NATIONAL REQUIREMENTS FOR REGISTRATION OF PLANT PROTECTION PRODUCTS (PPPs) IN SLOVENIA

FOR: EFFICACY, TOXICOLOGY WITH EXPOSURE ASSESSMENT, FATE AND BEHAVIOUR IN THE ENVIRONMENT and ECOTOXICOLOGY

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**General**

Data submitted for the authorization of plant protection product should fulfil the data requirements laid down in the Commission Regulation 284/2013 of March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market.

Risk assessment should be performed according to the latest guideline documents and EU agreed methodologies.

dRR should be submitted in the currently agreed format described in the guidance document SANCO/6895/2009 rev 2.2.

# EFFICACY

### Minimum effective dose

* Slovenia is a member of the group of countries that belong to South – East EPPO zone. For this reason, a set of minimum effective dose trials performed in South East EPPO zone is required for all major target organisms (not for all listed in the Table GAP). In the case that insufficient number of trials are available from the South-East EPPO zone, trials from Maritime EPPO zone are also acceptable.
* When trials from Maritime EPPO zone are submitted, justification of comparability of climatic conditions and agriculture practices between zones is required.
* When it is not possible to provide data from the South East EPPO zone to support intended uses (e.g Mediterranean crops), data from the Mediterranean EPPO zone are acceptable as well.
* Trial results presented in BAD and corresponded dRR should be addressed separately by the EPPO zone.

### Efficacy testing

* Due to the reason already indicated under previous section, each of proposed uses should be supported with the set of efficacy trials performed in the countries belonging to the South East EPPO zone.
* In the case that insufficient number of trials are available from the South-East EPPO zone, trials from Maritime EPPO zone are also acceptable.
* When trials from Maritime EPPO zone are submitted justification of comparability of climatic conditions and agriculture practices between zones is required.
* When it is not possible to provide data from the South East EPPO zone to support intended uses (e.g Mediterranean crops), data from the Mediterranean EPPO zone are acceptable as well.
* Trial results presented in BAD and corresponded dRR should be addressed separately by the EPPO zone

### Adverse effects on treated crops

* Data on adverse effects on treated crops for fungicides and insecticides on pome fruits should be provided for apple and pear separately. The same principle is expected for stone fruits where data on adverse effects should include data for peach, cherry, apricot and plum separately.
* As regards distribution of trials across EPPO zones the same principle should be followed as for minimum effective dose and efficacy tests.

### Succeeding crops

Sufficient data should be provided for herbicides to permit an evaluation of all possible negative effects of PPP on succeeding crops. In selection of cultivated plants as replacement or rotational crops specific agronomic conditions in Slovenia should be considered.

### Resistance

The applicant should provide a specific country resistance management strategy.

# TOXICOLOGY INCLUDING OPERATOR AND WORKER EXPOSURE

### General

Data submitted for the authorization of plant protection product should fulfil the data requirements laid down in the Commission Regulation 284/2013 of March 2013.

Regulation 1107/2009 prescribes that no new studies shall be conducted in vertebrate animals where validated alternative methods are available. Validated alternative methods are in vitro methods which allow the prediction of in vivo apical endpoints and for which OECD Test Guidelines have been adopted. When new OECD Test Guidelines for alternative in vitro methods fully or partially replacing an in vivo test are adopted, any new studies should be conducted using these alternative methods.

For the purposes of fulfilling the toxicological data requirements for Plant Protection Products (PPPs), the calculation method of Regulation 1272/2008 may be an acceptable alternative method. Waiving/bridging of tox studies for formulation is possible if scientifically valid argumentation is provided by the applicant.

In vivo tests conducted either before 14 June 2011 or before alternative OECD Test Guidelines where adopted may be submitted, subject to the requirements of Article 62 regarding data sharing and duplicate testing.

The toxicity profile of metabolites predicted to occur in groundwater should be provided as given in the Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council Directive 91/414/EEC, Sanco/221/2000 –rev.10, 25 February 2003.

Dermal absorption of active substances from the plant protection products should be addressed in line with the EFSA Guidance on Dermal Absorption (EFSA Journal 2017;15(6):4873). If no dermal absorption study is submitted, the default values from the cited Guidance document should be applied, or a justified read-across from the similar formulation might be applied.

### Classification and labelling of plant protection products

For the active substance the latest available information on classification and labelling should be taken into account during the evaluation of plant protection products. This may be the classification in Annex VI of Regulation 1272/2008 or Committee for Risk Assessment (RAC) Opinion proposing harmonised classification and labelling at EU level.

In cases where no harmonized classification exists and CLH dossier was not submitted to ECHA, but in EFSA conclusion a CMR classification was proposed this might be taken into consideration for classification of plant protection product.

In absence of harmonized classification of active substance RAC opinion (if available) is taken into account also for relevance assessment of groundwater metabolites. Groundwater metabolites of active substances proposed to be classified as carcinogenic or reprotoxic in a RAC Opinion are considered relevant unless demonstrated to the contrary.

The proposed classification and labelling of the co-formulants should be submitted as well as updated MSDS for each co-formulant.

C&L of formulation according to 1272/2008 is mandatory.

### Operator exposure (OPEX)

**2.3.1 OPEX models**

Operator exposure estimations according to the 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) using the Agricultural Operator Exposure Model (AOEM) are acceptable.

For the indoor use, the Indoor hand held EUROPOEM model is accepted as well as ECPA Southern greenhouse operator exposure model or Dutch model

For seed treatment the SEEDTROPEX model is accepted.

When the PPP are sold to the general public, the models for amateur use should be taken into consideration. The UK POEM model: home garden sprayer (5 L tank). Outdoor, low level target; should be used only when the PPP needs to be diluted before the application. When Ready to Use Products – space sprayers, surface sprayers and dustable powder applications operator exposure can be estimated on the basis of the data published in TNsG / TNSG on Human Exposure / Report 2002 part 2. The excel spreadsheet can be found on the UK Health & Safety Executive (HSE) website.

For other proposed uses that are less common, the operator exposure should be estimated by appropriate model if existing (e.g. for biocidal product uses).

* + 1. **Use of Personal Protective Equipment (PPE)**

The PPE should be used in the Operator exposure models when:

1. The exposure exceeds the AOEL and the use of PPE will reduce the exposure to an acceptable level.
2. The hazard classification of the PPP requires wearing of specific PPE (PPE used even though the exposure without wearing PPE does not exceed the AOEL).

The applicant should submit detailed information on the type of certain PPE that is considered to reduce the risk of operators to the acceptable level.

### Worker (re-entry) exposure

#### Data

Exposure of workers estimated according to the 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) using the Agricultural Operator Exposure Model (AOEM) is acceptable.

Acceptable refinements of worker exposure are:

* Specific data of Dislodgeable foliar residues (DFR), measured on crop under evaluation. If data was obtained on other crop than the one under evaluation, justification why this information is applicable to evaluated crop must also be submitted.
* DT50 values for dissipation of active substance residues on plant surface. If data was obtained on other crop than the one under evaluation, justification why this information is applicable to evaluated crop must also be submitted.

The higher dermal absorption value is generally considered in the worker exposure estimation. The use of protective gloves is acceptable for the reduction of worker exposure for some uses, depending on crop, type of re-entry task, season of application.

### Bystander and resident exposure

Bystander and resident exposure is performed for adults and children according to the 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) using the Agricultural Operator Exposure Model (AOEM).

For Slovenia the use of drift reducing nozzles is not an acceptable risk mitigation measure. Buffer zones are also not acceptable refinement of resident and bystander exposure.

Dermal absorption value for the spray dilution is generally considered for bystander exposure estimation. For resident or bystander exposure estimation, the higher dermal absorption value is generally considered.

### Combined exposure

In cases where PPP contains more than one active substance (including safeners, agonists and synergists) the combined risk assessment for all active substances should be performed according to approach as proposed in Human health risk assessment from combined exposure in the framework of plant protection products and biocidal products, Stein et al., 2014, [Journal für Verbraucherschutz und Lebensmittelsicherheit](https://link.springer.com/journal/3),  9,  367–376.

Combined exposure should be assessed for operators, workers, residents and bystanders.

As soon as the new revised EFSA Guidance document on Operator, worker, resident and bystander exposure will be available, it should be used in the risk assessment for all exposed groups.

1. FATE AND BEHAVIOUR

### Predicted Environmental Concentration in Groundwater (PECGW)

Not yet harmonised. Follow the approaches that are used for the Approval submission of the (individual) active substance(s). PEC soil calculations should be based on guidance of the FOCUS workgroup on degradation kinetics [FOCUS Kinetics (2006, 2014)]. A soil bulk density of 1.5 g/cm3 and a soil layer depth of 5 cm should be assumed for the calculations. If necessary, the PEC soil accumulation potential of active substance and metabolites should be presented.

### Predicted Environmental Concentration in Groundwater (PECGW)

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 and using for Slovenia relevant ground water scenarios Chateaudun, Hamburg, Kremsmuenster, Piacenza, and Okehampton.

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).

### Predicted Environmental Concentration in Surface water/Sediment (PECSW)

Only exposure via spray drift is considered at national level. PECsw/sed values are calculated with PEC Excel calculator and 'Surface water – spray drift values based on BBA spray drift tables according to Rautmann et al. The Excel calculator can be found on the UK Health & Safety Executive (HSE) website. For horizontal boom sprayer, maximum non-spray buffer zone of 20 m can be considered. For vineyards, orchards and hop maximum non-spray buffer zone of 50 m can be considered. Drift reduction nozzles in combination with non-spray buffer zone are currently not a RMM in Slovenia.

# ECOTOXICOLOGY

### Aquatics

Only exposure via drift is considered (see Chapter 3).

### Birds and mammals

Higher tier assessment following guidance in EFSA (2009). However, if the risk assessment for mammals considers the common vole (*Microtus arvalis*) and the wood mouse (*Apodemus sylvaticus*) to be relevant species, the acceptability criterion can be modified. These species can indeed be viewed as the “worst case” for agricultural areas in Slovenia, with regard to their size and potential exposure. Since the toxicological endpoints for the assessment are still detected on phylogenetically closely related species, a TER ≥ 5 in the acute exposure scenario and a TER ≥ 2 in the long-term exposure scenario can be accepted as adequate.

### Non-target arthropods

In case of HQ>50 for bees, risk phrase 'Dangerous to bees' should be added to the label.

### Possible Risk Mitigation Options

In certain cases drift reduction nozzles allowed to reduce exposure (see Chapter 3).

Run-off predictions in the FOCUS Surface Water R-scenarios are not accepted as a reliable basis for decision-making.

# COMPARATIVE ASSESSMENT

Active substances with certain properties specified in Regulation (EC) No 1907/2006 1107/2009 are considered as candidates for substitution. For plant protection products containing active substances that are candidates for substitution, Member States are required when assessing an application for authorization to evaluate if they can be replaced by other appropriate chemical or non-chemical methods.

Applicants for the registration of such PPPs in Slovenia have to submit additional data enabling comparative assessment. Data have to be provided on template which is available in attachment below. The template is prepared in accordance with the Draft Guidance document on Comparative Assessment and Substitution of Plant Protection Products in accordance with Regulation (EC) No 1107/2009 (SANCO / 11507/2013 rev. 12 10 October 2014) and EPPO Guidance on efficacy aspects of comparative assessment (PP 1/271 (3)).

Comparative assessments which are an integral part of the application and will be submitted after 1 June 2022, must be prepared using a template attached below otherwise an amendment will be required.

