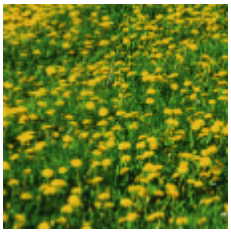

ECPA guidance on performing comparative assessment under Regulation 1107/2009

Appendix to Document No 21245

Revision 2

Brussels
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Introduction

Regulation (EU) No 1107/2009 replaced Directive 91/414/EEC on 14 June 2011 and has applied since that date. It implements comparative assessment and substitution provisions which did not exist in the Directive. In Document No 21245, ECPA presents its recommendations on how to implement these provisions.

ECPA welcome the adoption of a guidance document on comparative assessment by the Standing Committee on Plants, Animals, Food and Feed in October 2014 (SANCO/11507/2013 rev.2), which contains a scheme outline for comparative assessment (section 5).

This document is an appendix to ECPA Document No 21245 and includes further details on how ECA recommends to perform comparative assessment under the guidance document SANCO/11507/2013 rev.2.

Process and conditions for comparative assessment

Stepwise approach

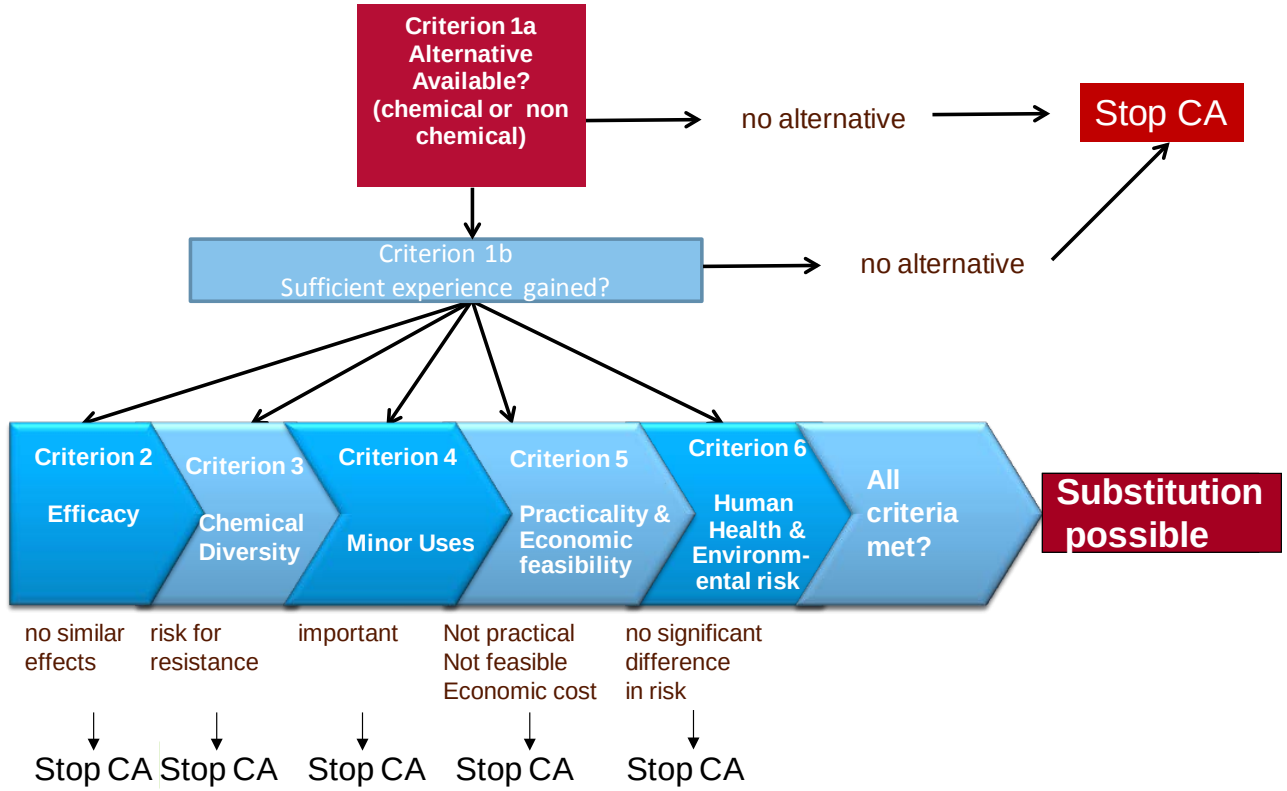
Annex IV of Regulation 1107/2009 lists a number of criteria as the basis for a decision on whether substitution should be applied; these are listed below.

In **Diagram 1** below, ECPA proposes a stepwise approach to comparative assessment which, in line with the Regulation, includes the criteria described in section 3 and which involves stopping the process as soon as one condition for substitution is not fulfilled.

Article 50 of Regulation 1107/2009 states that “a comparative assessment shall be performed by Member States when evaluating an application for authorisation of a plant protection product containing a candidate for substitution”. ECPA recommends that when comparing the results of risk assessments, these should be based on the same exposure and risk methods. If this not the case, it must be taken into account in comparative assessment.

Although the comparative assessment shall be conducted by Member States, applicants and/or authorisation holders (as appropriate) should be consulted during the process. It should be possible, although not mandatory, for applicants/authorisation holders to submit a benefits case/comparative assessment statement for affected products.

Diagram 1: Stepwise approach for Comparative Assessment



Criterion 1a

The first criterion in the stepwise approach is the identification of alternative plant protection solutions (chemical or non-chemical). An alternative can be defined as a plant protection solution, either chemical or non chemical, which controls the target organisms in the crop at the required timing as the candidate product without adverse impact on yield, productivity or quality. If no suitable alternatives are available, substitution should not be applied and comparative assessment should stop. If alternative plant protection solutions are available comparative assessment continues.

It is recommended that comparative assessment should not be carried out with alternatives containing the same candidate for substitution.

Criterion 1b

Has sufficient experience been gained?

Chemical alternatives: These should be widely available and have been fully approved and used for at least 5 years.

Non chemical alternatives: Ideally there would be a positive list of non chemical alternatives. If this is not the case the non chemical alternative should be widely available in the MS and should have been available and used for at least 5 years. It should be recognised as a viable alternative by the MS authority.

Comparative assessment can be carried out with both chemical and non chemical alternatives, ECPA recommend that the following criteria should apply:

Criteria 2-6

Annex IV of Regulation 1107/2009 lists a number of areas for evaluation, conditions and criteria to be followed:

- No negative effect on efficacy (including yield)
- Sufficient protection of chemical diversity to minimise occurrence of resistance
- Consequences for authorised minor uses
- No significant practical or economic disadvantages
- Significantly lower risk to man and the environment
- Availability of experience on the consequences of substitution

The authorities have an obligation to demonstrate that all above substitution conditions are met before making a substitution decision. Where any of the criteria are demonstrated not to be met, substitution is not applicable and there is no requirement to address the remaining conditions.

Known or expected regulatory developments under other legislation such as the water framework Directive[1] or the Directive on the sustainable use of pesticides[2] should also be taken into account when considering a substitution solution.

Final conclusion of the CA

The assessor should establish a summary table listing all crop/pest combinations of the candidate products and indicating for which uses substitution is possible as part of the assessment report. All stages of the comparison should be documented and made available to the notifier for comment prior to any substitution taking place, including reasons why the substitution is considered valid.

Detailed guidance

The guidance for carrying out a comparative assessment is set out in the following pages.
The order of the sections is not prescriptive and, once an alternative has been identified, comparative assessment can be continued anywhere from criteria 2-6. However, when it is not immediately possible to clearly identify a criterion that will fail to meet the conditions of substitution, ECPA recommends that the sequence laid out in Diagram 1 above be adopted. This sequence is more likely to conserve evaluators time than any other assessment sequence in situations where conditions for substitution will not (all) be met.
There are a number of questions listed under each criterion. Each question should be given the same level of importance within the assessment. The order in which the questions are presented is not prescriptive and they can be addressed in any sequence that the evaluator believes to be appropriate.

[1] For example any significant restriction of use resulting from river basin management
[2] For example, any restrictions in national action plans and/or the suitability of a particular product to integrated pest management

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Detailed guidance for performing comparative assessment

Criterion 2: Assessing comparability regarding efficacy

1. Is the effectiveness of the alternative comparable (see note **1**) with the candidate product for that use?
If yes, go to 2
If considerably less effective stop CA

2. Is the crop safety (including effects on adjacent crops, succeeding crops, taint or transformation processes) of the alternative comparable with the candidate product for that use?
If yes, go to 3
If unacceptably lower, stop CA

3. Will substitution of the candidate product by the alternative lead to pest problems for which there are no acceptable mitigation possibilities? (See note **2**)
If yes, stop CA
If no, go to 4

4. Will substitution of the candidate product by the alternative lead to disruption of established IPM systems or have a negative impact on organisms beneficial to crop protection for which there are no acceptable mitigation possibilities? (See note **3**)
If yes, stop CA
If no, go to next section or consider substitution

Guidance notes for assessing comparability regarding efficacy:
The detailed guidance for efficacy, resistance risk management and minor use protection have been taken from the draft EPPO guidance on comparative assessment 11-16700 and adapted to fit the ECPA stepwise approach.

It should be noted that this list is not exhaustive and the MS competent authorities should also consider the benefits of PPPs containing candidates for substitution during the comparative assessment process.

Note 1
In comparing two PPPs it is generally likely that both PPPs have the same mode of application and result in the same or similar controlling effect on the target. Differences in effectiveness, e.g. differences in level, consistency and longevity of control and, where relevant, yield or quality, provide a good basis for comparison. The weed /pest spectrum should be examined carefully to ensure that the candidate product controls the same range. 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. The evaluation of the potential impact on the ability of farmers to produce crops without significant net financial losses should be considered.

It is also proposed that any differences in efficacy should be evaluated on a case-by-case basis, in the context of each GAP. The requirement for a “similar effect” in Annex IV should therefore be interpreted within the context of “economic and practical disadvantages” for farmers.

Note 2
For example: The candidate product has broad spectrum control compared with the alternative and substitution may lead to pest problems for which the alternative has no registered label use.

Note 3
It should be considered whether the candidate product is essential within an established IPM system. Regarding the acceptability of mitigation possibilities, **see note 4.**

Note 4
Practical or other disadvantages should be considered, e.g.

- Lack of labour availability for hand weeding,

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- Insufficient land available to permit sufficiently long rotations to enable pest, weed or disease management through crop rotation,
- Versatility of alternatives, the windows of application of other methods may differ considerably from the application of the candidate and limit the feasibility of the alternative.
- Consider the need and acceptability of use of additional plant protection products or alternative measures to control additional pest problems.
- Consider the number of applications that may need to be made per crop cycle.

[1] In this document the word ‘candidate’ is used to designate ‘candidate for substitution’. The words ‘candidate product’ designates the plant protection product containing the candidate for substitution and evaluated by comparative assessment

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Criterion 3: Assessing comparability regarding risk of developing resistance

1. Does the target pest have a high or medium inherent resistance risk (see note **1**)?
If Yes, go to 2
If No, go to 5

2. Is there a product within the same Mode of Action (MoA) group authorised for use against the target pest?
If Yes, go to 5
If No, go to 3

3. Are there other MoA products authorised for use against the target pest?
If Yes, go to 4
If No, stop CA

4. Does the candidate exhibit negative cross-resistance (see note **2**) in the target pest(s)?
If Yes, stop CA
If No, go to 5

5. Given the available alternatives (chemical and non-chemical), is the candidate an important component (see note **3**) of the resistance management strategy for the target pest and for other pests in the crop not themselves subject to the comparative assessment?

If Yes, stop CA
If No go to next section or consider substitution

Guidance notes for assessing comparability of risk of developing resistance:

The detailed guidance for resistance risk management has been taken from the draft EPPO guidance on comparative assessment 11-16700 and adapted to fit the ECPA stepwise approach.

It should be noted that this list is not exhaustive and the MS competent authorities should, in practice, consider the benefits of PPPs containing candidates for substitution during the comparative assessment process.

Note 1
The risk of resistance can be analysed based on PP 1/213 *Resistance risk analysis.* In CA the impact on a risk management strategy in the situation that a plant protection product is subject to substitution is assessed.

Note 2
See detailed guidance provided in PP1/213, section 5.3.5

Note 3
Based on expert judgment it is recommended that, in a low resistance risk situation, a sustainable resistance management strategy includes at least two modes of action. However, in cases where there is evidence of a medium risk of resistance of one or more of these PPPs or a medium risk of resistance in the target organism, at least three modes of action are recommended. In cases where there is evidence of a high risk of resistance for one or more of these PPPs or a high risk of resistance in the target organism, at least 4 modes of action are recommended. Current resistance situation should be considered when evaluating the required number of mode of actions.
In considering the effect of substitution for a resistance management strategy other factors of inherent risks (e.g. target site resistance versus metabolic resistance, cross resistance) or agronomic risks should be taken into consideration (see EPPO standard PP 1/213).

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Criterion 4: Assessing the effect on minor uses (see note 1)

1. Is candidate product authorised for minor uses (on-label or off-label)?

If yes,	go to 2
If no,	go to next section or consider substitution

2. Is substitution of candidate product on a major crop anticipated to lead to unsustainable control (**see note 2)** of pests on a minor crop?

If no,	go to next section or consider substitution
If yes,	Stop CA

Guidance notes for assessing the effect on minor uses

The detailed guidance for assessing the effect on minor uses has been taken in part from the draft EPPO guidance on comparative assessment 11-16700 and adapted to fit the ECPA stepwise approach.

It should be noted that this list is not exhaustive and the MS competent authorities should also consider the benefits of PPPs containing candidates for substitution during the comparative assessment process.

Note 1
The definition and identification of minor uses is a pre-requisite to comparative assessment. Ideally a European list of minor uses should be made available by the Commission prior to or in conjunction with the release of the list of candidates for substitution. If such a list is not available, the competent authority in each member state should develop and communicate such a list.
When considering minor uses this should include both on label and off label uses of the candidate product.

Note 2
Unsustainable control in the context of pests in minor uses should be defined as:

"The inability to ensure effective control without adverse practical or economic effects on crop production, or unacceptable resistance risk to the targets controlled"

Unsustainable control should be clearly substantiated for the minor use and should describe the importance of its production. It should detail the absence of effective alternatives for the candidate or the lack of adequate chemical diversity for the minor use. Analysis of the efficacy of pest control and assessment of resistance risks may be extrapolated from data on relevant major uses. The information required should come from experts, which may include the product approval holder in case of on-label use of the candidate, or from the benefiting organisations in case of off-label use of the candidate.

In the situation that answering this question leads to the end of the CA, the reasons should be documented. It is also necessary to consider whether retaining one (or more) minor uses as the sole use of a candidate product, may (because of the subsequently reduced market size) lead to the termination of the supply of the candidate product by companies in the short as well as longer term.

A consideration of whether one or more of the major uses of the product should be maintained to secure the supply of the product is needed. In such cases the benefits of sustaining the minor crop production should be balanced against the larger scale use.

It should be noted that a removal of major label uses for the candidate product needs to be considered with respect to brand equity of the product to the notifier. Any request to change brand equity may result in removal of the product from the market.

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Criterion 5: Assessing comparability regarding practical or economical disadvantages of the alternatives

1. Are there significant practical or other disadvantages (**see note 1**) resulting from the use of the alternative if the candidate is no longer available?

If no,	go to 2
If yes,	stop CA

2. Is gaining pest control with the alternative(s) considerably more expensive **(see note 2)** than the use of the candidate?

If no,	go to 3
If yes,	stop CA

3. Are there any wider consequences for maintaining effective crop protection, including the security of future pest control that might influence the decision of making a substitution (**see note 3**)?

If no,	go to 4
If yes,	stop CA

4. Are there any other practical or economic consequences of making a substitution (**see note 4**)?

If no,	go to next section or consider substitution
If yes,	stop CA

Guidance notes for Assessing comparability regarding practical or economical disadvantages of the alternatives

The detailed guidance for assessing the practical or economical disadvantages of the alternatives has been taken in part from the draft EPPO guidance on comparative assessment 11-16700 and adapted to fit the ECPA stepwise approach.

It should be noted that this list is not exhaustive and the MS competent authorities should also consider the benefits of PPPs containing candidates for substitution during the comparative assessment process.

Note 1

Practical or other disadvantages should be considered, e.g.

- 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, the windows of application of other methods may differ considerably from the application of the candidate and limit the feasibility of the alternative.
- Consider the need and acceptability of use of additional plant protection products or alternative measures to control additional pest problems.
- Consider the number of applications that may need to be made per crop cycle.

Note 2

The EU regulation defines significant economic disadvantage to the user as a major quantifiable impairment of business activity leading to an inability to control the target organism.

Informed judgment should be applied in order to decide whether it concerns a considerably more expensive form of pest control or not. For example, the alternative leads to a substantive increase in production costs to obtain the same yield value (cost/ha).

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 returned from the soil seed bank. Independent experts should be consulted where necessary.

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The purchase and availability of specialized equipment shall be considered, e.g cost of machinery to lay fleeces.

The cost of substitution with resistant varieties shall be evaluated in the context of diseases/pests controlled by the resistant variety and the need for further methods of control for different diseases/pests.

When the CA is being carried out against another PPP, consideration shall be given to the range of pests/diseases controlled by the alternative, ie will substitution necessitate the purchase of additional products thus significantly increasing the cost/ha.

Note 3
For example:

- 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
- Creating a dominant position in the market

Note 4

- Will substitution have a negative impact on employment for all stakeholders in the value chain (e.g closure of manufacturing sites potential unacceptable reduction in staff at farm level etc)?
- Will substitution have a negative impact on competitiveness of European agriculture? e.g.
    - Will substitution cause production costs to increase thus increasing food prices both for the consumer and export, resulting in reduced competitiveness?
- Will substitution have a negative impact on any other aspect of international food and feed trade?
- Will substitution cause distortion of the market through removal of competition?
- Will substitution have a negative impact on EU food security?
- Will substitution have a negative impact on food prices through increased costs? (Either from purchase of machinery, increased labour costs, increase in chemical costs, increase in fuel needed if the substitution results in increased applications).

In addition to considering what is currently authorized, consideration should be given to actives which may be at risk of losing authorisation, based on current knowledge.
Known or expected regulatory developments under other legislation such as the water framework Directive[3] or the Directive on the sustainable use of pesticides[4] should also be taken into account when considering a substitution solution.

[3] For example any significant restriction of use resulting from river basin management
[4] For example, any restrictions in national action plans and/or the suitability of a particular product to integrated pest management

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Criterion 6: Comparability of risks for the environment and for human health

Criterion 6 is divided into 6a, risk for the environment; 6b, risk to human health and 6c a comparison of the risk for the environment and for human health. Although assessed separately, 6a and 6b should be considered contiguously unless it is shown that, at any point, substitution is not possible and comparative assessment should end.

Criterion 6c should be considered only when the criteria 6a (risks to the environment) and 6b (risks to human health) have been assessed.

This is necessitated by the fact that protection of human health cannot take precedence over protection of the environment nor the other way around, and the alternative should be significantly better in both areas in order for comparative assessment to continue/substitution to take place.

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Criterion 6a: Comparability of risks for the environment (see note 1)

1. Is the alternative significantly better than the candidate product when considering the risk mitigation measures applied for birds? **(See note 2)**

If yes	go to 2
If no	Stop CA

2. Is the alternative significantly better than the candidate product when considering the risk mitigation measures applied for bees? **(See note 3)**

If yes	go to 3
If no	Stop CA

3. Is the alternative significantly better than the candidate product when considering the risk mitigation measures applied for mammals **(See note 4)**

If yes	go to 3
If no	Stop CA

4. Is the alternative significantly better than the candidate product when considering the risk mitigation measures applied for soil organisms? **(See note 5)**

If yes	go to 4
If no	Stop CA

5. Is the alternative significantly better than the candidate product when considering the risk mitigation measures applied with respect to aquatic organisms by drift or run-off when using similar equipment? **(See note 6)**

If yes	go to 6
If no	Stop CA

6. Are the number of ground-water scenarios passed by the alternative significantly greater than the number passed by the candidate product (for the crop)? **(See note 7)**

If yes	go to 7
If no	Stop CA

7. Is the alternative significantly better than the candidate product when considering the risk mitigation measures applied for non-target arthropods? **(See note 8)**

If yes	go to 8
If no	Stop CA

8. Is the alternative significantly better than the candidate product when considering the risk mitigation measures applied for non-target plants? **(See note 9)**

If yes	go to 9
If no	Stop CA

9. Is the alternative significantly better in all environmental exposure scenarios? **(See note 10)**

If yes	go to 10
If no	stop CA

10. Are there any other unacceptable risks to environmental health not considered above? **(See note 11)**

If yes and criterion 6b has been assessed	go to criterion 6c
If yes and criterion 6b has not been assessed	go to criterion 6b
If no	stop CA

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Guidance notes for comparability of risks for environmental health

It should be noted that this list is not exhaustive and the MS competent authorities should also consider the benefits of PPPs containing candidates for substitution during the comparative assessment process.

Note 1:
The assessment of the environmental aspects of the candidate and any chemical and/or non-chemical alternatives shall be made by the appropriate experts.

When considering comparability for environmental protection for PPP's, consideration should be given to the guidance used at the time the submission was made. If the guidance used for the products differs, this shall be taken into account when performing the comparative assessment in order to ensure there is a truly equivalent risk comparison. Some products have a more extensive data package than others. This does not mean that these products are less safe but that the higher tier data reduces uncertainty.

Note 2: When considering the risk mitigation measures applied for the protection of birds, the assessor should include a comparison of all risk mitigation measures used. These should include the need for seed incorporation and spillage clean up for seed treatment, limiting application timings, limiting timing of application in the case of reproductive risk to avoid the breeding season and the need for spot or row applications to limit exposure. This assessment should be carried out by an expert in the field.

Note 3:
When considering the risk mitigation measures applied for the protection of bees, the assessor should include a comparison of all risk mitigation measures used. These should include the length of any pre-flowering restrictions, the need for mulching flowering weeds, length of re-entry periods, restrictions with respect to timing of application (e.g when bees are not actively foraging), bee brood health and minimization of dust-off. This assessment should be carried out by an expert in the field.

Note 4:
When considering the risk mitigation measures applied for the protection of mammals, the assessor should include a comparison of all risk mitigation measures used. These should include the need for seed incorporation and spillage clean up for seed treatment, limiting application timings, limiting timing of application in the case of reproductive risk to avoid the breeding season and the need for spot or row applications to limit exposure. This assessment should be carried out by an expert in the field.

Note 5:
When considering the risk mitigation measures applied for the protection of soil organisms, the potential buffer zone to off crop areas should be considered. The assessor should also include a comparison of the restrictions to use (e.g. glasshouse only applications).

Note 6:
When considering the risk mitigation measures applied for the protection of aquatic organisms the assessor needs to consider fish, aquatic plants and aquatic invertebrates. When considering the risk mitigation measures applied for the protection of these organisms in surface water the assessor should include a comparison of the following points (not exhaustive):

- The size of buffer zones and vegetative run-off buffers,
- Restrictions in window of application (e.g. restriction to spring use only),
- The use of low drift nozzles,
- The use of wind breaks,
- Changes in the application method,
- Restrictions on application to artificially drained or vulnerable soils,
- Restrictions in boom height,
- Restrictions in sprayer type (shielded boom sprayers, tunnel sprayers air assisted sprayers etc).

Note 7:
When considering the risk of reaching groundwater it should be recognized that this is not a risk based approach. If the FOCUS groundwater scenarios are not used at a national level then use the national modeling.
When considering the risk to groundwater the assessor needs to consider:

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- Numbers of scenarios passed that are relevant to that crop (a significant difference in number of scenarios passed is considered to be a difference of 3),
- Restrictions in the number of applications per year may be considered.

Note 8:
When considering the risk mitigation measures applied for the protection of Non-Target Arthropods (NTA's) the assessor should include:

- A comparison of restrictions in application frequency and interval,
- Restrictions in application timing,
- Use of unsprayed headlands,
- Size of buffer zones and restrictions regarding sensitive areas,
- Need for wind breaks,
- Use of drift reduction techniques

Note 9:
When considering the risk mitigation measures applied for the protection of Non-Target Plants (NTP's) the assessor should include:

- A comparison of restrictions in application frequency and interval,
- Restrictions in application timing,
- Use of unsprayed headlands,
- Size of buffer zones and restrictions regarding sensitive areas,
- Need for wind breaks,
- Use of drift reduction techniques

Note 10:
It is not possible to compare risks in different compartments for the environment (e.g. risk to GW cannot be given precedence over risk to birds and mammals) therefore when carrying out a comparative assessment for environmental health the alternative should be significantly better than the candidate product in all of the exposure scenarios.

Note 11:
Are there any other unacceptable risks to environmental health not previously considered?

- Will substitution have a negative impact on the environment? e.g:
    - impact of ploughing on soil flora and fauna when used as a method of weed control
    - Assessment of impaction risks from regular ploughing,
    - Increase in carbon emissions due to increased numbers of applications?

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Criterion 6b: Comparability of risks for Human health (see note 1)

1. Is the alternative significantly better than the candidate product when considering acute consumer risk assessment?

If Yes	go to 2
If No	Stop CA

2. Is the alternative significantly better than the candidate product when considering chronic consumer risk assessment (on a crop by crop basis)?

If Yes	go to 3
If No	Stop CA

3. Is the alternative significantly better than the candidate product when considering risk to operators (taking account of mitigation applied) and to re-entry workers?

If Yes	go to 4
If No	Stop CA

4. Is the alternative significantly better than the candidate product when considering risk to bystanders and residents?

If Yes	go to 5
If No	Stop CA

5. Is the alternative significantly better than the candidate product in all of the exposure scenarios **(See note 2)**

If yes	go to 6
If no	stop CA

6. Are there any other unacceptable risks to human health not considered above? **(see note 3)**

If yes and criterion 6a has been assessed	go to criterion 6c
If yes and criterion 6a has not been assessed	go to criterion 6a
If no	stop CA

Guidance notes for comparability of risks for human health

It should be noted that this list is not exhaustive and the MS competent authorities should also consider the benefits of PPPs containing candidates for substitution during the comparative assessment process.

Note 1
In order to provide a meaningful comparison, the assessments in each area should be made using agreed EU endpoints and the same exposure/risk modelling tools. Consideration of each outcome should not be limited to a simple numerical comparison but should use expert judgement taking into account underlying factors driving any numerical differences between the candidate and alternative as part of an overall weight of the evidence approach.

Note 2
It is not possible to compare risks in different exposure scenarios for the human health (operator cannot be given precedence over consumer) therefore when carrying out a comparative assessment for human health the alternative should be significantly better than the candidate product in all exposure scenarios.

Note 3.
When evaluating any other unacceptable risks to human health not previously considered:

- Risk assessment/analysis of non chemical alternatives such as weed control through burning,
- Health risks associated with manual weed control methods,

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Criterion 6c: Comparability of risks for the environment and for human health

1. Is the alternative significantly better than the candidate product in all environmental and human health exposure scenarios? **(See note 1)**

If yes	go to next section or consider substitution
If no	Stop CA

Guidance notes for comparability of risks for the environment and for human health

It should be noted that this list is not exhaustive and the MS competent authorities should also consider the benefits of PPPs containing candidates for substitution during the comparative assessment process.

Note 1.

Annex IV.1 considers that the alternative should show significantly lower risk to human health or the environment.

It should be noted that it is not possible to establish any hierarchy between the risk to human health and the risk to the environment therefore, in order for comparative assessment to continue and for a substitution to take place, the alternative should be significantly better than the candidate product for both human health risk and environmental health risk (as determined by the answers to questions 6a Q9 and 6b Q5). If this is not the case comparative assessment should stop as substitution is not possible.