

PLANT PROTECTION

COMPARATIVE ASSESSMENT

National Guidance for Belgium



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DOCUMENT INFORMATION

Comparative Assessment, National Guidance for Belgium

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Version and date	Changes
02/02/2018 Version 1.1	<p>Point 6 and 8: clarification that no CA is required in case of an extension for a minor use.</p> <p>Point 8 : clarification that exemption is possible in case of just one new active substance.</p> <p>Point 9 : adaptation to foresee that no alternatives need to be available for minor uses.</p> <p>Point 12 : clarification that not the whole decision tree needs to be followed until the end.</p> <p>Annex 1 is adapted:</p> <p>To reflect above mentioned modifications</p> <p>Step 4 and 7 : to foresee need for 4 modes of action for alternatives</p> <p>Step 6a : to consider all non-chemical methods as one single mode of action</p> <p>Annex 2 is adapted:</p> <p>Step 4, 6 and 7 : to reflect above mentioned modifications</p> <p>Step 9 : to allow for better identification of alternatives</p>

Purpose

To explain how the Belgian competent authority (the Service Plant Protection Products and Fertilisers, SPF) will undertake comparative assessment and substitution, a new requirement for plant protection products introduced by EU Regulation 1107/2009, and to announce new guidance for applicants.

To propose applicants a Belgium specific form for submitting information to support the process of comparative assessment.

Guidance on comparative assessment.

This national guidance supplements [the EU Guidance document](#) of the European Commission. The UK HSE guidance was taken as basis for this document, with some more or less significant modifications reflecting the situation in Belgium. It provides information on the types of application that require a comparative assessment and example sources of reference to Belgium specific information that will assist applicants in providing the relevant information to support a comparative assessment. The application form in annex 2 integrates the information of the appendix of the EU Guidance document, which would hence no longer be needed.

EU Regulation 1107/2009 requires Member States to complete a comparative assessment when evaluating applications for plant protection products containing an active substance approved as a candidate for substitution. Member States are not to authorise, or must restrict the use of such products, where a comparative assessment in accordance with the regulation demonstrates that there is a significantly safer option for that use.

Member States must weigh up the risks and benefits of the use and must include consideration of resistance risk management and minor uses, and ensure that the alternatives do not present significant practical or economic disadvantages.

The alternative controls available will differ between Member States and as such this aspect of the EU regulation requires specific consideration by individual Member States.

When does this apply?

Comparative assessment is required for relevant applications submitted after 1 August 2015. Revision 1 of this document can be applied as soon as it is published.

Contact Information

If you have any questions relating to this Regulatory Update, please contact the Service Plant Protection Products and Fertilisers. Contact details are available on www.phytoweb.be.

Comparative Assessment and Substitution

Guide for applicants for Plant Protection Product authorisations in Belgium

Summary

- Comparative assessment and substitution is required by Regulation (EC) 1107/2009.
- Individual Member States undertake the assessment.
- This guidance is provided for applicants seeking authorisation of plant protection products in Belgium. Other Member States may provide their own guidance.
- Supplements the EU guidance for applicants and replaces its appendix.
- Explains what information is required for a comparative assessment, when it should be submitted and how it should be presented.

What are the legal requirements for comparative assessment and substitution?

1. In summary, Article 50 of 1107/2009 specifies that ‘a comparative assessment shall be performed by Member States **when evaluating an application** for authorisation for a plant protection product containing an active substance that has been approved as a ‘candidate for substitution’¹. Article 50 explains the need to weigh up the risks and benefits in line with the regulation requirements (Annex IV) in considering whether there is a significantly safer alternative control or prevention method that could be substituted without specified adverse consequences on crop protection. Member States must not authorise a plant protection product or must restrict its use where this assessment concludes that there is a suitable significantly safer alternative.
2. Candidates for substitution are approved active substances meeting one or more of the conditions listed in Annex II point 4 of Regulation 1107/2009. They have all been evaluated and are approved for use in the EU in authorised plant protection products. Uses of plant

¹ The list of candidates for substitution considering active substances approved before 1 January 2013 is available on <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015R0408&rid=1> . Active substances considered as candidates for substitution approved on a later date will be published in a second list or considered as such in the approval regulation.

protection products considered under the comparative assessment process have all been evaluated and all have an acceptable risk assessment in accordance with Regulation 1107/2009.

3. SPF would like applicants to provide information to enable to fulfil their responsibilities under Article 50.

What about optional comparative assessments (Article 50(2)) and availability of formulations presenting lower risks (Article 29(1)(d))?

4. SPF will as a matter of principle not be undertaking any of the optional comparative assessments allowed for by Article 50(2), except in exceptional cases. Therefore this guidance only considers the requirements for obligatory comparative assessment and substitution as foreseen by Article 50(1). On the other hand, in application of Article 29(1)(d), an authorisation will be refused if the technical formulation of another product containing the same active substances leads to significantly lower risks; this is the case for any product, hence also those products not containing a candidate for substitution. Article 29(1)(d) and the principle of “significantly lower risks” will be applied by SPF during the authorisation process on a case by case basis, and as always applicants will be given the possibility to engage an appeal procedure. As a matter of example, a rodenticide dusting powder could be refused if liquid formulations are already on the market, as liquids lead to a lower operator exposure.

In which cases should I provide information for comparative assessment ?

5. [The EU Guidance document²](#) of the European Commission on comparative assessment came into force on 1 April 2015. The list of Candidates for Substitution comes into force on 1 August 2015. Since SPF will in principle not be undertaking optional assessments under Article 50(2), in practice this means that you will need to provide information for comparative assessment from 1 August 2015.

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http://ec.europa.eu/food/plant/pesticides/approval_active_substances/docs/comparative_assessment_substitution_rev_1107-2009.pdf

6. You only need to provide the information in this guidance for applications for plant protection products containing one or more active substances approved as a candidate for substitution that you make from 1 August 2015 for:
 - Authorisation of new products within a certain category of users (professional or non-professional);
 - New or additional uses (except if the new or additional use is a minor use, see point 8);
 - Renewal (re-registration following renewal of the approval of an active substance).
 - and this independent of the fact that Belgium acts as zonal rapporteur or as concerned member state, hence also for mutual recognition applications.
7. Any relevant conclusions will be applied to any parallel import permit and any authorisation for identical 'back to back' products which are based on the same application (be it via a letter of access or on behalf of the same company).
8. Comparative assessment is not required for following kinds of applications even if the product contains a candidate for substitution, and hence no additional information needs to be submitted :
 - Authorisation of identical products within a certain category of users (professional or non-professional), based on access to a previously evaluated application;
 - Authorisation of products containing at least one new active substance, approved less than five years ago, including extensions of use of such products;
 - Extension of an authorisation for minor use(s);
 - Permits for parallel import
9. SPF considers that a substitution is not appropriate for products authorised for at least one minor use, and in this case all uses of the concerned product will be maintained (including the major uses). This is valid for:
 - applications for extension of use with minor uses
 - applications for authorisation of new products including at least one minor use;
 - applications for re-registration of products registered for or including at least one minor use.

How should I submit the information?

10. Your conclusion on comparative assessment and substitution should be included in the national addendum to part A of the draft Registration Report (dRR). Your detailed consideration of this, using the form attached to this guidance in Annex 2, should be provided as the supporting 'data'. Instructions for completion are given in Annex 1.

When do I submit the information ?

11. As a zonal rapporteur, Belgium will need this information included in the application. As a concerned member state, Belgium will need this information when the registration report of the zonal rapporteur becomes available for peer review or at the latest when the registration report of the zonal rapporteur has been finalised.

What does the information need to cover?

12. Follow the decision tree through steps 1-11 of Annexes 1 and 2 and decide which information you need to submit for your product. The process of CA may be terminated at any stage and it might not be necessary to continue through all steps.
13. Where the application is for an amendment to the authorisation to include additional uses, your comparative assessment need only consider the additional uses requested. Where the application is for renewal of authorisation you should consider all uses of the product. A 'use' is defined as any single combination of crop/pest.

How do I address comparative assessment for Zonal applications where Belgium is the rapporteur Member State?

14. As comparative assessment and substitution is a Member State responsibility, it cannot be considered appropriately by the zonal rapporteur Member State. It remains the responsibility of the individual Member States and you should follow their advice and procedures. You should include the Belgian comparative assessment information in your application as a national addendum to part A.

Transitional arrangements for 'following zonal' applications (Belgium acting as concerned Member State):

15. 'Following zonal' applications submitted before 1 August 2015 will be accepted in Belgium without comparative assessment once the zonal rapporteur has completed their work.

How will comparative assessments be completed in Belgium?

16. The intention is to enable both applicants and SPF identify quickly and with minimum effort those uses of plant protection products where a substitution would not be appropriate even if a significantly safer alternative exists. This is because a comparison of risk assessments to determine whether one method of control is significantly safer than another is complex and potentially very time-consuming. A comparison of risk assessments will only be undertaken by SPF where it is initially identified that a substitution may be appropriate.
17. If your information in the form 'applicant information to support the process of comparative assessment' (Annex 2) indicates that a substitution may be appropriate, SPF will complete a more detailed comparative assessment following the approach outlined in the EU guidance on comparative assessment here: http://ec.europa.eu/food/plant/pesticides/approval_active_substances/docs/comparative_assessment_substitution_rev_1107-2009.pdf. This could also happen if the applicant information is incomplete or if SPF has other information available. SPF will in any case check all legal obligations.
18. If a more detailed comparative assessment is performed by SPF, the following principle from the EU guidance on comparative assessment will be followed: The properties of an active substance that mean it is a candidate for substitution will define the first aspect of the comparison to determine whether there are significantly safer options. For example, if the active substance is classified persistent and bioaccumulative (two of the Persistent, Bioaccumulative and Toxic criteria), the comparative risk to the environment will be considered first; if the active substance is classified as a Category 1B Carcinogen, then comparative risk to humans will be considered first.
19. If SPF concludes that an alternative control might provide a significantly safer option in this first comparison, other areas of the risk assessment will be considered. If these require stricter risk reduction measures, a substitution will not be appropriate. For example, if it is concluded that product 'A' might be a significantly safer option for the pesticide user to control a certain pest than product 'B' (and the active substance in product 'B' was a candidate for substitution due to a significantly lower AOEL), it will be necessary then to check whether there are strict environmental risk reduction measures required for the use of product 'A'. If there is a requirement for a larger 'no spray buffer zone' to protect surface water, it is likely that substitution will not be appropriate.
20. Taking all of these aspects into consideration, SPF will make an expert judgement on whether a substitution is appropriate and thus whether authorisation can be granted for the uses considered.

Regulatory action at the end of comparative assessment

21. If SPF concludes that a substitution for any of the uses of your product is appropriate, withdrawal or amendment of that use will be proposed in line with Article 50(5). This will take effect three years after the decision to withdraw or amend the authorisation, or at the end of the approval period for the candidate for substitution, where that period ends earlier. A period of grace will be granted for sale (six months) and use (one year) of products on the market after these three years. You will have the opportunity to consider the proposals for an amendment or withdrawal of an authorisation in line with Article 44 of EU Regulation 1107/2009 and in application of the appeal procedure foreseen by Article 27 or 29 of the Royal Decree of 28/02/94. This provides an opportunity for the authorisation holder to submit comments or to provide further information. Applying for extension of the use in a minor crop will however not be accepted as a matter of appeal; such an extension should be part of the original application in order to be considered.

What if the availability of alternatives changes after a decision to substitute my product has been made?

22. If you believe that suitable significantly safer alternatives to your product are no longer available and a comparative assessment would not reach the conclusion that a substitution is appropriate, you may make an application for re-instatement of your product using the appropriate regular application route foreseen by article 33 of Regulation 1107/2009. If the active substance is still approved as a candidate for substitution, this application should include a new consideration for comparative assessment together with any other data or information that may be required for re-instatement at that time.

Annex 1. Instructions for completing the form ‘applicant information to support the process of comparative assessment for Belgium’ in Annex 2

The form in Annex 2 does not need to be completed for :

- Authorisation of identical products within a certain category of users (professional or non-professional), based on access to a previously evaluated application;
- Authorisation of products containing at least one new active substance, approved less than five years ago, including extensions of use of such products;
- Extension of an authorisation for minor use(s);
- Permits for parallel import

Please start at step 1 and follow the indications until you reach step 11.

Step 1. Is your product destined for non-professional users ?

In that case, the derogation of Article 50(3) is not possible (step 2) as it should not be necessary to acquire experience before making a product available for non-professional users neither would there be any feed-back from such experience. Neither does the consideration of minor uses interfere (steps 3-5), so you can directly go to step 6.

Step 2. Do you want to make use of the derogation in Article 50(3) for uses where it is necessary to acquire experience first through using that product in practice?

Examples where you may wish to use this derogation include a new use (a first use of an active substance on that crop or against that pest; significant advance in formulation type; introduction of a new active substance to a sector of agriculture).

You will need to make the case that there is a need to gain experience, but you do not need to provide any further information to support a comparative assessment.

If you seek to make use of this derogation any authorisation will be limited to a shorter period, not exceeding five years, following which a new application with a comparative assessment will be required to continue the authorisation.

If the derogation according to Article 50(3) is used, please state your reasons. Then go to step 11. If not, please proceed with step 3.

Step 3. Does your application include a minor use?

Minor uses are defined as: 'Use of a plant protection product on:

- any crop other than a major crop (=minor crops, see list on <http://phytowebe.be>) or
- a major crop against a minor pest for which no practicable control measures are available'.

If the application includes at least one minor use, or the product is already authorised for a minor use, please indicate these uses in the table under step 4. If not, go to step 5. In case this minor use will be accepted, substitution could only apply if enough alternatives are available for the minor use. As it cannot be guaranteed that the minor use will be accepted during the authorisation process, it is recommended to submit the data needed for comparative assessment anyway. Use the table under step 4.

Step 4. Is the chemical diversity of the active substances in alternative products adequate to minimize the occurrence of resistance for the minor uses?

Please include a list of the minor uses of your product and those authorised for other products, including the mode of action.

For each use considered, specify how many different modes of action are available. If there are four modes of action or fewer available, substitution will not be appropriate as the chemical diversity of the active substances is unlikely to be sufficient to minimise the occurrence of resistance. European Plant Protection Organisation (EPPO) guidance requires at least four modes of action to manage a high resistance risk. Whilst lower levels of resistance risk might be managed with fewer modes of action, the impact of the re-registration programme and of other legislation, such as the Water Framework Directive, can, in practice, further reduce the availability of alternatives.

Where more than four modes of action are available, please provide a further analysis of whether you consider the chemical diversity is sufficient to minimize the occurrence of

resistance. For example, information about specific resistance problems for a particular use might mean additional concern is merited.

Please explain the agricultural consequences if the minor uses under consideration were to be replaced by a safer alternative. If there are many minor uses, you may wish to focus specifically on uses where there is likely to be sufficient chemical diversity to minimize the occurrence of resistance. You might also have specific commercial information that may be of use in explaining the consequences on minor uses.

If the chemical diversity is not adequate to minimize the occurrence of resistance for the minor uses, please go to step 11. Otherwise, please proceed with step 5.

Step 5. What is/are the major use(s) of your product to be considered in a comparative assessment?

You need to consider all major uses at renewal, but only the proposed new/amended use in other applications.

In line with EU guidance, consideration of alternative control measures in a comparative assessment is required for all uses of the product. 'Use' means authorised specific crop/pest combinations.

If you apply for a major use, please indicate so in the table in step 7. Proceed now with step 6.

Step 6. What other options are available for the proposed uses to be assessed?

a) Non-chemical alternatives:

The UK authorities have funded research into non-chemical alternatives available in the UK (PS2809)³. This research concluded that few, if any, non-chemical alternatives suitable to substitute for uses of plant protection products are available for professional farmers. Thus you do not need to consider non-chemical alternatives further and appropriate reference to this publication will be sufficient.

These non-chemical alternatives are options that a grower can consider for the specific situation of the crop that needs treating, usually as a part of a programme of integrated pest

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<http://randd.defra.gov.uk/Default.aspx?Menu=Menu&Module=More&Location=None&ProjectID=17861&FromSearch=Y&Publisher=1&SearchText=PS2809&SortString=ProjectCode&SortOrder=Asc&Paging=10%23Description>
phytowebe.be

management. As a consequence, all relevant non-chemical alternatives together can be considered as one MoA.

For non-professional uses, please consider non-chemical alternatives in general or use by use, as appropriate. All relevant non-chemical alternatives together can be considered as one MoA.

b) Other authorised plant protection products:

Relevant information on alternative plant protection products is available from a range of sources including specialist agronomic advisory databases and the database of authorised products on www.phytoweb.be. Please list the alternative products in step 7, providing the information specified in the table. If there are many alternative products, it is unlikely to be necessary to consider them all. You may be able to select one or two products containing each of the possible alternative active substances as examples.

Information about the chemical mode of action of the active substances in your product and of the alternative active substances can be found in information published by the relevant resistance action committees (RAC) and groups.

The Weed Resistance Action Committee (WRAC) has produced a list of herbicide resistance groups which is at:

<http://www.hracglobal.com/pages/classificationofherbicidesiteofaction.aspx>

The Insecticide Resistance Action Committee (IRAC) list of modes of action is at:

<http://www.irac-online.org/modes-of-action/>

The Fungicides Resistance Action Committee (FRAC) of fungicide modes of action is at:

<http://www.frac.info/docs/default-source/publications/frac-code-list/frac-code-list-2015-finalC2AD7AA36764.pdf?sfvrsn=4>

Step 7. Is the chemical diversity of the active substances in alternative products adequate to minimize the occurrence of resistance?

For each use considered, specify how many different modes of action are available. If there are four modes of action or fewer available, substitution will not be appropriate as the chemical diversity of the active substances is unlikely to be sufficient to minimise the occurrence of resistance. European Plant Protection Organisation (EPPO) guidance requires at least four modes of action to manage a high resistance risk. Whilst lower levels of resistance risk might be managed with fewer modes of action, the impact of the re-registration programme and of

other legislation, such as the Water Framework Directive, can, in practice, further reduce the availability of alternatives.

Where more than four modes of action are available, please provide a further analysis of whether you consider the chemical diversity is sufficient to minimize the occurrence of resistance. For example, information about specific resistance problems for a particular use might mean additional concern is merited.

If the chemical diversity is not adequate to minimize the occurrence of resistance for the major uses, please go to step 11. Otherwise, please proceed with step 8.

Step 8. Can the alternative controls be used with similar effect on the target pest and without significant economic and practical disadvantages to the user?

The uses authorised for alternative controls have all been assessed against the specific requirements for product efficacy, and are in principle considered to give similar effect. However, it is perfectly possible that in practice, these alternatives have not the same level of efficacy. Such an argumentation can be taken into account.

The EU guidance on comparative assessment defines significant disadvantages as ‘quantifiable impairment of working practices or business activity leading to an inability to maintain sufficient control of the target organism’. Information that might provide useful evidence includes the need for and availability of specialist application equipment or techniques⁴ for some alternative products where these would result in such a disadvantage, the availability of necessary infrastructure such as specialist storage facilities, restrictions on flexibility in the timing of treatments to respond to environmental and other conditions. Product labels or authorisations often contain information about other aspects of the use of the products such as the application equipment recommended or required, the life stage of the pest that is controlled, and the pre-harvest intervals required following use. You might also hold specific commercial information useful in addressing this consideration that would support your case.

As far as products for non-professional users are concerned, please take into account that non-professional users are not considered to suffer economical disadvantages if the product or some uses would be substituted, and that mechanical weeding is considered to be an acceptable alternative to herbicides, be it possibly not for all situations or products. Your

⁴ Clearly some specialist application technologies are beneficial in reducing risk and do not present such disadvantages

application should contain information to allow a case by case evaluation of these considerations.

Step 9. Is there a significant difference in risk ?

Annex IV of Regulation 1107/2009 indicates that a range of criteria are to be used to determine a significant difference in risk. These include:

- the properties of the active substance and plant protection product;
- the possibility of exposure of different population subgroups directly or indirectly through food, water or the environment;
- the stringency of imposed restrictions on use and PPE prescribed.

List the risk mitigation measures required for your product and for the alternative controls in the table.

Risk mitigation measures such as PPE, buffer zones or restrictions on timing of applications are available in the product authorisations on www.phytoweb.be.

Some differences in mitigation measures may simply reflect assessment under different guidance. The objective is to identify any significant differences that will be indicative that a more detailed consideration is required. More marginal differences will be ignored.

If there are many alternative products, it is unlikely to be necessary to consider them all. You may be able to select one or two products containing each of the possible alternative active substances to exemplify whether there are any significant differences in risk mitigation.

If the risk mitigation measures of the alternative products are significantly different, or there are other reasons to believe that there are significantly safer alternative products, SPF will undertake a more detailed comparative assessment.

Step 10. Do you have any other relevant information that will enable a comparison of risk?

This is your opportunity to provide any additional information that you consider significant in the comparative risk assessment of your product.

Step 11. What is your conclusion on comparative assessment and substitution ?

For example:

The conclusion of the comparative assessment is that it is not suitable for substitution because there is only one alternative mode of action available amongst alternative products for all of its uses and thus the chemical diversity remaining is not sufficient to minimise the occurrence of resistance.

Annex 2. Applicant information to support the process of comparative assessment in Belgium

BE National addendum to the draft Registration Report (dRR)

Country	Belgium
Product under evaluation	
Candidate for substitution (active substance name)	
Reasons for approval as candidate for substitution (delete as appropriate).	low ADI, ARfD or AOEL; two of PBT; significant proportion of non-active isomers; classified Carcinogen 1A or 1B; classified as toxic for reproduction 1A or 1B; endocrine disruption; other reasons for concern

Step 1. Is this product destined for non-professional users ?

If yes, then go directly to step 6.

Step 2. Do you want to make use of the derogation in Article 50(3) for uses where it is necessary to acquire experience first through using that product in practice?

If yes, please state your reasons. Then go to step 11.

Step 3. Does your application include a minor use?

If you apply for a minor use or a minor use has been authorised for the product, please indicate so in the table under step 4. If not, go to step 5.

Step 4. Is the chemical diversity of the active substances in alternative products adequate to minimize the occurrence of resistance for minor uses?

Please indicate the products authorised for the minor use and their mode of action, including the product under consideration. Evaluate the chemical diversity of the active substances in the products to minimize the occurrence of resistance for the minor uses. If the chemical diversity is not adequate to minimize the occurrence of resistance, go to step 11. If the chemical diversity is adequate, please proceed with step 5.

Crop	Pest	Number of modes of action per use	Mode of action of each a.s.	RAC-code of each a.s.	Active substance	Products per a.s.
Crop1	Pest1	2	MoA1	AB	AS1	ABC
			MoA2	CD	AS2	XYZ
Crop1	Pest2	1	MoA1	AB	AS1	ABC

Step 5. What are the major uses of your product to be considered in a comparative assessment?

If you apply for a major use, please indicate so in the tables under step 6 and 7.

Step 6. What other options are available for the proposed uses to be assessed?

- a) **Non-chemical alternatives** : In case of agricultural use, please state "Agricultural use, no non-chemical alternatives available". For other uses, please consider non-chemical alternatives in general or use by use, as appropriate. Indicate alternatives below.

Crop	Pest	Alternative	Mode of Action

- b) **Authorised plant protection products** : Please indicate the authorised products and their mode of action in step 7.

Step 7. Is the chemical diversity of the active substances in alternative products adequate to minimize the occurrence of resistance in major uses ?

Please indicate the products authorised for the major uses and their mode of action, including the product under consideration in the table below. Mention the total number of modes of action available per use.

Are there more than 4 modes of action available?

If not, go to step 11.

If yes, please provide an analysis of whether the chemical diversity is sufficient to minimise the occurrence of resistance for each use with more than 4 modes of action available. If 4 modes of actions is sufficient to minimise the occurrence of resistance, please proceed with step 8.

Crop	Pest	Number of modes of action per use	Mode of action of each a.s.	RAC-code of each a.s.	Active substance	Products per a.s.
Crop1	Pest1	2	MoA1	AB	AS1	ABC
			MoA2	CD	AS2	XYZ
Crop1	Pest2	1	MoA1	AB	AS1	ABC

Step 8. Can the alternative controls be used with similar effect on the target pest and without significant economic and practical disadvantages to the user?

Please indicate any economic and practical disadvantages of using the alternative controls identified under step 6 and 7. As far as products for non-professional users are concerned, clearly demonstrate that substitution would lead to practical disadvantages for the users and

take into account that mechanical weeding would in principle be considered as an acceptable alternative for herbicides for garden use. Then proceed with step 9.

Alternative Disadvantages

Step 9. Is there a possible significant difference in risk?

Please indicate such differences in risk by listing the risk mitigation measures imposed for the alternative controls identified in step 6 and 7. Then proceed with step 10.

Alternative Active substances H-sentences of formulation Risk mitigation measures

Step 10. Do you have any other relevant information that will enable a comparison of risk?

Please conclude with step 11.

Step 11. What is your conclusion on comparative assessment and substitution ?

The conclusion of the comparative assessment is:

suitable for substitution/not suitable for substitution (delete as appropriate)

because

(specify your conclusion for each use assessed).