

# GUIDANCE ON THE TECHNICAL REQUIREMENTS FOR THE SECTION FATE AND BEHAVIOUR IN THE ENVIRONMENT

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



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## DOCUMENT INFORMATION

Guidance on the technical requirements for the section Fate and  
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# Table of Contents

1.	Introduction .....	5
2.	Recommendations for each environmental compartment.....	7
2.1	Soil .....	7
2.1.1	General.....	7
2.1.2	Calculation tools for PEC in soil.....	7
2.1.3	Accumulation in soil.....	8
2.1.4	Formulation PEC in soil .....	8
2.2	Groundwater .....	8
2.2.1	General.....	8
2.2.2	Zonal assessment (Central Zone).....	8
2.2.3	National assessment (Belgium).....	9
2.2.4	Crop interception values.....	9
2.3	Surface water and sediment .....	9
2.3.1	General.....	9
2.3.2	Zonal assessment (Central Zone).....	10
2.3.3	National assessment (Belgium).....	10
2.4	Air .....	13
3.	Specific data requirements .....	14
3.1	Use in protected crops .....	14
3.2	Use on hardened surfaces.....	14
3.3	Non-professional uses (home and garden uses).....	15
3.4	Adjuvants.....	16
4.	Recurring issues .....	17
4.1	New active substance data vs. EU agreed endpoints .....	17
4.2	Confirmatory data vs. EFSA data gaps .....	17
4.3	Revised DT50 values 1,2,4-triazole .....	18
4.4	Spot application.....	18
4.5	Conversion factors for vertical crops .....	19



# 1. Introduction

This guidance for the Applicant concerning the technical requirements for the Section Fate and Behaviour in the Environment aims to provide references to the relevant legislation and guidance documents, recommendations for the risk assessment and clarifications on recurring issues when drawing up the environmental fate part of the application dossier. This guidance does not replace the legislation in force.

The legislation pertaining to the authorisation of a plant protection product 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 plant protection products and repealing Council Directives 79/117/EEC and 91/414/EEC.

Applications for authorisation are evaluated in the light of the uniform principles, as set out in Regulation (EU) No. 546/2011. Principles on decision-making concerning fate and behaviour in the environment are specified in Part I C, section 2.5.1 and Part II C, section 2.7 of the Annex.

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 plant protection products. 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:

- Associated Communication to Commission Regulation (EU) No 283/2013: [https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52023XC0929\(02\)](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52023XC0929(02))
- Associated Communication to Commission Regulation (EU) No 284/2013: [https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52023XC0929\(01\)](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52023XC0929(01))

For predicting the expected concentrations (PEC values, 'Predicted Environmental Concentrations') in each environmental compartment, the guidance documents and recommendations from the FOCUS group concerning the environmental fate and behaviour have to be followed. These documents are available on the FOCUS website:

[esdac.jrc.ec.europa.eu](https://esdac.jrc.ec.europa.eu). All other guidance documents are available via the website of DG Health and Food Safety from the European

Commission: [https://food.ec.europa.eu/plants/pesticides/approval-active-substances-safeners-and-synergists/guidelines-active-substances-and-plant-protection-products\\_en](https://food.ec.europa.eu/plants/pesticides/approval-active-substances-safeners-and-synergists/guidelines-active-substances-and-plant-protection-products_en). Test methods are available on the OECD website: <http://www.oecd-ilibrary.org/books>. An overview on the most recent guidance documents and their date of entry into force is available on Phytoweb: <http://fytoweb.be/en/guide/crop-protection/overview-recent-guidance-documents>.

In order to improve the harmonisation within the Central Zone, the Central Zone Steering Committee noted a working document for the section Environmental Fate and Behaviour. This document includes recommendations for drafting the core assessment in the case of zonal applications. The first version of this document (version 1.0) is into force since the 1<sup>st</sup> of July 2016. An updated version (version 1.1) has been published in June 2018 and enters into force by the 1<sup>st</sup> of December 2018.

This working document is available in the public part of the European database CIRCABC:

- Version 1.0 (January 2016):  
<https://circabc.europa.eu/sd/a/530da147-7196-4e39-b2f6-b764e6815546/Working%20document%20of%20the%20central%20zone%20Environmental%20Fate%20-%20Ver%201%20January%202016.docx> ;
- Version 1.1 (June 2018):  
<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>.

## 2. Recommendations for each environmental compartment

This section contains recommendations –in addition to the pertinent EU guidance documents– for the risk assessment for each environmental compartment. Furthermore, the models accepted in Belgium for estimating the expected concentrations in the environment are specified.

### 2.1 Soil

#### 2.1.1 General

The maximum acceptable PEC values in soil are determined by the ecotoxicological values for non-target organisms. More information is available in the section Ecotoxicology on [www.phytoweb.be](http://www.phytoweb.be).

In accordance with the Uniform Principles, it has to be demonstrated for persistent molecules (active substance and/or metabolites) that under field conditions there is no accumulation in soil at such levels that unacceptable residues in succeeding crops occur and/or that unacceptable phytotoxic effects on succeeding crops occur and/or that there is an unacceptable impact on the environment.

#### 2.1.2 Calculation tools for PEC in soil

Excel sheets allow to carry out soil exposure calculations. Estimations of the concentrations in soil can be made for multiple applications within one season or repeated applications over multiple years of a persistent substance (accumulation).

The basic Excel sheet is available on Phytoweb: <http://fytoweb.be/en/guide/crop-protection/spreadsheet-pecs>. Another spreadsheet for the calculation of multiple applications and accumulation PEC in soil is available on the website of the Chemicals Regulation Directorate (CRD) from the United Kingdom: <https://www.hse.gov.uk/pesticides/data-requirements-handbook/fate/environmental-fate-models.htm>

As indicated in the FOCUS guidance document on estimating persistence and degradation kinetics (Sanco/10058/2005 v.2.0), other tools can be used to estimate the concentrations in

soil, such as the ESCAPE tool (available at the German authorities) for determining the concentration in soil of active substances with a kinetic other than single first order (SFO).

### 2.1.3 Accumulation in soil

In accordance with SANCO/9188/VI/97 rev.8 (European Commission, 2000), the accumulated plateau concentration in soil has to be calculated for persistent substances. If applicable, a ploughing depth of 20 cm can be taken into account. The worst-case accumulation PEC in soil is then calculated by adding the initial PEC following a single-year application over 5 cm to the background carryover concentration over 20 cm.

For crops where the ground will not be ploughed (e.g. permanent crops), the worst-case accumulation PEC in soil has to be calculated over a 5 cm soil layer.

### 2.1.4 Formulation PEC in soil

The PEC in soil for the formulation needs to be calculated if this is required by the ecotoxicological risk assessment. The calculations of the PEC in soil for the formulation may be based on the maximum single application load on soil, unless a toxic co-formulant shows indications of persistence.

## 2.2 Groundwater

### 2.2.1 General

The maximum permissible concentration in groundwater is 0.1 µg/L for active substances and relevant metabolites, with a maximum of 0.5 µg/L for the sum of all individual pesticides. The guidance document SANCO/221/2000-rev.11 has to be followed for the assessment of the relevance of metabolites in groundwater.

### 2.2.2 Zonal assessment (Central Zone)

For zonal evaluations (applications submitted under Regulation (EC) No 1107/2009) with Belgium as zonal Rapporteur Member State, simulations have to be carried out for all European standard scenarios considered relevant for the Central Zone (Châteaudun, Hamburg, Kremsmünster, Okehampton, Piacenza and Porto). The modelling has to be conducted according to the recommendations of the Working document for the Central Zone (<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](https://esdac.jrc.ec.europa.eu/projects/ground-water/e8a7ef5e81c0/Working%20document%20of%20the%20central%20zone%20Environmental%20Fate%20-%20Ver%201.1.docx)).

More information (guidance documents, FOCUS PEARL software) is available on the FOCUS GW website: <http://esdac.jrc.ec.europa.eu/projects/ground-water>.

### 2.2.3 National assessment (Belgium)

For the authorisation of plant protection products in Belgium, the FOCUS PEARL model has to be used in combination with the European standard scenarios considered as representative for Belgian conditions (Châteaudun, Hamburg, Kremsmünster and Okehampton) to estimate the expected concentrations in the groundwater.

### 2.2.4 Crop interception values

The crop interception values from Appendix C of the EFSA Guidance Document to obtain DegT50 values (EFSA Journal 2014;12(5):3662) should be used, which are also listed in the Generic Guidance for Tier 1 FOCUS Ground Water Assessments (from Version 2.2 onwards). These values are only valid for applications made directly to the crop. Examples where these data do not apply include herbicide applications made beneath orchard crops and vines.

For the use of herbicides in pre-sowing weed control, in cereal stubbles or tree trunks, a weed cover of maximum 10% can be assumed, except when the treatment is preventive (pre-emergence of the weeds). In the latter case, an interception of 0% has to be assumed.

## 2.3 Surface water and sediment

### 2.3.1 General

The maximum acceptable PEC values in surface water and sediment are determined by the ecotoxicological values for aquatic organisms. More information is available in the section Ecotoxicology on [www.phytoweb.be](http://www.phytoweb.be).

The FOCUS Surface Water modules Steps 1 till 4 have to be used for the estimation of the expected concentrations in surface water and sediment.

### 2.3.2 Zonal assessment (Central Zone)

For zonal evaluations (applications submitted under Regulation (EU) No. 1107/2009) with Belgium as zonal Rapporteur Member State, simulations have to be carried out for all European standard scenarios considered relevant for the Central Zone (D3, D4, D5, R1, R3 and R4). The modelling has to be conducted according to the recommendations of the Working document for the Central Zone (<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>).

More information (guidance documents, FOCUS software Steps 1-2, SPIN, SWASH, MACRO, PRZM, TOXSWA and SWAN) can be found on the FOCUS SW website: <http://esdac.irc.ec.europa.eu/projects/surface-water>.

### 2.3.3 National assessment (Belgium)

For the authorisation of plant protection products in Belgium, the FOCUS models have to be used in combination with the European standard scenarios considered as representative for Belgian conditions (D3, D4 and R1) to estimate the expected concentrations in the surface water and sediment.

When a crop is not included in the list of relevant scenarios, the user should select a crop resembling the intended crop based on expert judgment. The choice of crop should be justified.

#### Mitigation measures in Belgium

The brochure on surface water risk mitigation (available on <https://fytoweb.be/nl/gewasbeschermingsmiddelen/gebruik/professionele-gebruiker/watercontaminatie>, in Dutch and French only), which is intended for the user, defines the risk mitigation measures to protect surface water, practical instructions and drift-reducing equipment which are recognized by the Federal Public Service.

Following Articles 5 to 9 of the Royal Decree of 19 March 2013 concerning the sustainable use of plant protection products and adjuvants, minimal 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 downwards spraying applications (e.g. in field crops) and for other application methods where exposure to non-target aquatic organisms can occur (e.g. granular applications), while a buffer zone of minimum 3 meter applies for other than vertically downwards spraying applications (e.g. applications in orchards). The minimum buffer zone of 1 meter applies also for seeds and tubers treated with a plant protection product: treated seeds

may not be sown at less than 1 meter distance from surface water and treated seed potatoes may not be planted at less than 1 meter distance from surface water.

### Drift reduction

Based on appropriate FOCUS Step 4 simulations, the following measures can be proposed for professional products in Belgium to mitigate the risk via drift exposure for aquatic organisms:

- For field crops, vegetables in open air, pastures, low ornamentals, herbicides in orchards and unhardened permanently uncultivated terrains buffer zones of 2, 5, 10 or 20 m with respect to surface water are possible (drift-reducing).  
In combination with a buffer zone of 20 m, drift-reducing techniques of 50%, 75% or 90% can be proposed.
- For orchards, small fruit, ornamental trees and shrubs buffer zones of 5, 10, 20 or 30 m with respect to surface water are possible (drift-reducing).  
In combination with a buffer zone of 20 m, drift-reducing techniques of 50%, 75% or 90% can be proposed.  
In combination with a buffer zone of 30 m, drift-reducing techniques of 90% can be proposed.

Please note that these mitigation measures are intended to protect aquatic organisms and should therefore be applied with respect to surface water. In addition, drift-reducing techniques may be required to protect non-target arthropods or non-target plants. Such measures are determined based on the ecotoxicological risk assessment and must be applied to the whole parcel (and not only along surface water bodies). More information is available on: <https://fytoweb.be/nl/handleiding/gewasbescherming/driftreducerende-maatregelen-voor-niet-tot-de-doelsoorten-behorende> (in Dutch and French only).

Manufacturers of spraying devices can let classify their equipment in the list of approved drift-reducing equipment, as described in the document “*Evaluation of new drift-reducing equipments: classification criteria and procedure in Belgium*”, available on [www.phytoweb.be](http://www.phytoweb.be).

### Run-off reduction

The implementation of measures mitigating run-off exposure is a regional competence in Belgium. The Authorisation Committee has decided that when the run-off scenario (R1) exceeded the ecotoxicological trigger values, a risk phrase (« *SPe2: To protect aquatic organisms do not apply to parcels sensitive to erosion. For the Flemish region and the region of Brussels-Capital, this applies to parcels classified as ‘sterk erosiegevoelig’*. For the Walloon region, this corresponds to the parcels identified with the code R. The product can nevertheless be used on these parcels if measures are taken against soil erosion such as fixed in the regional

*legislations.* ») has to be mentioned on the label of the plant protection product. Full versions of the risk mitigation phrase in Dutch and French are given below.

*NL: « SPe2: Om de waterorganismen te beschermen mag het product niet gebruikt worden op erosiegevoelige percelen. Voor het Vlaams Gewest en het Brussels Hoofdstedelijk Gewest geldt dit voor percelen geklasseerd als 'sterk erosiegevoelig'. Voor het Waals Gewest komt dit overeen met percelen geïdentificeerd met een R-code. Indien voorzorgsmaatregelen tegen erosie zoals vastgelegd in de gewestelijke wetgevingen toegepast werden is het gebruik wel toegestaan. »*

*FR: « SPe2: Afin de protéger les organismes aquatiques, le produit ne peut pas être utilisé sur les parcelles sensibles à l'érosion. Pour la Région flamande et la Région de Bruxelles-Capitale, cela vaut pour les parcelles classées comme 'sterk erosiegevoelig'. Pour la Région wallonne, cela correspond aux parcelles identifiées avec le code R. Le produit peut néanmoins être utilisé sur ces parcelles à condition que des mesures de lutte contre l'érosion des sols telles que fixées dans les législations régionales soient mises en œuvre. »*

To model run-off reduction at FOCUS Step 4, the 90<sup>th</sup> percentile worst-case values for reduction efficiencies for different widths of vegetated buffers and different phases of surface runoff from SANCO/10422/2005 (Volume 1, version 2.0, September 2007) have to be used.

The use of specific modeling tools, such as the VFSSMOD tool, is not accepted at the Belgian national authorisation level.

A special case is described in the news of 26/11/2015 concerning the obligation to respect a 20 m **vegetated buffer strip** towards surface water for products containing terbuthylazine. More information on the practical aspects concerning the installation of a 20 m buffer strip are available in the document "*Frequently asked questions (FAQ) on the vegetated buffer zones for products containing terbuthylazine*". Both the news and the FAQ are available on [www.phytoweb.be](http://www.phytoweb.be) (in Dutch and French only).

## Accumulation in the sediment

In case of a persistent substance in the water/sediment system, consecutive years of treatment may result in accumulation of this compound. Where DT50 in the sediment (or when not available whole system DT50) indicate that it cannot be excluded that accumulation in sediment may occur as a consequence of applications of a product in successive years, the accumulation potential in sediment should be estimated. An approach to determine concentrations as a result of accumulation is explained in the Generic Guidance for FOCUS surface water Scenarios (version 1.4, May 2015).

However for national assessment in Belgium, a more simple but globally more conservative approach is preferred. This approach consists of determining the maximum plateau concentration based on the DT50 in sediment and the most critical PEC (as determined) in sediment, with the following formula:

$$\text{Maximum plateau } PEC_{SED} = \frac{\text{Maximum initial } PEC_{SED}}{1 - e^{-ki}}$$

where  $k = \ln 2/DT50_{sed}$  and  $i = 365$  d.

E.g. when the maximum  $PEC_{sed}$  for the D3 scenario after one year treatment equals  $10 \mu\text{g}/\text{kg}$ , the maximum plateau concentration after consecutive years of treatment will be  $30 \mu\text{g}/\text{kg}$  with a  $DT50_{sed}$  of 626 days.

## PEC in surface water for volatile substances

For substances with a potential for short-distance transport in air according to the criteria of the FOCUS Air guidance (SANCO/10553/2006 Rev 2, June 2008), deposition after volatilisation should be considered in the surface water assessment if drift mitigation measures are required (FOCUS SW Step 4).

According to the FOCUS Air guidance, deposition after volatilisation is not significant compared to spray drift within the short-range (i.e. < 2 m). Consequently, deposition from volatilisation need only be considered in addition to drift for distances greater than 1 m for field crops and 3 m for orchards and vines.

The use of the EVA model is accepted for the estimation of volatilisation and subsequent deposition where no experimental deposition data are available.

## 2.4 Air

The maximum acceptable concentrations in air are determined by the AOEL and the toxicological limit values for operators, bystanders and workers.

The potential for short- and long-distance transport in air is assessed in accordance with the FOCUS Air guidance (SANCO/10553/2006 Rev 2, June 2008) during the active substance approval/renewal process at EU level. For the authorisation of a plant protection product, no additional assessment is required unless during the EU review specific issues have been identified, requiring consideration at Member State level.

For substances with a potential for short-distance transport in air, deposition after volatilisation should be considered in the surface water assessment as explained above.

## 3. Specific data requirements

### 3.1 Use in protected crops

The document “*Emissions of plant protection products from protected crops to the environment*”, available on [www.phytoweb.be](http://www.phytoweb.be), provides guidance on the risk assessment for uses in protected crops. This document describes the data requirements for the interzonal core assessment with Belgium acting as interzonal Rapporteur Member State (izRMS) and the national approach for Belgium, in accordance with the Guidance Document on protected crops (SANCO/12184/2014 – rev. 5.1 of 14 July 2015).

Further clarifications on the definition of ‘*crops grown under cover*’ – the term used in the Belgian authorisation certificates – can be found in the document “*Wat is een teelt onder bescherming? – Qu’est-ce qu’une culture sous protection?*”, also available on [www.phytoweb.be](http://www.phytoweb.be) (in Dutch and French only; document intended for the users of plant protection products).

### 3.2 Use on hardened surfaces

In the absence of a harmonised approach within the EU Central Zone, the Belgian authority applies the national approach described hereafter.

To assess the risk related to the use of plant protection products on hardened surfaces, calculations with the HardSPEC model are required. This model predicts the concentrations in surface and groundwater for several exposure scenarios. The term ‘*hardened surfaces*’ (‘*verharde permanent onbeteelde terreinen*’ in Dutch, ‘*terrains revêtus non cultivables*’ in French) includes the non or poorly water permeable areas, such as paved, concreted and stabilised surfaces and surfaces covered with dolomite, gravel or ballast (e.g. sidewalks, roadsides,...). The HardSPEC model should also be used for applications on railways.

The model is available on the UK’s Health and Safety Executive (HSE) website:  
<https://www.hse.gov.uk/pesticides/data-requirements-handbook/fate/hardspec.htm>

## 3.3 Non-professional uses (home and garden uses)

### National approach for Belgium

In the absence of a harmonised approach within the EU Central Zone, the Belgian authority applies the national approach described hereafter.

In Belgium, a risk assessment for Fate and Behaviour in the Environment is not required for ready-to-use sprays or aerosol dispensers (AE) in packaging < 5 L.

For all other non-professional uses, the **soil and groundwater** exposure assessment should be conducted in the same way as for professional uses. In many cases, professional uses are requested for the same product. The soil and groundwater assessment for the professional uses may simply be copied to the dRR of the non-professional uses if it is considered to be sufficiently protective.

The **surface water** exposure assessment is based on simple spray drift calculations (Excel), assuming a water depth of 30 cm. FOCUS Surface Water simulations are not required for the Belgian risk assessment. The following specific drift values for non-professional uses must be used in the Excel calculations:

- 0 m buffer zone: 100 % drift ('overspray')
- 10 m buffer zone: 0.09 % drift for low crops (including shrubs, vines,...) and 0.24 % drift for high crops (trees)

Following Articles 5 to 9 of the Royal Decree of 19 March 2013 concerning the sustainable use of plant protection products and adjuvants, the authorisation certificate will impose a minimal buffer zone of 1 or 3 m, even if the risk is considered acceptable assuming overspray. Exceptionally, a 20 m drift buffer zone may be approved by the Authorisation Committee on a case by case basis if the risk is considered acceptable based on a specific justification or study.

For applications to uncultivated surfaces, simulations with the HardSPEC model are required. To avoid surface water contamination, the following use restriction must be mentioned on the labels of all non-professional plant protection products intended to be used on hardened surfaces: « *Do not apply to hard surfaces, permanently uncultivated (paved, concrete, stabilised or asphalt areas, areas covered with dolomite, gravel or ballast), connected to a sewage network (kerbs, gully-pots,...) or connected to a surface water (watercourses, lakes, ponds, canals, drainage networks, surface water ditches,...).* »

Full versions of this risk mitigation phrase in Dutch and French are given hereafter:

NL: « Niet toepassen op verharde permanent onbeteelde terreinen (geplaveide, gebetonneerde, gestabiliseerde, geasfalteerde of met dolomiet, grind of ballast verharde oppervlakken) aangesloten op een rioleringsstelsel (goten, rioolputten,...) of aangesloten op een oppervlaktewater (waterlopen, meren, plassen, vijvers, kanalen, drainage-netwerken, met water gevulde grachten,...). »

FR: « Ne pas traiter sur terrains revêtus non cultivables (comme les surfaces pavées, bétonnées, stabilisées, asphaltées, couvertes de dolomies, graviers ou de ballast) reliés à un réseau d'égouttage (caniveaux, avaloirs,...) ou à une eau de surface (cours d'eau, lacs, étangs, mares, canaux, réseaux de drainage, fossé humide,...). »

An estimation of the concentrations in surface water is not required if the product is not applied by spraying (e.g. granular application) or if the product is only applied under protection.

## Zonal applications

In case of zonal applications for non-professional uses where Belgium acts as zRMS, the applicant is requested to follow the recommendations of the Working document for the Central Zone (<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>).

Please note that for Belgium, the FOCUS Step 1-2 simulations will not be used to define the buffer zone. Spray drift calculations with the specific drift values for Belgium are required, as explained above. This information should be included in the national addendum for Belgium.

## 3.4 Adjuvants

The data requirements for adjuvants can be found in the document “Requirements applied in Belgium to an application for authorization of an 'adjuvant' for agricultural use”, available on [www.phytoweb.be](http://www.phytoweb.be).



## 4. Recurring issues

### 4.1 New active substance data vs. EU agreed endpoints

Applicants should follow the approach agreed within the Central Zone, as written down in the Working document for the Central Zone

(<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>).

This means that the risk assessment for Fate and Behaviour should be based on the EU agreed endpoints, available at the date of submission of the application. If EU agreed endpoints are missing for some of the input parameters needed for the exposure modeling, then the simulations should be performed using worst case input parameters based on conservative assumptions.

If this assessment based on EU agreed (or worst case) endpoints does not provide safe uses or if adverse data are available, a refined assessment can be presented in addition, using revised input parameters based on new data. The reason for using new active substance/metabolite data should be clearly explained in the dRR Part B Section 8.

Applicants are not required to update Koc values in line with the DegT50 Guidance Document (SANCO/12117/2014 – final of 12 December 2014 and EFSA Journal 2014;12(5):3662) for the authorisation of plant protection products. The EU agreed Koc values should be used in the product risk assessments. However, if the agreed Koc is an arithmetic mean value and no safe use can be demonstrated using this endpoint, then the simulations may be refined using the geometric mean Koc value. In the same way, DT50 soil values should only be recalculated if this is necessary to demonstrate that the proposed uses of a plant protection product are safe.

### 4.2 Confirmatory data vs. EFSA data gaps

**Confirmatory data** are assessed at EU level within the framework of the active substance approval process. Therefore, these data should not be assessed within individual applications for plant protection products. For such product applications, the Belgian Authorisation

Committee will consider the list of missing information. The Committee can either decide that sufficient information is available to grant a provisional authorisation for a specific product/use, awaiting the assessment of the confirmatory data at EU level, or to refuse the authorisation awaiting the outcome of the confirmatory data assessment, if the missing information is considered essential to complete the risk assessment for the proposed use.

**Other data gaps, listed in the EFSA Conclusion**, will be assessed at EU level at the next active substance renewal. However, it is possible that (part of) the missing information is essential to complete the risk assessment for the requested uses of a plant protection product, for example if the proposed uses are more critical than the representative uses assessed during the EU review, or if the proposed uses are similar to the representative uses and the EU evaluation indicates that the risk is not acceptable. In such cases, the data gaps should be considered in the product risk assessment and an assessment of new active substance/metabolite data may be required.

## 4.3 Revised DT50 values 1,2,4-triazole

In December 2013, new DT50 values have been approved at EU level for the metabolite 1,2,4-triazole. Instructions for the use of these values in the risk assessments can be found in the document “*New Endpoints DT50 for metabolite 1,2,4-triazole*”, available on: [http://fytoweb.be/sites/default/files/news/docs/124-triazole\\_dt50.pdf](http://fytoweb.be/sites/default/files/news/docs/124-triazole_dt50.pdf).

## 4.4 Spot application

In the absence of a harmonised approach within the EU Central Zone, the Belgian authority applies the national approach described hereafter.

In case of localised applications (spot applications) of a plant protection product, only part of the surface will be treated. The Belgian Authorisation Committee accepts the use of a reduced dose in the risk assessment for Fate and Behaviour in the Environment: the PEC calculations for the different environmental compartments can be conducted with 40 % of the proposed application rate (expressed /ha). This approach is based on the assumption that the user would no longer choose for localised applications if more than 40 % of the surface needs to be treated.

For localised applications to hardened surfaces, the HardSPEC calculations should be performed with the full application rate, because in this model the dose reduction is already incorporated in the scenario definitions.

## 4.5 Conversion factors for vertical crops

In Belgium, the doses for the application of plant protection products to the canopy of vertical crops are expressed **per ha Leaf Wall Area (LWA)**. The risk assessment for Fate and Behaviour in the Environment is based on the equivalent application rate **per ha ground surface**.

Standard conversion factors for Belgium and further clarifications on the conversion of the dose /ha LWA to a dose /ha ground surface can be found in the guidance document "*Dose expression for vertical crops in Belgium*", available on [www.phytoweb.be](http://www.phytoweb.be).