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| DRAFT REGISTRATION REPORT Part A  Appendix 5  Comparative Assessment Report |
| Product code:  Product name(s):  Chemical active substance(s):  g/kg, g/L |
| Central Zone Zonal Rapporteur Member State: Slovenia |
| NATIONAL ASSESSMENT: Slovenia |
| **Applicant:**  Finalisation Date: |

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1. INTRODUCTION

This document should be used by the applicant as a template for Comparative assessment prepared at *Member State level. It has been also designed to provide some guidance for the applicant on the preparation of Comparative* Assessment *following SANCO Guidance document on comparative assessment and substitution of PPP in accordance with Regulation (EC) No. 1107/2009 (SANCO 11507/2013 rev. 12) and EPPO guideline PP 1/271(3) Guidance on efficacy aspects of comparative assessment. Comparative Assessment Report is not a standalone document, it is Appendix 5 of the Registration Report Part A.*

Notes: Green text provides some explanations and should be deleted when the document is finalized. Blue text presents examples and should be completed. If it is not relevant it should be removed.

Articles 24 and 50 of Regulation 1107/2009 require a comparative assessment of products containing active substances that are considered as candidates for substitution (CfS). This Comparative Assessment Report is based on the requirements of *SANCO Guidance document on comparative assessment and substitution of PPP in accordance with Regulation (EC) No. 1107/2009* and EPPO guideline PP 1/271 (3) *Guidance on efficacy aspects of comparative assessment*. Comparative Assessment Report covers the following points and stages:

- A brief description of the reasons why the Comparative assessment (CA) is needed,

- Description of active substance(s) according to the mode of action (MoA),

- Candidate product overview and defining the uses of the candidate product,

- Assessing impact on minor uses (Stage A of CA),

- Assessing comparability regarding the risk of developing resistance (Stage B of CA),

- Assessing efficacy and use within IPM of available alternatives for each use assessed (Stage C of CA),

- Assessing practical and economic disadvantages for each use assessed (Stage D of CA),

- Final conclusion of the comparative assessment.

[After completing the comparative assessment, stages not relevant should be removed.]

**A brief description of the reasons why the CA is needed**

[Example: Product XXXX is a herbicide/fungicide/insecticide/….., containing active substance/substances XXXX. According to the…….. (specify relevant Commission regulation reviewing the approval of active substance as CfS) active substance XXXX meets the criteria to be considered as a persistent/ bioaccumulative/ toxic substance, therefore it is considered as a candidate for substitution.]

**Description of active substance (s) according to the mode of action**

[Description should include: A Classification of AS according to HRAC/FRAC/IRAC, a brief description of the mode of action of AS, classification of AS according to the risk for resistance development]

**Candidate product overview and defining the uses of the candidate product**

[Example: The plant protection product XXXX is a suspension concentrate (SC)/………, herbicide/fungicide/insecticide containing XY g, kg/L a.s.1 and XY g, kg/L a.s.2 for control of ………. (insert targets) on ………..(insert crops). Only active substance a.s.1 is considered as a candidate for substitution.]

Uses of the product to be considered in comparative assessment are presented in summary Table 1-1.

**Table 1-1: List of uses of candidate product [name].**

| **Ref. No. in CAa)** | **Crop**  **(EPPO code)** | **Target name**  **(EPPO code)** | **Reference to the table “Product uses approved in Slovenia” b)** |
| --- | --- | --- | --- |
| 1 |  |  |  |
| 2 |  |  |  |
| 3 |  |  |  |
| 4 |  |  |  |

a) Reference to the Decision support scheme, stage B (See Section 2 Comparative assessment of this document)

b) Reference to Registration Report Part A, Point 2.3 Conclusion, Table “Product uses approved in Slovenia”

2 COMPARATIVE ASSESSMENT

The decision supporting scheme follows a tiered approach based on a series of questions grouped within four stages (A–D described above).

[The order of stages presented in the decision scheme below shall be considered fixed. However, the order of stages may be reversed upon justification. E.g. If resistance risk is the key concern, then Stage B is more suitable starting point. Explanation notes in CA decision support scheme are available in EPPO guideline PP 1/271 (3) (See https://pp1.eppo.int/standards/PP1-271-3). In each point in stages below, relevant text should be highlighted. Where required, explanations are mandatory. Please read “NOTES” in details before starting the assessment.]

Decision support scheme - Stage A

**Assessing impact on minor uses**

|  |  |
| --- | --- |
| **A1 Is the candidate product authorised, or authorisation requested, for minor use?** | |
| Yes | Go to A2 |
| No | Go to next appropriate stage B, C, D. |
| **A2 Are minor uses sufficient to stop CA, according to the available national procedure?**  [Please consider, when extrapolation from major use is possible, minor use cannot be justified. When the applicant would like to authorise the certain use as minor use and another PPP containing the same active substance is already approved for this use then minor use could not be justified.] | |
| Yes | STOP CA and add explanation below. |
| No | Go to A3 |
| Explanation [if necessary] | |
| **A3 Is the substitution of candidate product on a major crop anticipated to have a significant impact (see Note A) on minor uses?** | |
| Yes  (Please explain below) | STOP CA and add explanation below. |
| No | Go to next appropriate stage |
| Explanation [if necessary] | |
| [If CA stops at the stages A2 or A3 further assessments in not required. Further stages of assessment are removed.] | |

Decision support scheme - Stage B

**Assessing comparability regarding the risk of developing resistance**

|  |  |  |
| --- | --- | --- |
| **[\****When product is intended for use against different pests then comparability assessment has to be done for each intended target.* When one target organism (e.g. *Botrytis*) can occur on multiple crops, one assessment is sufficient.  If CA stops at this stage explanation is necessary, further assessments in not required further stages of assessment are removed.] | | |
| **Use No. 1** | [Pest and EPPO code ]\* | |
| **B1 Does the target pest have a high or medium inherent resistance risk?** | | |
| Yes  (Please explain below) | | Go to B2 |
| No  (Please explain below) | | Go to B5 |
| Explanation: [Resistance status for individual target has to be explained.] | | |
| **B2 Is there a product with the same mode of action (MoA) group authorised for use against the target pest?.** | | |
| Yes | | Go to B3 |
| No | | Go to B5 |
| [Before answering the question, the table B2 in Appendix 1 should be filled in. Table includes list of product with the same MoA group authorised in Slovenia for use against individual target pest. Acceptability relating to chemical resistance risk has to be presented. List of PPP registered in Slovenia and classified according to the MoA Group is available on:   * For fungicides: <https://spletni2.furs.gov.si/FFS/REGSR/FFS_FRAC.asp?top=1> * For herbicides: <https://spletni2.furs.gov.si/FFS/REGSR/FFS_HRAC.asp?top=1> * For insecticides and acaricides: <https://spletni2.furs.gov.si/FFS/REGSR/FFS_IRAC.asp?top=1>] | | |
| **B3 Are there products with another MoA authorised for use against the target pest(s)?** | | |
| Yes | | Go to B4 |
| No | | STOP CA and add explanation below. |
| [Before answering the question, the table B3 in Appendix 1 should be filled in. Table includes list of product with another MoA group authorised in Slovenia for use against individual target pest. Acceptability relating to chemical resistance risk has to be presented. Links to the lists of PPP registered in Slovenia and classified according to the MoA group are available below point B 2.] | | |
| Explanation: [if necessary] | | |
| **B4: Does the candidate exhibits negative cross resistance in the target pest(s)?** | | |
| Yes | | STOP CA and add explanation below. |
| No | | Go to B5 |
| Explanation: [if necessary] | | |
| **B5: Given the available (chemical and non-chemical), is the candidate an important component of the resistance management strategy for the target pest and other pests in the crop not themselves subject to CA?** | | |
| Yes | | STOP CA and add explanation below. |
| No | | Go to next appropriate stage (A, C or D)\* |
| [Before answering the question, the table B5 in Appendix 1 should be filled in.]  Table B5 is Summary table of all available PPP and all available Mode of actions which can be used as an alternative to candidate product. (For example please see Appendix 1, Table B5: Summary of alternative products).] | | |
| NOTE: Based on expert judgment it is recommended that in a low resistance risk situation a sustainable resistance management strategy includes at least two MoAs. However, in the case where there is evidence of a medium risk of resistance to one or more of these PPPs or a medium risk of resistance in the target organism, at least three MoA are recommended. In the case where there is evidence of a high risk of resistance to one or more of these PPPs or a high risk of resistance in the target organism, at least 4 modes of action are recommended (Rotteveel et al., 2011). The current resistance situation should be considered when evaluating the required number of mode of actions. | | |

**Decision support scheme - Stage C**

**Assessing efficacy and use within IPM of available alternatives for each use assessed.**

|  |  |
| --- | --- |
| [The applicant prepares stage C only if less MoA is available than required by the sustainable resistance management strategy. See also Note at the end of stage B. The tabular form is preferred for easier comparison. The sources of information are label and publicly available part of authorisation decision.] | |
| **C1. Do alternatives (chemical or non-chemical) exist for controlling the target organism (or regulating plant growth) in the target crops of the candidate product for that use?** | |
| Yes | Prepare list of alternative methods and  Go to C2 |
| No | STOP CA |
| [List of alternative methods should be prepared. If no alternatives exist, brief explanation is required.] | |
| Explanation: [if necessary] | |
| **C2. Is the effectiveness of the alternative(s) comparable (see Note) with the candidate product for that use?** | |
| Yes | Go to C3 |
| If the alternative(s) is (are) unacceptably less effective | STOP CA and add explanation below |
| [If alternative method(s) are unacceptably less effective than CfS, situation should be explained.] | |
| Explanation: [if necessary] | |
| **C3. Is the crop safety of the alternative comparable (e.g. comparing existing label crop safety warnings and restrictions on succeeding crops) with the candidate product for that use?** | |
| Yes | Go to C4 |
| If unacceptably lower | STOP CA and add explanation below |
| If the crop safety of alternative method(s) is unacceptably lower than crop safety of CfS, situation should be explained. | |
| Explanation: [if necessary] | |
| **C4. Will substitution of the candidate product by the alternative lead to disruption of established IPM strategies, prohibit establishment of new IPM strategies or, for example, have a negative impact on beneficial organisms, for which there are no acceptable mitigation possibilities?** | |
| Yes | STOP CA and add explanation below |
| No | Go to next appropriate stage |
| Explanation: [if necessary] | |
| NOTE: When comparing two PPPs, in some cases they will have the same mode of application and result in the same or similar controlling effect on the target. Differences in effectiveness, e.g. indicated by differences in level, consistency and longevity of control, and where relevant yield or quality, provide a good basis for comparison. Limitations in the use according to the label (e.g. number and timing of applications, buffer zones) of the alternative also need to be taken into account. This information may come from the authorized label claims, independent technical institutes and researchers. | |

Decision support scheme - Stage D

**Assessing practical and economic disadvantages for each use assessed.**

|  |  |
| --- | --- |
| **D1. Are there signiﬁcant practical or other disadvantages (see Note D (i)) resulting from the use of the alternative if the candidate is no longer available?** | |
| No | Go to D2 |
| Yes | Stop CA and add explanation below |
| Explanation: [if necessary] | |
| **D2. Is gaining pest control with alternative(s) considerably more expensive (see Note D (ii)) than the use of the candidate?** | |
| No | Go to D3 |
| Yes | Stop CA and add explanation below |
| Explanation: [if necessary] | |
| **D3 Are there any wider consequences for maintaining effective crop protection, including e.g. the security of future pest control that might inﬂuence the decision of making a substitution and/or adverse impacts for non-crop uses (see Note D (iii))?** | |
| Yes | Stop CA and add explanation below |
| No | Approval of candidate product [NAME OF PRODUCT]is not acceptable, there are other alternative methods that can effectively replace it. |
| Explanation: [if necessary] | |
| NOTES:  **D(i):** Practical or other disadvantages include lack of labour availability for hand weeding, insufficient land available to permit sufficiently long rotations to enable pest, weed or disease management through crop rotation, versatility of alternatives, etc. For herbicides in particular, the lack of weed control can significantly adversely impact the following crop in the crop rotation. The windows of application (including pre-harvest intervals) of other methods may differ from the application of the candidate and limit the feasibility of the alternative. Consideration should be given to the need and acceptability of the use of additional PPPs or alternative measures to control additional pest problems.  **D(ii):** The EU Regulation 1107/2009 defines significant economic disadvantage to the user as a major quantifiable impairment of business activity leading to an inability to control the target organism. A clear criterion should be established to decide whether it concerns a considerably more expensive pest control or not. For example, the alternative leads to a substantive increase in production costs to obtain the same yield value. It should be remembered that economic disadvantage with a non-chemical method may need to be considered over more than a single year. When, for example, fleeces are used as an alternative, their durability may be such that they can provide effective insect control for several years, and cultivation methods as alternatives may result in high seed return from the soil seed bank. Independent experts should be consulted where necessary.  **D(iii):** Wider consequences include:  • dependence on a single product for a major use  • sustainable production of the crop concerned  • control possibilities for quarantine pests  • control possibilities for emerging pests  • need for diversity of products to minimize impacts on water quality and biodiversity  • impact on human health, for example mycotoxin levels in cereals, contamination of harvested produce with poisonous weeds, allergic reaction to Lepidoptera species such as Oak processionary moth  • impact on human safety, for example airfield management to avoid bird strikes, vegetation management in railway line verges In addition to considering products that are currently authorized, consideration should be given to active substances which may be at risk of losing authorization, based on current knowledge. | |

3. FINAL CONCLUSION OF THE COMPARATIVE ASSESSMENT

The conclusion of the comparative assessment is

Product **[**name**]** is suitable for substitution /not suitable for substitution

Due to the following reason(s)……

[Specify the conclusion separately for each crop/pest combination.]

4. REFERENCES

[References relevant for CA]

APPENDIX 1: Tables, part of stage B (B2, B3, B5) of Comparative assessment for product [name of PPP].

**B2 [Herbicides/Insecticides /Fungicides/etc*]* with the same MoA group**

**Table B2-1: [Herbicides/Insecticides /Fungicides/etc*]* with the same MoA group approved for use on [*CROP (EPPO Code)]*** to control **[target (EPPO code)]**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **No** | **Product** | **Active substance** | **Expiry date** | **xRAC group** | **Resistance risk** | **Acceptability of product relating to resistance YES/NO**  **(comment - if necessary, see FRAC/HRAC /IRAC comments on resistance)** |
|  | AAAAAA | AS 1 |  | A3 | high | HIGH RISK FOR RESISTANCE DEVELOPMET.  NO |
|  | BBBBBB | AS 2 |  | A3 | medium to high | MEDIUM TO HIGH RISK FOR RESISTANCE DEVELOPMET  NO |

[List of approved products should be prepared for individual target or target group (e.g. annual broad leaved weeds, perennial broad leaved weeds, grasses) as listed in the Table 1-1 under section Product overview. For every individual target, table B2 should be prepared. Tables should be numbered as B2-2, B2-3 etc.

Different products containing the same CfS should not be compared therefore should not be listed in the table above.]

**B3 [Herbicides/Insecticides /Fungicides/etc*]* with another MoA group**

**Table B3-1: [Herbicides/Insecticides /Fungicides/etc*]* with another MoA group approved for use on [*CROP (EPPO Code)]*** to control **[target (EPPO code)]**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **No** | **Product** | **Active substance** | **Expiry date** | **xRAC**  **group** | **Resistance risk** | **Acceptability of product relating to resistance YES/NO (comment if necessary)** |
|  | CCCCCC | AS 3  AS 4 |  | C5  C4 | medium  medium | C5: Cross resistance within the group, D: resistance known for several target species.  NO |
|  | DDDDDD | AS 5 |  | D5 | LOW | YES |
|  | EEEEEEE | AS 6 |  | D6 | LOW | YES |

[List of approved products should be prepared for individual target or target group (e.g. annual broad leaved weeds, perennial broad leaved weeds, grasses) as listed in the Table 1-1 under section Product overview. For every individual target, table B3 should be prepared. Tables should be numbered as B3-2, B3-3 etc.]

**B5. Alternative products**

**Table B5: Summary of alternative products**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Target**  ***(EPPO Code)*** | **Crop**  ***(EPPO Code)*** | **Product(s) available as alternative** | **Active substance** | **xRAC**  **group** | **Number of MoA alternatives** |
| 1 | 1 | DDDDDD  EEEEEEE | AS 5  AS 6 | D5  D6 | 2 |
|  |  |  |  |  |  |

[Only products acceptable as a part of resistance management strategy which do not present risk of developing resistance and cross resistance are acceptable as alternatives to CfS containing products and should be listed in above table.]

APPENDIX 2: Tables, part of stage C of Comparative assessment for product [name of PPP].

APPENDIX 3: Tables, part of stage D of Comparative assessment for product [name of PPP].