WORKING DOCUMENT OF THE CENTRAL ZONE IN THE AUTHORISATION OF PLANT PROTECTION PRODUCTS

SECTION 8

ENVIRONMENTAL FATE AND BEHAVIOUR

Version 1 rev. 1 – June 2018

Editing log - Working Document of the Central Zone in the Authorisation of Plant Protection Products - Part B section 8 - Environmental fate and behaviour

Date	Revision	Issues	Responsible	Implementation date
May 2015	0.0	Draft guidance on work-sharing in the central zone in the authorisation of plant protection products - Section 5 - Environmental fate and behaviour	AGES (Dayteg, Hutzenlaub) + Expert group	~~1 October 2015~~
November 2015	0.1	Implementations of the comments from the participating Member States	AGES (Dayteg, Hutzenlaub) + Expert group	~~1 May 2016~~
January 2016	0.2	Finalisation of the Guidance Document	AGES (Dayteg) + Expert group	1 July 2016
January 2016	1.0	Working Document of the Central Zone in the Authorisation of Plant Protection Products	AGES (Dayteg) + Expert group	1 July 2016
June 2018	1.1	Working Document of the Central Zone in the Authorisation of Plant Protection Products	AGES, CRD + Expert group	1 December 2018

1. Legal Status

This document does not intend to produce legally binding effects and by its nature does not prejudice any measure taken by a Member State/country within the implementation prerogatives under Annex II, III and VI of Council Directive 91/414/EEC or subsequently Regulation EC 1107/2009, nor any case law developed with regard to these provisions. This document also does not preclude the possibility that the European Court of Justice may give one or another provision direct effect in Member States.

2. Introduction

This document describes a procedure for the assessment of environmental fate and behaviour of applications for authorisation and re-authorisation of plant protection products following Annex I inclusion of an active substance under Directive 91/414/EEC or its approval under Regulation EC 1107/2009 in the Central zone.

It has been agreed by the responsible competent authorities in Austria, Belgium, Czech Republic, Germany, Hungary, Ireland, Luxembourg, the Netherlands, Poland, Romania, Slovak Republic, Republic of Slovenia and the United Kingdom. It is intended that it should be used in the context of the work sharing framework for registration of plant protection products to reduce the workload for both applicants and authorities. Where the transitional measures of Regulation EC 1107/2009 apply the work-sharing is conducted on a voluntary basis with the aim to improve mutual recognition and facilitate the development of a registration work-sharing program. The procedures in this document will be applied for re-authorisation of products containing active substances.

For applications of new authorisations submitted after 14 June 2011 the provisions of the EU guidance document on zonal evaluation and mutual recognition under Regulation EC 1107/2009 applies.

It should be noted however, that new product applications on-going at the time of adoption of the new Regulation, and re-registration for all existing products containing active substances on Annex I to 91/414/EEC should be assessed in accordance with the transitional measures in Article 80.5 of regulation EC/1107/2009.

This document will be updated to take account of developments and practical experience of the procedures, new data requirements and/or guidance on risk assessment, risk mitigation and further harmonisation processes.

Since the preparation of dossiers may have started before the details in this guidance document were known to applicants flexibility will be applied, regarding what is put into the core part of the dossier and what should be in national addenda. Therefore an implementation period of 6 months will be given, until the latest version of this guidance has to be followed.

For this version the transitional period will be 6 months after the release in June 2018, which means by 1st of December 2018 at the latest. However, this working document can be voluntarily followed before its implementation.

Wherever possible, the procedures in this document have been aligned with those in the new Regulation, to allow a smooth transition between the two processes.

3. Assessment of Environmental Fate and Behaviour

Disclaimer: This guidance is for assembling a core assessment and does not fully cover the various national requirements for risk assessments. In some cases specific national guidance must be consulted additionally.

Many of the specific national requirements are to be included in the core assessment as outlined below. These national requirements were included in the frame of the core assessments as they represent requirements needed by a majority of member states.

However if member states require additional national requirements to grant authorisation of a plant protection product, these requirements should be addressed in national assessments.

The following guidance documents should be used for the core assessment:

- SANCO/221/2000 rev.10 (final). 25 February 2003. Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under council directive 91/414/EEC.
- SANCO/10058/2005 version 2.0 (final). June 2006. Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration.
- Generic guidance for Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration. Version 1.1. 18 December 2014.
- SANCO/4802/2001 rev.2 (final), version 1.2. December 2012. Focus surface water scenarios in the EU evaluation process under 91/414/EEC.
- SANCO/13144/2010, version 3, 10 October 2014. Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU.
- SANCO/12117/2014 – final. 12 December 2014. 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. 2014. 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.
- SANCO/10553/2006 rev. 2. June 2008. Pesticides in air: considerations for exposure assessment.
- SANCO/12184/2014 – rev. 5 – 27 January 2015. 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.

The risk assessment should be based on the agreed List of Endpoints resulting from the EU approval procedure. Generally, revision of active substance and metabolite data endpoints should be dealt with in the process of the Renewal of the active substance and not during post-approval Plant Protection Product authorisation submissions.

3.1. Soil

Not yet harmonised. Follow the approaches that are used for the Approval submission of the (individual) active substance(s).

3.2. Groundwater

A table of agreed endpoints (the latest valid LoEP) for the active substances and metabolites for GW calculations is to be provided in the Core assessment.

Assessment based on EU agreed endpoints:

Groundwater simulations are to be performed based on the table of agreed endpoints and with the latest versions (at the time of submission) of both FOCUS PEARL and FOCUS PELMO. Results from both simulations (where both models are run) are to be presented in the dRR/RR. However, if the results of one of these models show the PEC_{GW} results to be <0.001 µg/l in all relevant scenarios for all substances triggering groundwater assessment, it is not necessary to perform simulation runs with the other model. In that case, a statement should be presented in the Core assessment.

Important note: some Member States may request simulations performed with the missing model if the results of that specific model are deemed essential to comply with the national requirements.

MACRO is required if the requested crop is parameterized for scenario Châteaudun, for submissions from May 2015 onwards. No MACRO simulations are necessary if the PEC_{GW} values calculated with FOCUS PEARL and FOCUS PELMO are <0.001 µg/L for all substances which trigger groundwater assessment.

Assessment based on updated input parameters (if needed):

If the assessment based on EU agreed endpoints does not provide safe-uses or adverse data are available, groundwater simulations can be refined by using mitigation measures or by reviewing the input parameters. Note that according to the guidance document on the evaluation of new active substance data post approval (SANCO/10328/2004– rev 8, 24.01.2012) new active substance/metabolite data should not be considered unless they are necessary in order to show a safe use, they are needed as additional uses/crops are applied for authorisation, or they are "adverse" data. If new active substance/metabolite input parameters have been used in one part of the risk assessment, they will not be automatically applied to other parts, but an explanation should be presented as to why these new data are not adversely affecting another part of the assessment. If new endpoints are needed, they should be inserted in an additional column in the

table and clearly marked as such. The applicant should offer clear explanations for providing new active substance/metabolite data. It is to be noted that these refined assessments are to be presented additionally to the assessment based on EU agreed endpoints.

Groundwater simulations are to be performed for at least the following FOCUS scenarios:

- Châteaudun
- Hamburg
- Kremsmünster
- Okehampton
- Piacenza
- Porto

Simulations have to be conducted for all crops included in the GAP. 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 judgement. The choice of crop should be justified.

The application timing should be selected using the most actual version of the software AppDate (M. Klein, Fraunhofer-Institut). However, AppDate should always be combined with an expert judgement based on 'common sense' and information in the section Efficacy. If the application window is very large (e.g. applications possible from March to October), then two separate simulations are necessary (early and late application window).

The (draft) registration report should contain following information in part B section 8:

- Input parameters according to the latest valid List of Endpoints
- Input parameters and justifications
- Relevant values related to the GAP: crop, number of applications, application rate, interval, interception, application dates, application method
- Versions of the models used

In addition to the summary in the dRR, the modelling report with representative files should always be provided in document K. Remaining input/output files shall be made available when requested from the regulatory authority.

3.3. Surface water

A table of agreed endpoints (the latest valid LoEP) for the active substances and metabolites for the SW calculations is to be provided in the Core assessment. As far as possible, the latest versions of the models should be used for the simulations.

Assessment based on EU agreed endpoints:

FOCUS Step 1 and 2 PEC calculations are to be performed and provided based on the table of agreed endpoints. FOCUS Step 3 simulations are to be provided, except if FOCUS STEP 3 calculations were not provided for the active substance approval (comparable GAP).

Simulations have to be conducted for all crops included in the GAP. Following scenarios are relevant for the Central Zone:

- D3 Vredepeel
- D4 Skousbo
- D5 La Jailliere
- R1 Weiherbach
- R3 Ozzano, Bologna
- R4 Roujan

Assessment based on updated input parameters (if needed):

Surface water simulations can be refined by using mitigation measures or updated by reviewing the input parameters. Note that according to the guidance document on the evaluation of new active substance data post approval (SANCO/10328/2004– rev 8, 24.01.2012) new Annex II data should not be considered unless they are necessary in order to show a safe use, they are needed as additional uses/crops are applied for authorisation, or they are "adverse" data. If new active substance/metabolite input parameters have been used in one part of the risk assessment, they will not be automatically applied to other parts, but an explanation should be presented as to why these new data are not adversely affecting another part of the assessment. If new endpoints are needed, they should be inserted in an additional column in the table and clearly marked as such. The applicant should offer clear explanations for providing new Annex II data. It is to be noted that these refined assessments are to be presented additionally to the assessment based on EU agreed endpoints.

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 judgement. The choice of crop should be justified. FOCUS default values should be applied where appropriate.

The application timing should be selected using the most actual version of the software AppDate (M. Klein, Fraunhofer-Institut). However, AppDate should always be combined with an expert judgement based on 'common sense' and information in the section Efficacy. If the application window is very large (e.g. applications possible from March to October), then two separate simulations are necessary (early and late application window).

The (draft) registration report should contain following information in Part B section 8:

- Input parameters according to the latest valid List of Endpoints
- Input parameters used (+ justification)
- GAP: crop, number of applications, application rate, interval, interception, application time, application window (dates and Julian days), application date, application method
- Versions of the models used

In addition to the summary in the dRR, the modelling report with representative files should always be provided in document K. Remaining input/output files shall be made available when requested from the regulatory authority.

If mitigation measures are needed to grant an authorisation of the plant protection product, Step 4 simulations are to be provided in the Core assessment using widely applicable approaches of spray drift and run-off mitigations as implemented in e.g. SWAN. Step 4 calculations might need the addition of deposition after volatilisation for relevant active substances. The FOCUS scenarios presented in the following matrix should be simulated.

The following table provides information on the 90th percentile worst-case values for reduction efficiencies for different widths of vegetated buffers and different phases of surface runoff (SANCO/10422/2005, version 2.0, September 2007). Other approaches for simulating run-off mitigation reductions (e.g. VSFMod) are not recommended for the Core Assessment. Applicant should check with individual MS whether such approaches will be acceptable for national authorisations; such approaches should only be presented in National Assessment Report.

Buffer width (m)	10-12	18-20
Reduction in volume of runoff water (%)	60	80
Reduction in mass of pesticide transported in aqueous phase (%)	60	80
n (for aqueous phase)	*36*	*30*
Reduction in mass of eroded sediment (%)	85	95
Reduction in mass of pesticide transported in sediment phase (%)	85	95
n (for sediment phase)	*19*	*11*

The following table is a template for recording the FOCUS initial PEC_{SW} Step 3 and 4 outputs. The use of this template facilitates the peer-review of the simulations.

PEC_{SW} [µg/L]	**Scenario**	**STEP 4**						
Nozzle reduction	**Vegetative strip [m]**	**None**	**None**	**None**	**None**	**None**	**10**	**20**
	No spray buffer [m]	**FOCUS default**	**5**	**10**	**15**	**20**	**10**	**20**
None	D3 Ditch							
50 %								
75 %								
90 %								
None	D4 Pond							
50 %								
75 %								
90 %								
None	D4 Stream							
50 %								
75 %								
90 %								
None	D5 pond							
50 %								
75 %								
90 %								
None	D5 stream							
50 %								
75 %								
90 %								
None	R1 pond							
50 %								
75 %								
90 %								
None								

PEC_{SW} [µg/L]	**Scenario**	**STEP 4**						
Nozzle reduction	**Vegetative strip [m]**	**None**	**None**	**None**	**None**	**None**	**10**	**20**
	No spray buffer [m]	**FOCUS default**	**5**	**10**	**15**	**20**	**10**	**20**
50 %	R1 stream							
75 %								
90 %								
None	R3 stream							
50 %								
75 %								
90 %								
None	R4 stream							
50 %								
75 %								
90 %								

3.4. Air

Not yet harmonised. Follow the approaches that are used for the Approval submission of the (individual) active substance(s).

3.5. Assessment of the relevance of metabolites in groundwater

A metabolite is considered to be of concern when the concentration is above 0.1 µg/L (80th percentile concentration (annual/biannual/triannual average as appropriate according to GAP) predicted in FOCUS GW models, or annual average concentration in lysimeter leachate). An assessment of the relevance of metabolites of concern in groundwater should be included in the core assessment if the metabolite has not been assessed during the EU evaluation.

The assessment of the relevance should cover all the requirements in the GD (SANCO/221/2000 – rev.10) on the relevance of metabolites in groundwater. The full relevance assessment is to be presented in the core dRR, Part B section 10.

3.6. Further areas

3.6.1. Q_{10} value

Preliminary remark: The following approach reflects the opinion of the MS of the central zone with the exception of DE according to the discussions in the central zone Steering Committee (czSC)

It is recommended to use the DT_{50} value as indicated in the LoEP and to adjust the Q_{10} value in the FOCUS model shell to the Q_{10} value which was used to normalise DT_{50} value in the LoEP.

The latest release of the FOCUS model (groundwater and surface water) at the time of submission should be used in order to account for revisions with respect to soil and climate conditions (defining the target vulnerability of the scenario).

The Q_{10} value is a substance specific parameter (independent whether it is measured or defined by a default value) which was at that time agreed on for Annex I inclusion. In line with the GD the agreed Q_{10} value from the LoEP should not be changed unless safe use cannot be demonstrated. As a matter of principle this is considered true also if no temperature normalisation was necessary for Annex I inclusion (i.e. studies conducted at 20 °C).

If no Q_{10} value was agreed on for Annex I inclusion (e.g. no FOCUS modelling available at that time), the new Q_{10} value of 2.58 should be used for pragmatic reasons.

If an acceptable risk cannot be demonstrated, the normalisation of degradation experiments may be re-done by the applicant in accordance to pertinent FOCUS guidance using a Q_{10} value of 2.58. In case of these re-evaluated Annex II endpoints, a Q_{10} value of 2.58 has to be used in the FOCUS model as well.

Re-calculation with new FOCUS degradation kinetics should - in the frame of zonal/national assessment - only be applied if no safe use can be derived by using the agreed endpoints.

3.6.2. Home and garden use

Home garden products are currently assessed using different approaches between CZ MS. The approach for the Core Assessment presented here takes into account the areas of agreement. This approach should be provided by the Applicant in the frame of a Core Assessment, but in addition, refinements can be presented to each MS in a National Assessment if required to conclude a safe use according to their National Requirements. The Core Evaluation is based on a tiered approach.

At Tier 1, the Applicant may refer to appropriate existing products. Hence, the Applicant must clearly demonstrate that the existing use represents the same or more critical GAP than the proposed home garden use. In the case that the home garden/non-professional GAP is the same as, or less critical than an existing professional use, no further assessment is necessary for the Core Assessment. The evaluation in the dRR/RR needs to present details of the reference evaluation which can be provided in Part C of the dRR/RR. Details of the reference evaluation should include at least a summary of the evaluation and a clear reference to the evaluation. A clear reference to the Part C should be included in Part B section 8.

If a professional use forming the similar or more critical GAP is subject to risk mitigation measures at national level, the Applicant should consider in the National Assessments the requirements of each MS and consider how appropriate those risk mitigation measures are to the home garden use in each MS.

Where a Tier 1 approach from professional products is not possible, inclusion in the Core Assessment will be required at Tier 2. At Tier 2 standard calculations at full rate must be provided for PEC_{SOIL}, PEC_{GW}, and $PEC_{SW/SED}$ using FOCUS SW Steps 1-2 only. Refinements of Tier 2 calculations should not be presented in the Core Assessment. Member State's specific refinements should be presented in National Assessments.

Proposals from Applicants for refinements taking into account, e.g. spray drift reduction, must be treated carefully. If it appears likely that these could be applicable to a number of MS, an assessment of the refinements of Tier 2 should be presented in the Core Assessment. However, the Core Assessment must contain a very clear statement that each MS needs to consider the validity of the refinement for their situation.

A summary of the tiered approach is presented in the table below.

	Soil	GW	SW	Notes
Tier 1	No assessment necessary if the home garden/non-professional GAP is the same as, or less critical than, an existing professional use. The GAP of the professional product should be clearly specified for ease of comparison (e.g.			zRMS must specify any risk mitigation requirements relating to the professional use within the core, however consideration of the implications of mitigation are

	inclusion of appropriate assessment in Part C or associated Registration Report shared on CIRCA).			a MS issue and should be assessed within National Addenda only.
Tier 2	Standard PEC_{SOIL} calculation at full rate.	Standard PEC_{GW} calculation at full rate.	Standard PEC_{SW} calculations using FOCUS Steps 1-2 only.	National reduction factors (if available), pack size considerations or non-FOCUS methodology can be applied in National Addenda. Assessment beyond FOCUS SW Step 2 should also be presented in National Addenda only.