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HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Safety of the Food Chain
Chemicals, contaminants, pesticides

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Draft

**Guidance document on Comparative
Assessment and Substitution of Plant
Protection Products in accordance with
Regulation (EC) No 1107/2009**

COMMISSION GUIDANCE DOCUMENT - DOES NOT NECESSARILY
REPRESENT THE VIEWS OF THE COMMISSION SERVICES

1. INTRODUCTION

The concept of comparative assessment and substitution in Regulation (EC) No 1107/2009 was introduced with the purpose to reduce risks. The objective of this document is to give Member States guidance on how to conduct the comparative assessment when evaluating an application for authorisation of a plant protection product.

The European and Mediterranean Plant Protection Organization (EPPO) has developed guidance on how to perform comparative assessment (Bulletin OEPP/EPPO Bulletin (2011) 41, 256–259). The EPPO standard PP 1/271 Guidance on comparative assessment concentrates on assessment of efficacy (effectiveness, crop safety, risk for resistance), practicability, economical disadvantages, alternative measures, and effects on minor uses. This document is meant to supplement the EPPO standard, i.e. to give Member States guidance on how to perform the comparative assessment of risks to health and the environment, and to provide an overall framework for comparative assessment. Comparative assessment and substitution is a Member State issue and so far limited experience is available. Different approaches may be followed at Member State level and as experience has been gained in the work under Regulation (EC) No 1107/2009 revisions of this guidance will likely be necessary.

This Guidance Document applies for applications submitted as from 1 April 2015.

This document does not cover the following procedures and elements:

- The procedure to approve substances as candidates for substitution according to Article 24 and the criteria laid down in point 4 of Annex II. This is a separate process at the Union level which falls outside the scope of this paper. Since the process will be centralized it is expected to bring harmonization to the system. The assessment will be carried out once and not repeated at Member State level.
- The concept of comparative assessment in point B 2.1.4. and substitution in points C 2.1.2. and 2.1.3. of the Uniform Principles (Commission Regulation (EC) No 546/2011) regarding the assessment and decision making of product efficacy. This assessment does not involve risk to health or the environment.

2. THE CONTEXT OF COMPARATIVE ASSESSMENT AND SUBSTITUTION

Overall aim

The aim of comparative assessment and substitution is to reduce risks by gradually replacing products containing candidates for substitution by methods and products of lesser concern in order to benefit the protection of human or animal health and the environment, while minimising the economic and practical disadvantages for agriculture. The wording related to comparative assessment and substitution in Regulation (EC) No 1107/2009 clearly indicates that substitution should be restricted to cases in which the benefit is evident. Hence, it is not considered relevant to apply substitution in cases where the difference in anticipated risk between products is only marginal, nor in cases where it cannot be demonstrated that substitution does not present significant practical or economic disadvantages for agriculture, nor in cases where effective resistance risk management would be compromised, nor in cases that would have adverse consequences on minor use authorisations.

A plant protection product can only be authorised if it complies with the requirements of Article 29, in this context notably if it has no harmful effects on human or animal health or no unacceptable effects on the environment (Article 29(1)(e) referring to requirements in 4(3)). Nevertheless, there are uncertainties involved in the risk assessments. Comparative assessment and substitution may serve as a useful tool for risk reduction making it possible to reduce risks to the minimum necessary.

Role of comparative assessment in Regulation No 1107/2009

The main concept of comparative assessment and substitution in Regulation (EC) No 1107/2009 appears in Article 50 and Annex IV and concerns the regulation of products. However, the regulatory principles of the concept do also occur in the Uniform Principles when it comes to the assessment and decision making of product efficacy¹.

The concept is also reflected in Article 29(1)(d) on product authorisation requirements regarding the technical formulation although the presence of a substance identified as a candidate for substitution is in that case not a requirement.

According to Article 50(1) of the Regulation Member States shall perform a comparative assessment “when evaluating an application for authorisation for a plant protection product containing an active substance approved as a

¹ According to point B 2.1.4. in the Uniform Principles, Member States shall evaluate the performance of a plant protection product in comparison with a suitable reference product. No authorisation shall be granted if the effects or yield responses are not similar to those resulting from the use of suitable reference products (points C 2.1.2. and 2.1.3.).

candidate for substitution". Article 50 (4) requires "Member States shall perform the comparative assessmentregularly and at the latest at renewal or amendment of the authorisation". As comparative assessment has to be performed on the level of the use, applications for "amendment" in this context is understood to refer to those applications for an extension of the authorisation to include an additional use or uses. The comparative assessment shall in this case only be performed for the additional uses applied for (not for the currently authorised uses). Furthermore, only the application for the additional use of the product applied for shall be considered for substitution and not all other existing authorisations for products containing the same candidate for substitution. Comparative assessment has to be limited to the application under evaluation.

The assessment should be done at member State level and not at zonal level. This is described as "Mandatory Comparative Assessment" below. An exception from this obligation is the case where it is necessary to "acquire experience first through using the product in practice", as described in Article 50(3). This derogation would only be applicable if the application concerns circumstances where there is a change that is likely to need practical experience. Examples would include (but are not limited to) a new use, i.e. new active substance/crop or pest combination, a significant advance in formulation –such as a controlled release approach and the introduction of a new active substance to a sector of agriculture. It is for the applicant to present the reason that experience is required. In such a case, authorisation shall be granted for a period of maximum 5 years without comparative assessment. Should an application for amendment of an authorisation issued in accordance with Article 50(3) be submitted during the 5-year period no comparative assessment would be required.

As stated in Article 50(2) Member States may also in exceptional cases apply comparative assessment when evaluating an application for authorisation of a plant protection product *not* containing a candidate for substitution. The condition for this is that "a non-chemical control or prevention method exists for the same use and is in general use in that Member State". This is described as "Optional Comparative Assessment" below. Many existing non-chemical control or prevention methods can be described as complementary in integrated pest control. However, "exceptional cases" can be interpreted as pest/crop-situations where a non-chemical control or prevention methods are of equivalent agronomic effect, significantly safer, and in common use as an alternative. In these cases, the existence of these methods can be regarded as exceptional. It is recommended that Member States make information on methods which play a primary role in pest control publically available on the websites of their competent authorities.

Article 50 and Annex IV of the Regulation describe the conditions for substitution, such as significantly lower risk to health or the environment, whilst ensuring similar effect of alternative(s) on target organism, sufficient methods or chemical diversity to minimize the occurrence of resistance, and lack of significant economic and practical disadvantages etc. The Regulation provides strongly formulated conditions for substitution related to potential

effects on agronomic conditions. In addition the consequences on minor use authorisations should be taken into account. This is interpreted to mean that the major uses of the product are the ones for which the alternatives are considered and, if the conclusion is reached that a substitution may be appropriate for some or all of them, a consideration of the consequences on the minor use authorisations is then the key aspect of comparative assessment involving minor uses. In accordance with point 3 of Annex IV expected significant disadvantages are defined as “quantifiable impairment of working practices or business activity leading to an inability to maintain sufficient control of the target organism” and shall be taken into account in the decision-making process.

The template in the Appendix may serve as a help for Member States in the assessment. On a case-by-case basis Member States may find it useful to ask registration holders to provide the information asked for in the template. The information provided by authorisation holders can be helpful, but should always be analysed and supplemented by the Member State.

Comparison of risks

Point 1 of Annex IV to Regulation (EC) No 1107/2009 says “...the alternative must [...] show significantly lower risk to health or the environment“. Therefore if an initial comparison of risks posed by different products reveals that there is only marginal difference in risk, further in-depth investigation could be avoided.

The risk assessment for plant protection products is very complex, considering a range of situations and exposure patterns, critical effects, and organisms. Furthermore, point 2 of Annex IV says a “significant difference in risk shall be identified on a case-by-case basis by the competent authorities“. It is also clear (recital 19) of the preamble to the Regulation and point 2 of Annex IV) that necessary risk mitigation and imposed restrictions in use must be taken into account. Based on these circumstances, it is not considered useful to propose guidance on what would characterise a significant difference in risk in absolute, quantitative terms, in particular not for the comparison of risks in *different* areas of the assessment (e.g. risk for health vs. risk for the environment)². Comparing risks in the *same* area of assessment may be easier (e.g. comparison of risk posed by different products to aquatic organisms). Regarding risks to the environment, point 2 of Annex IV says a factor of at least 10 for the toxicity/exposure ratio (TER) is considered as a significant difference in risk. However, this criterion only partly matches the general criteria for authorisation in the Uniform Principles in regulation (EU) 546/2011, where the "unless" clauses allow also for product authorisation referring to higher tier studies. A factor of 10 between two TER-values should only be applied when the authorisations of products are indeed compared based on conceptually equivalent TER-values. Where authorisations were

² Comparing risks in different areas of the assessment (e.g. risk for health vs risk to the environment) is not considered to be a practicable approach. To compare risks in different areas the individual risks would first have to be translated into a common value (e.g. by attributing costs to different components). The risk assessments for plant protection products are considered to be too complex for such a procedure.

granted based on higher tier studies this needs to be taken into account in when deciding on significant differences in environmental risk.

Furthermore, as stated above, also the necessary risk mitigation needs to be taken into account. Current risk mitigation measures vary between Member States and it might be helpful to develop further criteria on how to take risk mitigation and restrictions into account in the comparative assessment in light of experience with this guidance in the medium term.

Only the product/use that is evaluated for a possible authorisation is eligible for substitution, and only if it is concluded that it poses a significantly higher risk compared to alternatives already authorised. Products that are already on the market will be subject to comparative assessment if they contain a substance which is a candidate for substitution at the time of renewal or amendment of the authorisation for each product.

Compare candidates with candidates?

The Regulation does not clearly state whether or not candidate products should be compared to alternative chemical products that contain *other* candidates for substitution. Since such a comparison is explicitly neither included nor excluded in the Regulation, alternative products containing other candidates for substitution should be included in the assessment. It may seem less meaningful to do so, if it is assumed that all products containing candidates would pose high risks to health or the environment. However, this is not necessarily the case since some of the criteria in point 4 of Annex II are hazard-based criteria for substance evaluation, while the comparative assessment as described in the Regulation would focus on risks posed by the use of products.

A similar question is whether or not different products containing the *same* candidate for substitution should be compared. The interpretation of the Regulation, in particular recital (19) of the preamble to the Regulation, is that such products should not be compared. There may however be cases where the risks differ significantly for products containing the same candidate substance, e. g. a product containing additional active substances may result in a lower dose applied compared to a product containing only the candidate substance.

However, plant protection products containing no candidate for substitution should generally be preferred as substitutes.

3. STEP-WISE APPROACH

The EPPO standard PP 1/271 Guidance on comparative assessment covers assessment of efficacy (effectiveness, crop safety, risk for resistance), practicability, economical disadvantages, alternative measures, and effects on minor uses – but does not address comparative safety from the human and the environmental perspective. Below, a proposal on how comparative

assessment for human or animal health and the environment may be conducted is given. To enable an overview of all aspects of comparative assessment, also those aspects which are covered by the EPPO standard have been included as step 2 of the scheme presented in section 5 of this document.

In addition to the mandatory comparative assessment in accordance with Article 50(1) (described as “Mandatory Comparative Assessment”, in steps 2-4 in the scheme below) the possibility given in Article 50(2) to apply comparative assessment also for products not containing a candidate has been included as a separate “track” in the scheme below (described as “Optional Comparative Assessment”, in steps II-IV in the scheme below).

The EPPO standard for comparative assessment follows a step-wise approach, meaning that the process of comparative assessment may be terminated at any stage and it may not be necessary to continue through the whole scheme. Given the obvious merits of a step-wise approach it is suggested that where there are reasons to believe at the start of the comparative assessment that there might be a problem in a certain area, e.g., development of resistance, it may be useful to start the assessment in that particular area. A step-wise approach has also been used in the proposed comparison made in relation to risk to health or the environment set out below. It is important to document the assessment that has been done.

Assessment in relation to Article 50

Step 1 – identification of candidates in the product and consideration of further optional assessment in steps I-IV (Article 50(2))

In step 1 it is identified whether the product contains a substance identified as a candidate for substitution or not. In exceptional cases, optional comparative assessment may then be performed also when the product does not contain a candidate substance, if a non-chemical control or prevention method exists for the same use and it is in general use in that Member State, in accordance with Article 50(2). Chemical methods should therefore be compared with corresponding non-chemical control (e.g. biological and climatic control) and prevention methods such as crop rotation and mechanical weeding.

Step 2 – mandatory assessment (Article 50(1))- starting with agronomic aspects (EPPO standard PP 1/271 Guidance on comparative assessment)

The EPPO standard **PP 1/271** describes that the first step after initiation of a comparative assessment is to define the use(s) of the candidate product. When these have been specified, alternatives should be identified against which the comparative assessment would be performed. Chemical as well as non-chemical control or prevention methods should be considered. The comparative assessments of efficacy (effectiveness, crop safety, and risk for resistance), practicability, economical disadvantages, alternative measures, and effects on minor uses described in the EPPO standard are not further discussed here. If the conclusion of the assessment is that substitution is not

appropriate in view of agronomic considerations no further assessment is needed.

Step 3 - first step of assessment for health and the environment

The first step of the comparison for health and the environment is intended to clarify, based on a focused assessment, whether a potential for substituting a candidate product actually exists and should be further explored in a second step. Different approaches may be followed at Member State level, depending on the availability of e.g. national data bases on risks and risk mitigation measures.

As an example of one approach, an assessment focussed on the specific criterion, or criteria if more than one, that resulted in an active substance being defined as a candidate for substitution is described below and in the scheme in section 5. Therefore, in steps 3a-3e below the candidate product is first compared to alternative(s) *only* with respect to the individual criterion/criteria that was met by the candidate. This would seem the most straight-forward approach and is anticipated in most cases to reduce the workload. Hence, it would not be necessary to compare each individual endpoint related to risk (e.g., all individual TERs) for the candidate product with those for the alternative(s). The steps to follow in the comparative assessment for health and the environment proposed in steps 3a-3e in the scheme below have not been elaborated in great detail. At this stage they are primarily meant to illustrate the proposed approach.

As an example; a substance was listed as a candidate due to an ADI “significantly lower than those of the majority of the approved active substances within groups of substances/use categories” (point 4 of Annex II). According to the scheme proposed below the product containing the candidate should then be compared to alternatives with regard to the potential effect of this low ADI – i.e., taking the estimated exposure to consumers into account and comparing the estimated risk.

Most of the criteria in point 4 of Annex II to the Regulation are based on hazard, while the comparative assessment would take risk assessment into account. For the criteria of point 4 in Annex II that are based on risk it has to be taken into account that the areas of use of the candidate product may deviate from the areas of use considered at Union level (at which the candidate was identified). It is therefore assumed that the risk assessments during product review have been completed, and that the necessary risk mitigation measures have been identified, for the candidate product and the alternative product(s) before the comparative assessment for health and the environment would start.

Comparison of risks should be done on conceptually equivalent tiers of the risk assessment. A complication may be that in any given moment all products on the market have not been subject to risk assessment in accordance with the same standards. Guidance documents, exposure models etc. are subject to continuous development. Therefore it should be noted that risk assessments may be different over the time due to new guidance documents,

and this needs to be taken into consideration. Updating the risk assessments for the alternative chemical products to allow a comparison of the results will not be practicable within the timelines provided for in Regulation (EC) No 1107/2009. Hence a case by case expert judgement might be needed.

The Regulation mentions the requirement of risk mitigation measures as one of the aspects to consider for comparative assessment and substitution. In the comparison of estimated risks, stringency of imposed restrictions in use and necessary risk mitigation may facilitate the decision-making.

Step 4 – second step of assessment for health and the environment

As a second step of the comparison for health and the environment (4 in the scheme below), it is necessary to take into account the complete risk profiles of the candidate product and the potential alternative. When the candidate for substitution criteria are applied in the stepwise approach as described above, it may be that the alternative was not of concern in relation to the specific criterion used for the comparison (in 3a-3e) but instead poses obvious risk that warrant risk mitigation for some *other* aspect of the assessment for human or animal health and the environment. In such cases the conclusion may be that substitution would not be the best tool for risk reduction.

As an example; a product contains an active substance which was listed as candidate for substitution due to very low ADI. In the Comparative assessment under step 3a, the risks for human or animal health were compared. In this comparison, the alternative was clearly the better choice in that respect. However, for *other* aspects of the standard risk assessment done in accordance with Uniform Principles risks were identified following use of the alternative product, e.g. for aquatic organisms. Strict risk reduction measures would therefore be necessary for the particular area of use considered. Substitution would in such a case not be the preferred tool for risk reduction.

Assessment in relation to Article 29(1)(d)

A prerequisite for product authorisation is that the technical formulation of the product “is such that user exposure or other risks are limited as much as possible without compromising the functioning of the product”. The easiest way to determine this is perhaps in cases where different technical formulations already exist on the market with the same active substance. The concept of comparative assessment and substitution may therefore in certain cases also play a part in the process referred to in Article 29(1)(d) and offer a possibility for risk reduction.

Examples of formulation specific substitution that may fall under Article 29(1)(d):

Differences in technical formulations may require different labelling in terms of risks phrases. This could be the case when different solvents are used. For instance products based on certain organic solvents may be attributed risk phrases such as R41 (Risk of serious damage to eyes) whilst products containing the same active substance but in a water-based formulation do not have that labelling requirement. Such differences in labelling may constitute a useful basis for comparative assessments.

Another example is components in the formulation that are toxic to aquatic organisms which could be substituted with others that have the same function but are less toxic.

Differences in technical formulations may also affect exposure. For instance micro granule formulations may result in lower exposure to inhalable dust than a wettable powder formulation.

4. FINAL CONCLUSION AND REPORT

All steps of the comparative assessment, including the one following the EPPO guidance, should be appropriately documented as part of the Registration Report. A clear justification should be given for the conclusion of each step. The applicant should be given the possibility to comment, if the conclusion of the comparative assessment would be negative for the applicant.

5. SCHEME OUTLINE

1. Does the product contain candidate(s) for substitution? [Article 24, 50(1), 80(7)]

If yes, go to 2
If no, go to 1 (→)

2. START MANDATORY COMPARATIVE ASSESSMENT

Assessment of comparability of chemical and non-chemical alternatives regarding efficacy, and regarding risk of developing resistance, and assessment of practical/economical disadvantages, and effects on minor uses according to EPPO standard PP 1/271 Guidance on comparative assessment)³

Substitution of product by chemical or non-chemical alternative potentially appropriate in view of agronomic considerations?

If yes, go to 3
If no, stop CA

3. A comparison is first made *only* with respect to the criterion/criteria in point 4 of Annex II that was met by the candidate product; select step 3a-3e, as appropriate.

3a. The candidate product was subject to CA due to low ADI, ARfD, or AOEL:

- Where relevant, consider the exposure of different population subgroups (professional or non-professional users, bystanders, workers, residents, specific vulnerable groups or consumers), directly or indirectly (food, feed, drinking water or the environment), and compare the risk.

- Where relevant, compare the stringency of imposed restrictions and prescribed PPE. Significantly lower risk for health from use of chemical or non-chemical alternative?

If yes, go to 4
If no, stop CA unless available data or knowledge indicate a need for further evaluation in other areas of risk

3b. The candidate product was subject to CA since two of the criteria for PBT were met:

- Compare the risk for long-term effects on soil living organisms and on aquatic organisms using estimated cumulative exposure,
- Where relevant, compare the risk for bioconcentration, biomagnification and secondary poisoning of aquatic and terrestrial

³ If it is considered necessary to first acquire experience through using the candidate product in practice, Regulation 1107/2009 does not require comparative assessment to be performed. Product authorisation in such cases shall be granted once for a period not exceeding five years (Article 50(3) of Regulation (EC) no 1107/2009).

vertebrates, and

- Where relevant, compare also the potential for indirect exposure of humans.

Significantly lower risk for long-term effects⁴, or for bioconcentration, biomagnification, or secondary poisoning, also taking into account the risk mitigation options warranted, or significantly lower risk for indirect exposure of humans from use of chemical or non-chemical alternative?

If yes, go to 4
If no, stop CA unless available data or knowledge indicate a need for further evaluation in other areas of risk

3c. The candidate product was subject to CA since the critical effect in combination with use/exposure patterns could still cause concern, even with very restrictive risk management measures:

- Compare the risk management measures necessary together with the nature of the critical effect.

Significantly less restrictive measures needed to manage the risk posed by chemical or non-chemical alternative, and/or significantly lower level of concern?

If yes, go to 4
If no, stop CA unless available data or knowledge indicate a need for further evaluation in other areas of risk

3d. The candidate product was subject to CA due to a significant proportion of non-active isomers:

Is there on the market, alternative(s) that contain only the active isomer(s)?

If yes, go to 4
If no, stop CA unless available data or knowledge indicate a need for further evaluation in other areas of risk

3e. The candidate product was subject to CA since it is or is to be classified as carcinogen category 1A/1B, or as toxic for reproduction category 1A/1B, or it is considered to have endocrine disrupting properties that may cause adverse effects in humans - but the substance was not excluded in accordance with criteria in Annex II point 3.6.3, 3.6.4, or 3.6.5, respectively.

Consider the risk for exposure for the candidate product and compare the risk posed to human

⁴ For the long-term effects a comparison of toxicity/exposure ratios (TER) would seem relevant; a factor of at least 10 is considered a significant difference in risk (point 2 of Annex IV to Regulation (EC) No 1107/2009). Conceptually equivalent tiers of the risk assessment need to be considered.

health, in relation to the properties of the candidate product.

Significantly less restrictive measures needed to manage the risk posed by chemical or non-chemical alternative, and/or significantly lower risk from alternatives?

If yes, go to 4
If no, stop CA unless available data or knowledge indicate a need for further evaluation in other areas of risk

4. It has been concluded (from steps 3a-3e) that the alternative would be a better choice from the perspective of health or the environment based on the comparison in relation to the criterion that was met by the candidate. Since all aspects of risk assessment for health and the environment are not covered by all of the criteria (in 3a-3e) it would also be necessary to consider potential risks posed by the alternative in *other* aspects, as well as the stringency of imposed restrictions on use of the alternative and prescribed PPE.

Are there significant risks to health or the environment identified in the risk assessment for the chemical or non-chemical alternative in other aspects than those considered in 3a-3e (as relevant) and/or are extensive risk management measures necessary for the chemical or non-chemical alternative?

If yes, stop CA

MANDATORY CA COMPLETED

I. Does a non-chemical control or prevention method exist for the same use and is it in general use in the Member State? [Article 50(2)]

If yes, Go to II
If no, Stop CA

II. START OPTIONAL COMPARATIVE ASSESSMENT

Assessment of comparability of non-chemical method regarding efficacy (effectiveness, crop safety, risk for resistance), practicability, economical disadvantages, and effects on minor uses (see EPPO standard PP 1/271 Guidance on comparative assessment)

Substitution of product by non-chemical method potentially appropriate in view of agronomic considerations?

If yes, go to III
If no, stop CA

III. Identify potential risks posed by the alternative method to health or the environment:

- Where relevant, consider the potential risk to different population subgroups (professional or non-professional users, bystanders, workers, residents, specific vulnerable groups or consumers),

- Where relevant, consider the stringency of imposed restrictions on use of non-chemical method and prescribed personal equipment. Is the non-chemical method likely to present a significantly lower level of risk to health or the environment?

If yes, Go to IV
If no, stop CA

IV. Consider any negative effect on agronomic conditions identified vs. the reduction in estimated risk that may be achieved for health and/or the environment for a balanced decision on whether substitution is appropriate. Would expected reduction in risk to health or the environment outweigh any identified negative effect on agronomic conditions? If yes, withdraw or amend (restrict) authorisation

If no, stop CA

OPTIONAL CA COMPLETED

Appendix

Applicant information to support the process of comparative assessment

Country:	<< country name >>
Product under evaluation:	<< product name >>

Product Overview

All label uses for<<Product X>>.

Crop(s):	<< crop name >>			
Biology:	(1) << pest name >> (2) << pest name >>	(1) << pest name >> (2) << pest name >>	(1) << pest name >> (2) << pest name >>	(1) << pest name >> (2) << pest name >>
Date of first authorisation for the pest/crop combination described:	<< date >>			

Table 1: Summary information

Step	Ref: Reg. 1107/2009	Comments
1. Sufficient experience gained	Article 50.3Annex IV.1(c):	<i>Highlight when the product is new and requires experience.</i>
2. Non-chemical control or prevention method available	Article 50.1(a):	<i>There <<are /are not >> non-chemical control or other prevention methods available in <<MS X>> to control <<all pests/some pests>></i> <i>Where detailed information on alternatives is available to the applicant, identification and GAP analysis should be conducted by the applicant. Where such information is not available to the applicant, the MS authority shall conduct the analysis</i>
3. Chemical alternatives available	Article 50.1(a):	<i>There <<are /are not other>> chemical solutions available in <<MS X>> to control <<all pests/some pests>></i> <i>Where detailed information on alternatives is available to the applicant, identification and GAP analysis of these chemicals should be conducted by the applicant. Where such information is not available to the applicant, the MS authority shall conduct the analysis</i>
4. Chemical Diversity	Article 50.1(c): Annex IV.1(a):	<i><< product name >> includes active ingredients with the following MoA.</i> <i>For << pest name >>there are << X number >> of MoA available in <<MS >></i> <i>Details on the MoA for the candidate product, and where available to the applicant, for the alternatives, are supplied in Annex A</i>
5. Minor Uses	Article 50.1(d): Annex IV, final para:	<i>Where relevant, provide information about minor uses. Include information on impact of ‘major use substitution’ on minor uses.</i> <i>(Provide information in Annex B – Minor Uses)</i> <i>For << product name >>has the following minor uses on the label</i> <i>X</i> <i><< product name >> also has the following non label approvals associated with it which are supported by the applicant</i>
6. Practicality and economic feasibility	Article 50.1(b): Annex IV.3:	Annex IV.3. of the Regulation sets out a definition that should be considered in setting out the arguments in this section ⁵ . <i>Include info on PPP in established IPM solutions</i>

⁵ Annex IV.3, states:

3. Significant practical or economic disadvantages

Significant practical or economic disadvantage to the user is defined as a major quantifiable impairment of working practices or business activity leading to inability to maintain sufficient control of the target organism. Such a major impairment might be, for example, where no technical facilities for the use of the alternative are available or economically feasible.

Where a comparative assessment indicates that restrictions on and/or prohibitions of use of a plant protection product could cause such disadvantage, then this shall be taken into account in the decision-making process. This situation shall be substantiated.

Annex A

Details of MoA* and RAC** code for the candidate product

Product overview				
Name	Active substance(s)	MoA chemical class	RAC code	CfS
<< Product under evaluation >>	<< AS 1 >> << AS 2 >> ...	<< Type 1 >> << Type 2 >> ...	<< code >> >>	<< Y/N >> << Y/N >> ...

* Mode of action

** Resistance Action Committee

Summary of MoA information relating to the candidate product

Could include info on:

Are there sufficient MoA available to manage the resistance risk in the listed pests using the given information?

Does the PPP introduce a new MoA?

Does the PPP contain a MoA considered to be essential to resistance management?

ANNEX B

Minor Uses

There is no defined list of minor uses in the EU therefore an objective assessment should be made. It is clear that the definition of a minor use differs between all MS within a zone.

	Minor Use				Active substance(s)	MoA* chemical class	RAC** code
	1	2	...	n			
<< Candidate product >>	x				<< AS 1 >> << AS 2 >> ...	<< Type 1 >> << Type 2 >> ...	<< code >>

* Mode of action

** Resistance Action Committee

Summary

Should include details of ownership of minor uses and conclusion on the viability of defending the minor use in the absence of the major uses