

GUIDANCE ON THE TECHNICAL REQUIREMENTS FOR THE SECTION ECOTOXICOLOGY

**Guidance for the applicant for the authorisation of a plant protection
product in Belgium**



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DOCUMENT INFORMATION

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Document history

| Version | Comments | Date |
|--------------------|---|----------------|
| Version 2.0 | Full update of the original guidance document, updating hyperlinks and adding references to national guidance documents | September 2017 |
| Version 2.1 | New Section on Combitox risk assessment under headings 'Birds and mammals' and 'Aquatic organisms' | January 2018 |
| Version 2.2 | General update, minor adaptations | April 2019 |

1. Introduction

This guidance for the Applicant concerning the technical requirements for the Section Ecotoxicology aims to provide references to the relevant legislation and guidance documents, and recommendations for the risk assessment when drawing up the ecotoxicological part of the application dossier for a Plant Protection Product (PPP). This guidance does not replace the legislation in force.

The legislation pertaining to the authorization of a PPP is set out in Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing on the market of PPPs and repealing Council Directives 79/117/EEC and 91/414/EEC.

The data requirements are laid down in Commission Regulation (EU) No 283/2013 for active substances and in Commission Regulation (EU) No 284/2013 for PPP. The *Commission communications*, provided in the framework of the implementation of these data requirements, list the test methods and guidance documents to be followed and models to be used. Additionally, an overview of the most recent guidelines and their date of entry into force are published on Phytoweb.

SUPPORTING DOCUMENTS

EU legislation on PPPs:

http://ec.europa.eu/food/plant/pesticides/approval_active_substances/eu_rules/index_en.htm

Overview recent guidance documents: <http://fytoweb.be/en/guide/crop-protection/overview-recent-guidance-documents>

Following the zonal procedure, described in Regulation No 1107/2009, one *core* dossier is evaluated and finalised per zone by the zonal rapporteur member state after peer review by the concerned member states. Additionally, each member state may impose national requirements accounting for member state specific issues and concerns. An overview of these national requirements for each member state of the Central Zone is listed on Phytoweb.

SUPPORTING DOCUMENTS

National requirements for each member state of the Central Zone: <http://fytoweb.be/en/guide/crop-protection/national-requirement-member-state-central-zone>

2. Recommendations for non-target organisms

In addition to the information provided in the pertinent EU guidance documents, this section contains recommendations for the risk assessment for all non-target organisms. Furthermore, additional Belgian national refinement options, such as the use of risk mitigation measures to protect non-target organisms are described.

2.1 Birds and mammals

2.1.1 Guidelines

For all dossiers submitted as of 1st July 2010, bird and mammal risk assessments should be conducted according to the new EFSA Guidance document on risk assessment for birds and mammals (EFSA, 2009)¹. However, when the active substance is evaluated following the recommendations of the SANCO Guidance document on risk assessment for birds and mammals under Council Directive 91/414/EEC (SANCO/4145/2000, Sept 2002), it is up to the applicant to choose which guidance document will be followed in the registration report for the formulated product.

SUPPORTING DOCUMENTS

Risk assessment for birds and mammals (EFSA, 2009): <http://www.efsa.europa.eu/en/efsajournal/pub/1438>

Risk assessment for birds and mammals under Council Directive 91/414/EEC (SANCO/4145/2000, September 2002): https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_ecotox_ra_birds-mammals.pdf

2.1.2 Combitor

For products containing more than one active substance, the acute and longterm risk from combined exposure of active substances need to be addressed via the Concentration Addition (CA) Model, according to the EFSA Guidance Document (EFSA, 2009). Between the member

¹ European Food Safety Authority; Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA. EFSA Journal 2009; 7(12):1438. Doi:10.2903/j.efsa.2009.1438. Available online: www.efsa.europa.eu
www.phytoweb.be

states of the Central Zone it was agreed that the longterm combitox according to the CA model should be presented in the core dRR Part B for Tier 1 from **1st of June 2016**.

Concerning the applications for renewal of the approval of authorisations, no harmonised approach has been agreed in the Central Zone on when the combitox assessment should be present in the dossier. Therefore, a national approach is followed. 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 of the active substance, we understand the AIR process). The combitox is compulsory for the dossier submitted from 1st of June 2016, included. 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.

2.1.3 Moving Time Window

In case of multiple applications, the non-constant long-term exposure in the assessment for birds and mammals generally is converted to constant exposure by the use of a Multiple Application Factor (MAF) and an ftwa (time weighted average factor). However, this approach only yields reliable results for certain combinations of unchanging application rates, intervals and DT₅₀ values. In particular for changing rates and intervals, the moving time window approach is recommended to determine the appropriate MAF_m x TWA for the risk assessment (EFSA Guidance Document, Appendix H, 2009). This approach will often lead to higher TWA concentrations than the use of separate MAF and TWA factors, and should thus be considered as a worst-case.

During the Central Zone harmonization workshops in ecotoxicology (2014-2015), it was agreed among the member states to apply the moving time window approach in the second tier. Nevertheless, if the applicant wishes to use it already in the first tier, this can also be accepted, since it is considered as a worst-case approach.

Excel spreadsheets have been developed by Belgium and Germany. Both tools are considered acceptable at zonal level, since they produce the same results.

As default a 21 days period should be used, unless another period is mentioned in the DAR of the active substance.

SUPPORTING DOCUMENTS

Belgian calculation tool for moving time window: <http://fytoweb.be/en/guide/crop-protection/guidance-ecotoxicology>

2.1.4 Risk mitigation measures

If a high risk from a seed treatment is predicted, labelling should instruct the immediate removal of spills. As a result, the risk might in some cases be considered acceptable. Furthermore, it may be appropriate to consider that the seed be drilled or incorporated immediately after application (EFSA, 2009)². Therefore, risk phrases to impose these risk mitigation measures may be mentioned on the label.

² European Food Safety Authority; Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA. EFSA Journal 2009; 7(12):1438. Doi:10.2903/j.efsa.2009.1438. Available online: www.efsa.europa.eu

2.2 Aquatic organisms

2.2.1 Guidelines

For all new applications for authorisation or for amendment or renewal of authorisations submitted as of 1st January 2015, the aquatic risk assessment should be conducted according to the new EFSA Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters (EFSA, 2013)³. This Guidance document has been published as a revision of the SANCO Guidance document on Aquatic Ecotoxicology under Council Directive 91/414/EEC (SANCO/3268/2001 rev. 4 (final) – 17 October 2002).

SUPPORTING DOCUMENTS

Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters (EFSA, 2013): <http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2013.3290/abstract>

Guidance document on Aquatic Ecotoxicology under Council Directive 91/414/EEC (SANCO/3268/2001 rev. 4 (final) – 17 October 2002): http://www.hse.gov.uk/pesticides/resources/A/Aquatic_Ecotox_3268_rev4_final.pdf

2.2.2 Combitor

For products containing more than one active substance, the mixture toxicity needs to be addressed via the Concentration Addition (CA) Model, according to the EFSA Guidance Document (EFSA, 2013). The combitor assessment is compulsory for the dossiers submitted from **1st of June 2016**, included.

Concerning the applications for renewal of the approval of authorisations, no harmonised approach has been agreed in the Central Zone on when the combitor assessment should be present in the dossier. Therefore, a national approach is followed. A combitor 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 of the active substance, we understand the AIR process). The combitor is compulsory for the dossier submitted from 1st of June 2016, included. If a PPP contains a new active substance and an active substance renewed under the AIR process, the applicant has to present an appropriate combitor risk assessment.

³ 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. Available Online : www.efsa.europa.eu/efsajournal

An Excel spreadsheet and supporting .docx document are available on phytoweb, which can be used to assess the mixture toxicity.

SUPPORTING DOCUMENTS

Calculation tool and supporting .docx document for mixture toxicity: <http://fytoweb.be/en/guide/crop-protection/guidance-ecotoxicology>

2.2.3 Risk mitigation measures

Risk mitigation measures may be imposed in order to reduce the risk to aquatic organisms. These risk mitigation measures include no-spray buffer zones (untreated zones), or no-spray buffer zones in combination with drift-reducing techniques (such as drift-reducing nozzles, hedges,...) and/or an SPe2 phrase, for parcels sensitive to erosion, on the label. Usually, when a vegetated buffer strip is necessary to achieve an acceptable risk to surface water, this translates into a no-spray buffer zone (of the same width) and the mention of the SPe2 phrase on the label.

If needed, vegetated buffer strips towards surface water have to be respected. See for example the news of 04/10/2016 on Phytoweb, concerning the obligation to respect a 20 m **vegetated buffer strip** towards surface water for products containing terbuthylazine. Information on the practical aspects concerning the installation of a 20 m vegetated buffer strip for products containing terbuthylazine are available in the document on frequently asked questions on the vegetated buffer zones for products containing terbuthylazine, which is published on Phytoweb (only available in Dutch and French).

Reference is made to the brochure on the protection of surface water, which is published on Phytoweb (only available in Dutch and French). This brochure provides detailed information on the application of risk mitigation measures to protect aquatic organisms, including a list of the possible risk mitigation measures for each type of application, the risk phrases which indicate the need for risk mitigation measures, and drift-reducing equipment which is approved by the Federal Public Service.

In some cases, risk mitigation measures may be imposed for aquatic organisms as well as for non-target arthropods and/or non-target plants. As a consequence, a combination of both risk mitigation measures is mentioned on the label and on the registration certificate, and should be carefully followed. Reference is made to the brochure on the protection of non-target arthropods and non-target plants, which is published on Phytoweb (only available in Dutch and French). This brochure provides detailed information on the application of risk mitigation measures to protect non-target arthropods and non-target plants, including a list of all possible risk mitigation

measures for each type of application, the risk phrases which indicate the need for risk mitigation measures, and practical examples on the combination of risk mitigation measures imposed to protect aquatic organisms on the one hand and non-target arthropods and/or non-target plants on the other hand.

Note that - in application of Articles 5 to 9 of the Royal Decree of 19 March 2013 concerning the sustainable use of PPPs and adjuvants - minimum non-treatment zones with respect to surface water have to be taken into account in all circumstances: a buffer zone of minimum 1 meter applies for vertically downward spraying applications (e.g., applications in field crops) and for other application methods where exposure of non-target aquatic organisms can occur (e.g., granular applications) and a buffer zone of minimum 3 meter applies for other than vertically downward spraying applications (e.g., applications in orchards).

To alert the user to the need for risk mitigation measures (minimal buffer zones or additional risk mitigation measures) to protect aquatic organisms, an SPe3 and/or an SPe2 sentence is put on the label and the registration certificate.

SUPPORTING DOCUMENTS

Bescherming van het oppervlaktewater bij het gebruik van gewasbeschermingsmiddelen (NL):

<http://fytoweb.be/nl/handleiding/gewasbescherming/bescherming-van-het-oppervlaktewater-bij-het-gebruik-van>

Protection des eaux de surface lors de l'utilisation de produits phytopharmaceutiques (FR):

<http://fytoweb.be/fr/guides/phytoprotection/protection-des-eaux-de-surface-lors-de-lutilisation-de-produits>

Terbuthylazine: News of 04/10/2016 (NL): <http://fytoweb.be/nl/nieuws/terbuthylazin-de-met-gras-begroeide-bufferzone-blijft-van-toepassing>

Terbuthylazine: News of 04/10/2016 (FR): <http://fytoweb.be/fr/nouvelles/terbuthylazine-la-bande-enherbee-toujours-dapplication>

Terbuthylazine, met gras begroeide bufferzone: veelgestelde vragen (FAQ) (NL):

<http://fytoweb.be/nl/handleiding/gewasbescherming/terbuthylazin-met-gras-begroeide-bufferzone-veelgestelde-vragen-faq>

Terbuthylazine, bande enherbée : questions fréquentes (FAQ) (FR):

<http://fytoweb.be/fr/guides/phytoprotection/terbuthylazine-bande-enherbee-questions-frequentes-faq>

2.3 Bees

2.3.1 Guidelines

The risk assessment for bees should be performed as described in the currently agreed SANCO Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC (SANCO/10329/2002 rev 2 final, 17 October 2002). Additionally, a new EFSA Guidance document on the risk assessment of plant protection products on bees (EFSA, 2013)⁴ is available, but there has not yet been a take note of this guidance document in the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF). However, chronic toxicity studies for adult honeybees and honeybee larvae need to be submitted according to Regulation (EU) No. 284/2013. Since no agreed Guidance Document is available at this moment, it is unclear how these studies should be used in the risk assessment for zonal authorisations. Thus, a Belgian national approach was proposed, which was accepted by the Belgian Authorisation Committee on 08-11-2016. A document describing this Belgian national approach is published on Phytoweb, and provides an overview of:

- the exact data requirements for an application for authorisation of a PPP in Belgium;
- how the risk assessment should be performed, i.e. which guidance document needs to be used in the risk assessment for bees in the product evaluation for Belgium.

This national procedure needs to be followed for every new application for authorisation. It should be noted that it is considered as a temporary solution, until there is an agreement on a harmonized approach within the Central Zone or within the EU. BE will fully support any discussion to come to such a harmonized approach for bees.

SUPPORTING DOCUMENTS

Belgian National approach on risk assessment of bees : <http://fytoweb.be/en/guide/crop-protection/data-requirements-and-procedure-risk-assessment-bees>

Guidance document on Terrestrial Ecotoxicology under Council Directive 91/414/EEC (SANCO/10329/2002 rev 2 final, 17 October 2002): https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_ecotox_terrestrial.pdf

⁴ EFSA (2013). Guidance on the risk assessment of plant protection products on bees (*Apis Mellifer*, *Bombus* spp. and solitary bees). EFSA Journal 2013; 11(7):3295. Doi:10.2903/j.efsa.2013.3295

2.3.2 Risk mitigation measures

In order to reduce effects on bees within the cropped area, different restrictions can be imposed. This is done by mentioning a phrase (SPe8) on the label that restricts the use of a PPP during a specific period of time.

Additional measures are imposed for the protection of bees and other pollinating insects. These are described in a number of news reports, which are published on Phytoweb (only available in Dutch and French).

SUPPORTING DOCUMENTS

List of news reports related to bees and other pollinating insects, published on Phytoweb:

<http://fytoweb.be/en/plant-protection-products/use/bees>

2.4 Non-target arthropods other than bees

2.4.1 Guidelines

The risk assessment for non-target arthropods other than bees (NTA) should be performed as described in the currently agreed SANCO Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC (SANCO/10329/2002 rev. 2 final, 17 October 2002), which follows the recommendations made during the ESCORT II workshop (Candolfi et al., 2001)⁵.

SUPPORTING DOCUMENTS

Guidance document on Terrestrial Ecotoxicology under Council Directive 91/414/EEC (SANCO/10329/2002 rev 2 final, 17 October 2002): https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_ecotox_terrestrial.pdf

2.4.2 Risk mitigation measures

If unacceptable effects to NTA species within off-field areas are predicted, the exposure to these species can be reduced by different measures. In Belgium, only drift-reducing application techniques (such as drift-reducing nozzles, hedges,...) are implemented for practical reasons.

Reference is made to the brochure on the protection of surface water and the brochure on the protection of non-target arthropods and non-target plants, which are published on Phytoweb (only available in Dutch and French). These brochures provide detailed information on the application of risk mitigation measures to protect aquatic organisms, non-target arthropods and non-target plants, including a list of all possible risk mitigation measures for each type of application, the risk phrases which indicate the need for risk mitigation measures, and drift-reducing equipment which is approved by the Federal Public Service, and practical examples on the combination of risk mitigation measures imposed to protect aquatic organisms on the one hand and non-target arthropods and/or non-target plants on the other hand.

Recommendations for calculating risk mitigation measures for professional uses are given in the e-Fate guidance document, which is published on Phytoweb.

⁵ Candolfi MP, Barrett KL, Campbell PJ, Forster R, Grandy N, Huet MC, Lewis G, Oomen PA, Schmuck R and Vogt H, 2001: Guidance document on regulatory testing and risk assessment procedures for plant protection products with non-target arthropods. Report of the SETAC/Escort 2 workshop, Wageningen, the Netherlands, and SETAC-Europe, Brussels, Belgium.

To alert the user to the need for risk mitigation measures to protect non-target arthropods and non-target plants, an SPe3 sentence is written on the label and the registration certificate.

SUPPORTING DOCUMENTS

Bescherming van niet tot de doelsoorten behorende geleedpotigen/insecten en niet doelwitplanten bij het gebruik van gewasbeschermingsmiddelen en gevolgen voor het oppervlaktewater (NL):

<http://fytoweb.be/nl/handleiding/gewasbescherming/driftreducerende-maatregelen-voor-niet-tot-de-doelsoorten-behorende>

Protection des arthropodes/insectes non-ciblés et des plantes non-ciblées lors de l'utilisation des produits phytopharmaceutiques et conséquences pour l'eau de surface (FR):

<http://fytoweb.be/fr/guides/phytoprotection/mesures-de-reduction-de-la-derive-pour-les-arthropodesinsectes-non-cibles-et>

Guidance on the technical requirements for the section fate and behaviour in the environment:

<http://fytoweb.be/en/plant-protection-products/authorisation-procedure/technical-requirements/fate-and-behaviour>

2.4.3 IPM communication arthropods

Previously, additional national data requirements were imposed for crops grown according to the principles of Integrated Pest Management (IPM). The Authorisation Committee decided to no longer impose national requirements for the approval of PPPs in support of integrated cropping.

This measure follows the general principle of leaving the application of IPM entirely to the authorities at regional level, which are responsible for IPM policy. Additionally, it contributes to harmonization of the evaluation procedure at zonal level.

2.5 Earthworms and other soil macro-organisms

2.5.1 Guidelines

The risk assessment for earthworms and other soil macro-organisms should be performed as described in the currently agreed SANCO Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC (SANCO/10329/2002 rev. 2 final, 17 October 2002).

SUPPORTING DOCUMENTS

Guidance document on Terrestrial Ecotoxicology under Council Directive 91/414/EEC (SANCO/10329/2002 rev 2 final, 17 October 2002): https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_ecotox_terrestrial.pdf

2.6 Soil micro-organisms

2.6.1 Guidelines

The risk assessment for soil micro-organisms should be performed as described in the currently agreed SANCO Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC (SANCO/10329/2002 rev. 2 final, 17 October 2002).

SUPPORTING DOCUMENTS

Guidance document on Terrestrial Ecotoxicology under Council Directive 91/414/EEC (SANCO/10329/2002 rev 2 final, 17 October 2002): https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_ecotox_terrestrial.pdf

2.7 Non-target terrestrial higher plants

2.7.1 Guidelines

The risk assessment for non-target terrestrial higher plants should be performed as described in the currently agreed SANCO Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC (SANCO/10329/2002 rev. 2 final, 17 October 2002).

SUPPORTING DOCUMENTS

Guidance document on Terrestrial Ecotoxicology under Council Directive 91/414/EEC (SANCO/10329/2002 rev 2 final, 17 October 2002): https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_ecotox_terrestrial.pdf

2.7.2 Risk mitigation measures

The same principles regarding risk mitigation measures apply as described for non-target arthropods other than bees under 2.4.2.

3. Specific data requirements

3.1 Non-professional uses (home and garden uses)

In case of zonal applications for non-professional uses, the core should include a full risk assessment covering for all member states of the Central Zone.

Furthermore, the national data requirements for non-professional PPPs are described in the amateur use Guidance document, which is published on Phytoweb (only available in Dutch and French).

Recommendations for calculating buffer zones as a risk mitigation measure for non-professional uses are given in the e-Fate guidance document, which is published on Phytoweb.

SUPPORTING DOCUMENTS

Gids toelating amateurgebruik (NL): <http://fytoweb.be/nl/handleiding/gewasbescherming/gids-toelating-gewasbeschermingsmiddelen-voor-amateurgebruik>

Guidance autorisation usage amateur (FR): <http://fytoweb.be/fr/guides/phytoprotection/guide-autorisation-de-produits-pour-un-usage-amateur>

Guidance on the technical requirements for the section fate and behaviour in the environment:
<http://fytoweb.be/en/plant-protection-products/authorisation-procedure/technical-requirements/fate-and-behaviour>

3.2 Adjuvants

The national data requirements for adjuvants are described in the Guidance document, which is published on Phytoweb.

SUPPORTING DOCUMENTS

Requirements for the authorisation of adjuvants : <http://fytoweb.be/en/guide/crop-protection/requirements-authorisation-adjuvants>

3.3 Protected crops

Reference is made to the EFSA technical report on general recurring issues in ecotoxicology (2015)⁶. For additional guidance on national evaluation of the risk assessment, please refer to the guidance document on the environmental risk assessment of PPPs emitted from protected crops, which is published on Phytoweb.

SUPPORTING DOCUMENTS

Emissions form protected crops to the environment in Belgium: <http://fytoweb.be/en/guide/crop-protection/application-european-guidance-concerning-emissions-protected-crops-environment>

EFSA technical report on general recurring issues in ecotoxicology:
<http://onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2015.EN-924/epdf>

⁶ EFSA (European Food Safety Authority), 2015. Technical report on the outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology. EFSA supporting publication 2015:EN-924. 62 pp.

4. Recurring issues

4.1 Confirmatory data vs. EFSA data gaps

For guidance, reference is made to the e-fate guidance document, which is published on Phytoweb.

SUPPORTING DOCUMENTS

Guidance on the technical requirements for the section fate and behavior in the environment:
<http://fytoweb.be/en/plant-protection-products/authorisation-procedure/technical-requirements/fate-and-behaviour>