

http://fytoweb.be/en/guide/crop-protection/overview-recent-guidance-documents
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Technical EU guidance documents

Technical EU guidance documents	Date of entry into force as voted on the Standing Committee on Plants, Animals, Food and Feed	Concerned dossiers for the authorisation of plant protection products	Concerned dossiers for the approval of active substances for which Belgium is RMS
EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), 2013. Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters. EFSA Journal 2013;11(7):3290, 268 pp. doi:10.2903/j.efsa.2013.3290.	This document has been finalised in the Standing Committee on Plants, Animals, Food and Feed of July 10, 2014 and entered into force on January 1, 2015.	All new applications for authorisation, or for amendment or renewal of authorisations submitted by the industry to the FPS for Health from January 1, 2015 included. (*Note* : In the framework of amendments, e.g. extensions, only the amendment itself is subject to the application of the new guidance document) A combitox risk assessment has to be presented in the submission dossier at each renewal of approval of each active substance in the product (by renewal of approval, we understand the AIR process). The combitox is compulsory for the dossier submitted from 1st of June 2016, included. The combitox risk assessment applies to PPP containing more than one active substance. If a PPP contains a new active substance and an active substance renewed under the AIR process, the Applicant has to present an appropriate combitox risk assessment.	All applications for the approval, or for the amendment or renewal of the approval of active substances for which Belgium is the RMS, submitted to the FPS for Health from January 1, 2015 included. Concerning the applications for renewal of the approval, the deadline for the submission of the dossier as indicated in the Regulations of the Commission laying down the procedure for the renewal of the approval applies. (*Note* : In the framework of amendments, e.g. extensions, only the amendment itself is subject to the application of the new guidance document)

EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil. EFSA Journal 2014;12(5):3662, 37 pp., doi:10.2903/j.efsa.2014.3662	This document has been finalised in the Standing Committee on Plants, Animals, Food and Feed of December 12, 2014 and enters into force on May 1, 2015.	All new applications for authorisation, or for amendment or renewal of authorisations submitted by the industry to the FPS for Health from May 1, 2015 included. (*Note i*: In the framework of amendments, e.g. extensions, only the amendment itself is subject to the application of the new guidance document) (*Note ii*: Belgian authority will not require to update DT50soil/Koc values in line with the EFSA DegT50 guidance (2014) for the authorization of PPP's. Instead, the Belgian authority will continue to accept the agreed Annex I DT50/Koc endpoints. However, there is an exception: Applicants may update DT50soil/Koc values only if it is necessary to obtain the safe use of the GAP) (*Note iii*: Due to concerns over how the EFSA protected crops guidance document (2014) should be implemented, Applicants are requested to contact the Belgian authority for further advice on the application of this guidance document in the dossier where BE is zRMS. However, Applicants are required to prepare an elaborated proposal on how to make this assessment, which will be presented during the pre-submission meeting).	All applications for the approval, or for the amendment or renewal of the approval of active substances for which Belgium is the RMS, submitted to the FPS for Health from May 1, 2015 included. Concerning the applications for renewal of the approval, the deadline for the submission of the dossier as indicated in the Regulations of the Commission laying down the procedure for the renewal of the approval applies. (*Note i* : In the framework of amendments, e.g. extensions, only the amendment itself is subject to the application of the new guidance document) (*Note ii*: Due to concerns over how the EFSA protected crops guidance document (2014) should be implemented, Applicants are requested to contact the Belgian authority for further advice on the application of this guidance document. However, Applicants are required to prepare an elaborated proposal on how to make how to make this assessment, which will be presented during the pre-submission meeting).
European Commission (2014) "Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU" Report of the FOCUS Ground Water Work Group, EC Document Reference Sanco/13144/2010 version 3, 613 pp. Available on the website *https://esdac.jrc.ec.europa.eu/projects/focus-dg-sante.*	This document has been finalised in the Standing Committee on Plants, Animals, Food and Feed of October 9, 2014 and enters into force on May 1, 2015.		

EFSA Guidance Document on clustering and ranking of emissions of active substances of plant protection products and transformation products of these active substances from protected crops (greenhouses and crops grown under cover) to relevant environmental compartments. EFSA Journal 2014;12(3):3615, 43 pp., doi:10.2903/j.efsa.2014.3615.	This document has been finalised in the Standing Committee on Plants, Animals, Food and Feed of January 26, 2015 and enters into force on May 1, 2015. Please see also Communication Phytoweb January 25, 2017		
Generic Guidance for Tier 1 FOCUS GroundWater Assessments – version 2.2 – May 2014 Available on the website *https://esdac.jrc.ec.europa.eu/projects/focus-dg-sante.*	This document enters into force on May 1, 2015.		

Generic Guidance for FOCUS surface water Scenarios – version 1.4 – May 2015 Available on the website *https://esdac.jrc.ec.europa.eu/projects/focus-dg-sante.*	This document enters into force on May 1, 2015.		
Generic guidance for Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration – version 1.1 – 18 December 2014 Available on the website *https://esdac.jrc.ec.europa.eu/projects/focus-dg-sante.*	This document enters into force on May 1, 2015.		

Guidance Document on Botanical Active Substances used in Plant Protection Products	This document has been finalised in the Standing Committee on Plants, Animals, Food and Feed of March 20, 2014 and entered into force on October 1, 2014.	All new applications for authorisation, or for amendment or renewal of authorisations submitted by the industry to the FPS for Health from October 1, 2014 included. (Note : In the framework of amendments, e.g. extensions, only the amendment itself is subject to the application of the new guidance document)	All applications for the approval, or for the amendment or renewal of the approval of active substances for which Belgium is the RMS, submitted to the FPS for Health from October 1, 2014 included. Concerning the applications for renewal of the approval, the deadline for the submission of the dossier as indicated in the Regulations of the Commission laying down the procedure for the renewal of the approval applies. (*Note* : In the framework of amendments, e.g. extensions, only the amendment itself is subject to the application of the new guidance document)
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	This document has been finalised in the Standing Committee on Plants, Animals, Food and Feed of December 12, 2014 and enters into force on April 1, 2015.	All new applications for authorisation, or for amendment or renewal of authorisations submitted by the industry to the FPS for Health from April 1, 2015 included. (*Note* : In the framework of amendments, e.g. extensions, only the amendment itself is subject to the application of the new guidance document)	All applications for the approval, or for the amendment or renewal of the approval of active substances for which Belgium is the RMS, submitted to the FPS for Health from April 1, 2015 included. Concerning the applications for renewal of the approval, the deadline for the submission of the dossier as indicated in the Regulations of the Commission laying down the procedure for the renewal of the approval applies.

			(*Note* : In the framework of amendments, e.g. extensions, only the amendment itself is subject to the application of the new guidance document)
EPPO Standard PP1. The EPPO Standards for the efficacy evaluation of plant protection products (PP1) describe the conduct of trials carried out to assess the efficacy of plant protection products against specific pests. They are addressed to all institutions, official registration authorities, public institutes or private firms carrying out such trials. http://pp1.eppo.int/	At the date of first publication.	All	All
Adjuvant. French CEB Method MG08 and Technical Document DT22.	This document has been approved by the Belgian Committee for authorization of	All Adjuvants	All Adjuvants

http://www.afpp.net/Bases/methodesCEB/methodesRC.asp	PPP of May 23, 2014 and enters into force on May 23, 2014.		
EFSA 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, 55pp., doi:10.2903/j.efsa.2014.3874.	This document has been finalised in the Standing Committee on Plants, Animals, Food and Feed of May 29, 2015 and enters into force on January 1, 2016. A revision 1.7 has been finalised in the Standing Committee on Plants, Animals, Food and Feed of January 24, 2017. This revision 1.7 further clarifies the implementation schedule.	All new applications for authorisation, or for amendment or renewal of authorisations submitted to the FPS for Health from January 1, 2016 included. For applications submitted from March 1, 2017, the rev. 1.7 will apply. Consideration of acute exposure should only be made where an AAOEL has been established during an approval, review or renewal evaluation of an active substance, i.e. no acute operator, worker and bystander exposure assessments can be performed with the OPEX model where no AAOEL has been set. The guidance is well-developed in respect of operators and should be fully applied for the corresponding risk assessments, including the acute risk assessment where an AAOEL has been set. The guidance does not set out fully detailed higher-tier risk assessment schemes for bystanders or residents. However several risk management options are available for ad-hoc approaches for controlling risk or conducting a more refined assessment (note the EUROPOEM, old DE and UK models are not considered refinements) so there is no	All applications for the approval, or for the amendment or renewal of the approval of active substances for which Belgium is the RMS, submitted to the FPS for Health from January 1, 2016 included. For applications submitted from March 1, 2017, the rev. 1.7 will apply. Concerning the applications for renewal of the approval, the deadline for the submission of the dossier as indicated in the Regulations of the Commission laying down the procedure for the renewal of the approval applies. Consideration of acute exposure should only be made where an AAOEL has been established during an approval, review or renewal evaluation of an active substance, i.e. no acute operator, worker and bystander exposure assessments can be performed with the OPEX model where no AAOEL has been set. The guidance is well-developed in respect of operators and should be fully applied for the corresponding risk assessments, including the acute risk assessment where an AAOEL has been set.

		justification for a delay in implementation of bystander or resident assessments when it comes to chronic risk assessment. Bystander risk assessments, when not covered by the resident risk assessment, require an AAOEL to be set. So it is not possible to perform such assessments where an AAOEL value has not been established. The guidance does not contain suitable information to estimate acute worker exposure so without further development worker risks should only consider the longer risk assessment, using the AOEL.	The guidance does not set out fully detailed higher-tier risk assessment schemes for bystanders or residents. However several risk management options are available for ad-hoc approaches for controlling risk or conducting a more refined assessment (note the EUROPOEM, old DE and UK models are not considered refinements) so there is no justification for a delay in implementation of bystander or resident assessments when it comes to chronic risk assessment. Bystander risk assessments, when not covered by the resident risk assessment, require an AAOEL to be set. So it is not possible to perform such assessments where an AAOEL value has not been established. The guidance does not contain suitable information to estimate acute worker exposure so without further development worker risks should only consider the longer risk assessment, using the AOEL. (Note : In the framework of amendments, e.g. extensions, only the amendment itself is subject to the application of the new guidance document)
Long-term Combitox approach for Birds and Mammals	As the EFSA GD on Birds and Mammals actually does describe the steps that need to be taken to address the combined effects	All new applications for authorisation, or for amendment or renewal of authorisations	All applications for the approval, or for the amendment or renewal of the approval of active substances for which Belgium is the

of simultaneous exposure to several active substances (see Appendix B, EFSA GD on Birds and Mammals, taken note of in the Standing Committee in July 2012), it was agreed in the meeting of the Director's Consultation Group of the Central zone, of June 23, 2015 in Warsaw that, long-term combitox for birds and mammals should be assessed, and in the (draft) Registration Report a calculation of the long-term combitox risk according to the concentration addition (CA) model should be presented for tier 1 for dossier submitted from 1st of June 2016. If Tier 1 shows an unacceptable risk, further refinements have to be submitted.	submitted by the industry to the FPS for Health from 1st of June 2016 included. A combitox risk assessment has to be presented in the submission dossier at each renewal of approval of each active substance in the product (by renewal of approval, we understand the AIR process). The combitox is compulsory for the dossier submitted from 1st of June 2016, included. The combitox risk assessment applies to PPP containing more than one active substance. If a PPP contains a new active substance and an active substance renewed under the AIR process, the Applicant has to present an appropriate combitox risk assessment. (*Note* : The acute risk from combined exposure of active substances is addressed via the concentration addition model. The methodology to perform the long-term combitox risk assessment is as follows: a calculation of the long-term combitox risk according to the concentration addition (CA) model should be presented for tier 1. Refinement options and possible consequences are not clear yet, however: when the CA combitox assessment indicates no acceptable risk, applicants may present	RMS, submitted to the FPS for Health from 1st of June 2016 included. The combitox risk assessment applies to PPP containing more than one active substance.

		information to demonstrate that adverse effects of the actives are not similar.)	
Working Document of the Central Zone in the Authorisation of Plant Protection Products – Section 8 Environmental Fate and Behaviour Available via *https://circabc.europa.eu/d/d/workspace/SpacesStore/e4dac049-ae0e-4ea6-9dca-e8a7ef5e81c0/Working%20document%20of%20the%20central%20zone%20Environmental%20Fate%20-%20Ver%201.1.docx*	Version 1.0 (January 2016) of this document entered into force on July 1, 2016. Version 1.1 (June 2018) enters into force on December 1, 2018.	Version 1.0: All new zonal applications for authorisation, or for amendment or renewal of authorisations submitted by the industry to the FPS for Health from July 1, 2016 included. Version 1.1: All new zonal applications for authorisation, or for amendment or renewal of authorisations submitted by the industry to the FPS for Health from December 1, 2018 included. (*Note* : In the framework of amendments, e.g. extensions, only the amendment itself is subject to the application of the new guidance document)	/
Guidance document on semiochemical active substances and plant protection products	This document has been finalised in the Standing Committee on Plants, Animals, Food and Feed of May 19, 2016 and enters into force on January 1, 2017.	All new applications for authorisation, or for amendment or renewal of authorisations submitted to the FPS for Health from January 1, 2017 included.	All applications for the approval, or for the amendment or renewal of the approval of active substances for which Belgium is the RMS, submitted to the FPS for Health from January 1, 2017 included.

European Food Safety Authority, 2013. EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees). EFSA Journal 2013;11(7):3295, 268 pp., doi:10.2903/j.efsa.2013.3295	For the time being, the EFSA Bees guidance document has not yet been taken note of in the Standing Committee on Plants, Animals, Food and Feed. However, new data requirements on bees are applicable for dossiers submitted according to COMMISSION REGULATION (EU) No 284/2013. Therefore, the FPS for Health has published a procedure (see communication of February 2, 2017 on Phytoweb)	see document "Data requirements and risk assessment for bees – National approach for bees" of June 27, 2017 on Phytoweb (communication of July 5, 2017)	/
EFSA (European Food Safety Authority), 2017. Technical report on the outcome of the pesticides peer review meeting on the OECD 106 evaluators checklist. EFSA supporting publication 2017:EN-1326. 17 pp.doi:10.2903/sp.efsa.2017.EN-1326	Not discussed in Standing Committee on Plants, Animals, Food and Feed but useful tool to be used by Applicant/Regulatory Authority check the validity of the OECD 106 soil batch adsorption studies.	For all new OECD 106 soil batch adsorption studies submitted with all new applications for authorisation, or for amendment or renewal of authorisations submitted to the FPS for Health from January 1, 2018 included.	For all new OECD 106 soil batch adsorption studies submitted with all applications for the approval, or for the amendment or renewal of the approval of active substances for which Belgium is the RMS, submitted to the FPS for Health from January 1, 2018 included.
European Food Safety Authority, 2017. Guidance on dermal absorption.	This document has been finalised in the Standing Committee on Plants, Animals, Food and Feed	All new applications for authorisation, or for amendment or renewal of authorisations	All applications for the approval, or for the amendment or renewal of the approval of active substances for which Belgium is the

EFSA Journal 2017; 15(6):4873, 60 pp., doi: 10 2903/j.efsa.2017.4873 (update of Guidance of 2012)	of May 25, 2018 and enters into force on August 25, 2018.	submitted to the FPS for Health from August 25, 2018 included.	RMS, submitted to the FPS for Health from August 25, 2018 included.

Procedural guidance documents

Procedural Guidance Documents	Date of entry into force as voted on the Standing Committee on Plants, Animals, Food and Feed	Concerned dossiers for the authorisation of plant protection products	Concerned dossiers for the approval of active substances for which Belgium is RMS
Guidance Document on Zonal Evaluation and Mutual recognition under Regulation (EC) No 1107/2009 **(SANCO/13169/2010 rev 9)**	Rev. 9 of 11.07.2014 : Clarification regarding Art. 37(3) has been added in chapter 2.2.6.1. Entry into force : this guidance document is already in force	Please refer to this guidance for the concerned applications.	/
Guidance Document on the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009 **(SANCO/2010/13170 rev. 14)**	Rev. 14 of 07.10.2016 Update based on first experience gained : notifications, list of studies relied upon, lists of end-points, data matching and specification checks, Cat. 4 data processes. Entry into force : January 1, 2017	All applications for renewal of authorisations based on active substances for which approval is renewed under the Regulation (EC) No 1107/2009, and where safe uses have been demonstrated.	/

Technical guidelines on the presentation and evaluation of plant protection product dossiers in the format of a (draft) Registration Report **(SANCO/6895/2009 rev 2.2)** **+ Annexes (dRR templates, with report/without report)**	Rev 2.2 of 26 January 2018 Entry into force : this guidance document is already in force	This GD provides advice to applicants to help them prepare submissions for authorisation of plant protection products in the zonal process (new product and renewal). This document is also recommended for mutual recognition applications and other national applications. The templates should be used for all applications for authorisation, amendment of authorisation and renewal of authorisation of plant protection products.	/
Guidance document concerning the parallel trade of plant protection products **(SANCO/10524/2012 VERS.5.2)**	Vers. 5.2 of 14.07.2015 Amendment of the paragraph concerning Parallel trade of parallel traded products Entry into force : this guidance document is already in force	Application for a permit for parallel trade of a plant protection product	/

Guidance document on the Interpretation of the Transitional Measures for the Data Requirements for Chemical Active Substances and Plant Protection Products according to Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013 **(SANCO/11509/2013 rev. 5.2)**	Rev. 5.2 of 09.10.2015 : Reference is made to Regulation (EU) No 1136/2014. Some clarifications and editorial changes have been made. Entry into force : this guidance document is already in force	All new applications for authorisation, or for amendment or renewal of authorisations submitted by the industry to the FPS for Health. (Note : In the framework of amendments, e.g. extensions, only the amendment itself is subject to the application of the new guidance document)	All applications for the approval, or for the amendment or renewal of the approval of active substances for which Belgium is the RMS, submitted to the FPS for Health. Concerning the applications for renewal of the approval, the deadline for the submission of the dossier as indicated in the Regulations of the Commission laying down the procedure for the renewal of the approval applies. (Note : In the framework of amendments, e.g. extensions, only the amendment itself is subject to the application of the new guidance document)

Guidance Document for applicants on preparing dossiers for the approval or renewal of approval of microorganisms including viruses according to Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013 **(SANCO/ 12545/2014 rev. 2)** **March 2016**	March 2016 (rev. 2) : Clarification about the ToC for the dossier. Inclusion of the EU numbering system Entry into force of the revision : 1 October 2016.	/	All applications for the approval, or for the amendment or renewal of the approval of active substances which are micro-organisms as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market for which Belgium is the RMS, submitted to the FPS for Health from October 1, 2016 included. Concerning the applications for renewal of the approval, the deadline for the submission of the dossier as indicated in the Regulations of the Commission laying down the procedure for the renewal of the approval applies. (Note : In the framework of amendments, e.g. extensions, only the amendment itself is subject to the application of the new guidance document)

Template for Submission Demonstrating Access to a Complete Package According to Regulation (EU) 283/2013 and for the Data Matching Step **SANTE/2016/11449** **7 December 2016**	1 March 2017	This template should be used for applications for product authorisations or renewals	/