



REPUBLIKA SLOVENIJA  
MINISTRSTVO ZA KMETIJSTVO, GOZDARSTVO IN PREHRANO

UPRAVA REPUBLIKE SLOVENIJE ZA VARNO HRANO,  
VETERINARSTVO IN VARSTVO RASTLIN

### **Comparative assessment of plant protection products**

Pursuant to Article 80(7) of Regulation (EC) 1107/2009, the Commission has published the Regulation (EU) 2015/408 containing a list of active substances - candidates for substitution. Pursuant to Article 50 and Annex IV of Regulation (EC) 1107/2009, Member States shall perform a comparative assessment of plant protection products containing candidates for substitution with other chemical or non-chemical plant protection alternatives in following cases:

1. If the application has been submitted for a new authorisation of a PPP containing one or more candidates for substitution (hereinafter: the respective PPP),
2. If the application for re-authorisation of the respective PPP has been submitted,
3. If the application for a new use in the existing authorisation of the respective PPP has been submitted,
4. If the application as referred in to previous three items has been submitted after 1<sup>st</sup> August 2015, and
5. for the placing of the respective PPP on the market of the Republic of Slovenia.

### **Complying with Article 50 (1) of Regulation (EC) 1107/2009 the Member State shall not authorise the respective PPP or restrict its use in the following cases:**

- (a) For the intended uses in the application there are chemical or non-chemical control or preventive methods available which are significantly safer for health or animal health or the environment,
- (b) The substitution with chemical, non-chemical or preventive method as referred to in item (a) would not present significant economic or practical disadvantages,
- (c) The chemical diversity of active substances, where relevant, or other available methods for plant protection are adequate to minimise the occurrence of the resistance in the target organisms, and
- (d) The impact on minor use authorisations has been taken into consideration.

### **The cases in which the comparative assessment is not required**

The comparative assessment of PPPs not containing candidates for substitution pursuant to Article 50(2) of Regulation (EC) 1107 is not required.

It is not required for zonal authorisations; however, it is required for national authorisations.

The comparative assessment for existing respective PPPs on the market is not required immediately; it shall be implemented at the renewal of the authorisations in accordance with Regulation (EC) 1107/2009 review programme.

If the application for a minor use authorisation of the respective PPP has been submitted, the comparative assessment for this minor use authorisation is not required.

The comparative assessment is not required for permits in emergency situations and research and development permits. It is also not required for parallel trade permits and authorisations of identical products where the applicants refer to the original dossiers. The Administration would draw the same conclusions from the comparative assessment of the respective PPP to parallel trade permits and identical product authorisations.

In the case of submission of the application for unprofessional use of respective PPP when the risk for health or the environment has been evaluated as negligible due to its special manner of use or packaging, the comparative assessment is not required.

The comparative assessment is not required to compare risk among different candidates of substitution.

## Procedure

The applicant shall submit the additional information needed for comparative assessment according to the scheme as referred to in Annex 1 of this instruction together with the application for the authorisation of the respective PPP. The applicants shall include their own conclusions on comparative assessment of the respective PPP into the national agenda of draft Registration Report (dRR) as referred to in Annex 2 of this instruction. The assessment made according to the scheme in Annex 1 and the conclusions in the form of Annex 2 of this instruction shall be enclosed to the application. When the Republic of Slovenia is a concerned Member State in a zonal authorisation the applicant shall submit their conclusions using Annex 1 and 2 scheme after the zonal evaluation is finished.

In the case of application for a new use in the existing authorisation of the respective PPP, the comparative assessment shall be done for this new use only. In the case of the application for new authorisation or review of authorisation, the comparative assessment shall be performed for all intended uses.

The comparative assessment of the respective PPP containing two or more candidates for substitution shall be performed for all of them at first review of the PPP after the renewal of approval of the first candidate for substitution. The comparative assessment of the respective PPP shall not be performed a second time at the renewal of approval of the remaining candidates for substitution, unless the decision on approval, the classification or endpoints for these candidates for substitution are significantly modified; or availability of alternatives vary.

The applicant may submit the application for the respective PPP in accordance with Article 50(3) of Regulation (EC) 1107/2009 where by the way of derogation from comparative assessment the experience from the use of this PPP in practice is necessary. The Administration may grant the authorisation with no comparative risk assessment for the respective PPP only once for the period not exceeding 5 years; or for the period of validation of approval of this candidate for substitution, if the validation deadline is shorter than 5 years.

Based on the conclusions of the applicant submitted together with the application for the authorisation of the respective PPP the Administration shall perform the detailed comparative assessment in the case where the substitution is reasonable.

The comparative assessment of the properties of respective PPPs shall be done first for areas representing the greatest risk for health or the environment.

When the Administration performing the comparative assessment draw the conclusion that the substitution of the respective PPP with alternatives is feasible, the assessment of the risks of these alternatives shall also be taken into account. If for example considerable risk mitigation measures have been determined for the use of the chemical alternative, the substitution may not be reasonable.

The procedure of obligatory comparative risk assessment of PPPs based on Article 50(1) of Regulation (EC) 1107/2009 is performed in accordance with 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.

The Administration draw the conclusions concerning the authorisation of the respective PPP after finishing the comparative assessment. The conclusion shall be sent to the applicant for commenting. After the commenting, the Administration end this procedure by decision on authorisation of the respective PPP, whether the respective PPP shall be authorised or not, authorisation amended or its use restricted.

If the existing authorisation of the respective PPP is amended or withdrawn due to comparative assessment this withdrawal or amendment shall, in accordance with Article 50(5) of Regulation (EC) 1107/2009, take effect three years after the decision taken; or at the end of approval period for the candidate for substitution where this period ends earlier.

## Revised assessment

The circumstances concerning the properties of the candidate for substitution or availability of alternatives that influenced the decision-making may change after the negative decision on authorisation of the respective PPP or on certain uses of the respective PPP has been taken. In this case the applicant may submit a new application for the authorisation of the respective PPP concerned, enclose new relevant information and new conclusions for the comparative assessment of the respective PPP.

## Annex 1

### Submission of the information required for comparative assessment of the respective PPPs according to Article 50 of Regulation (EC) 1107/2009

The applicant may finish the assessment covering item by item below; or pick one item that suits. If the applicant can justify that the substitution of the respective PPP with alternatives is not reasonable using one of the items as follows, further information is not needed:

1. The applicant apply for authorisation of new respective PPP in accordance with Article 50(3) of Regulation (EC) 1107/2009 without performing comparative assessment due to necessity of obtaining experience from the use of this PPP in practice.

The applicant shall submit a justified detailed explanation of reasons why the obtaining of experience from the use in practice of this PPP is necessary first; for example, the use of the PPP is completely new on the market, a new significantly improved formulation or solving a resistance problem is in question, or anything similar.

2. Is the substitution of the respective PPP suitable and acceptable in the sense of agronomic practice and has no impact on the availability of efficient methods to control the target organisms?

Corresponding to the type of application for the authorisation of the respective PPP the applicant submit a justification for all intended uses (except for 'minor uses'); whereas there are or are not alternatives available, which are efficient, adequate, acceptable and significantly safer for human or animal health or for the environment.

The data on authorised uses and other methods can be found on web pages of the administration: [http://www.uvhvvr.gov.si/en/areas\\_of\\_competence/plant\\_protection\\_products/](http://www.uvhvvr.gov.si/en/areas_of_competence/plant_protection_products/)

The comparison of uses of the respective PPP shall be prepared for each use separately. However, if the applicant is able to justify a general comparison of all uses adequately the detailed comparison is not necessary.

3. The evaluation of economic or practical disadvantages of the substitution of the respective PPP with alternatives that have a similar effect on harmful organisms for the users of PPPs.

The applicant submit in accordance with EPPO guideline PP1/271 a justification concerning significant economic or other negative impacts for the users of PPPs if the respective PPP is to be substituted with alternatives.

4. Is the diversity and availability of alternatives large enough to prevent the development of resistance in target organisms if respective PPP is to be substituted?

The applicant submit a detailed explanation for all intended uses (with the exception of 'minor uses') on the extent of available alternatives with different mode of action on the market.

In EPPO Guidelines in cases of evidence of a high risk of resistance, at least four different modes of action of the available alternatives are recommended for the control of pests to prevent the occurrence of the resistance in target organisms.

If there are less than four different modes of action of alternatives available in cases of high risk of the resistance, the substitution of the respective PPP may not be reasonable.

If there are four or more different modes of action of alternatives for the control of pests the applicant shall submit further analyses if the diversity of available alternatives is sufficient for preventing the occurrence of the resistance. In this analyses the impact of EU PPP review programme in accordance with Regulation (EC) 1107/2009 and the water frame directive on use of PPPs shall be considered; as well as any issues related to the resistance. The Administration would review the submitted information and estimate, whether the substitution is reasonable.

5. The number of minor use authorisations of the respective PPP and the impact of the possible withdrawal of the authorisation of the respective PPP on minor use authorisations.

Applicant submit the list of minor use authorisations, detailed explanation concerning the minor use authorisations of the respective PPP and of the impact of substitution of the respective PPP with alternatives on crop production, availability of efficient plant protection methods and on the occurrence of resistance.

6. Is the risk for health or the environment when using the respective PPP significantly greater than when using available alternatives?

The properties of the candidate for substitution shall be compared with the properties of available alternatives.

Applicant submit an overview report on the properties of the candidate for substitution and chemical alternatives available in the EC Review Reports published on EU web pages (EU Pesticide Database). If there are many alternatives available on the market, the overview shall be prepared for one of each mode of action for certain use: for instance, if there are five products on the market with identical mode of action for one certain use, the overview shall be prepared for the representative one of them.

The Administration would use this overview report for performing the comparative risk and exposure assessment of different population groups, the environment and risk mitigation measures; and of the content of non-active isomers in the technical material of certain active substances.

7. The possible existence of significant risk established by the risk assessment of alternatives in any other aspect than here stated criteria; or the requirements for implementation of extensive risk mitigation measures for alternatives.

The comparative assessment of the respective PPP with alternatives performed according to previous items has concluded that the use of alternatives should be better choice regarding protection of health and the environment.

All aspects of the risk for health and the environment may not be covered by here stated criteria, therefore the possible risk caused by the use of alternatives in other aspects shall be examined; as well as the efficiency of risk mitigation measures and use of PPE for alternatives.

The applicant may submit the description of other risks not described here that the alternatives may bring about; for instance whether or not the use of alternatives depends on the use of PPE, or special constructions and devices, or special manner of use and similar.

8. The existence of other relevant information for comparative risk assessment.

The applicant may submit other additional information relevant to comparative risk assessment of the respective PPP if they have them at their disposal.

## Annex 2

A supplement to dRR part A.

Applicant's conclusions on comparative assessment and substitution of the PPP containing candidates for substitution.

»Trade name of PPP<sup>1</sup>« containing »active substance(s)« is/are listed as candidate(s) for substitution in the Regulation (EU) 2015/408 for the following reason(s):

Low ADI, ARfD or AOEL.

Two PTB criteria.

Significant proportion of non-active isomers in technical material.

Classification as carcinogen or toxic for reproduction category 1A or 1B or considered to have endocrine disrupting properties.

Other grounds for concern.

(Delete the statements not valid for this particular active substance).

»Name of the applicant« have performed the comparative risk assessment of »Trade name of PPP« and suggest that the substitution of the PPP in question with alternatives is/is not<sup>2</sup> reasonable for the following reason:

(Add the justification from comparative assessment according to one or several items (as appropriate) from Annex 1 of this instruction for each intended use of »Trade name of PPP« separately).

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<sup>1</sup> Insert actual names in all quotation marks.

<sup>2</sup> Delete as appropriate

## Fees

Complying with item IV of Annex 2 of Regulation implementing Regulations (EC) and (EU) concerning the placing of plant protection products on the market (UL RS 5/15) the fees for comparative assessment from 100 - 3.000 € shall be paid dependent on the amount of work required.

The amount of work required includes expert and administrative work for comparative assessment of the parameters as referred in to Annex 1 of this instruction.

The detailed fees are presented in the table below.

There are no fees charged, if applicant submit the conclusions concerning the comparative assessment, which after the consideration of the Administration due to their nature do not require any additional comparative assessment at the level of the Administration.

Table: Fees for comparative assessment of PPP containing candidates for substitution

<b>The type of work</b>	<b>fees</b>
The examination of existing information and data; the administrative comparison according to items 1 – 5 and 7 – 8 of Annex 1 of this instruction.	100,00 €
Comparative risk assessment according to item 6 of Annex 1 of this instruction for each intended use of the PPP in question (one combination crop/harmful organism), however, not above 3.000 € if there are more than 7 intended uses.	400,00 €