Step 0
before filling the NL addendum Comparative Assessment.

0. Is a Comparative Assessment (CA) relevant for the application?

A comparative assessment (CA) is only relevant in case the product application fulfils both of the following requirements:

1. The application is for product authorization in The Netherlands.
2. The product concerned contains one or more active substances approved as Candidate for Substitution (CfS).

If both requirements apply, **the NL addendum CA below needs to be filled**. This format applies for applications for authorization in NL of products based on a CfS, received from 1st July 2024 onwards. The applicant's conclusion should be copied in chapter 4 of part A.

When (not) to fill the NL addendum CA?

- CA is a national specific element of the assessment. In case the product does contain a CfS, but no authorization is sought for in The Netherlands (Ctgb-NL is only acting as zRMS on behalf of concerned Member States, as for some Article 43 renewal applications), **no CA** will be performed by Ctgb-NL. Ctgb will write a short statement in the conclusions in B0 to point MS to address the CA at national level. Filling the NL addendum CA below is **not needed**.

- If the application is for authorization in NL, but product does not contain a CfS, please state this in Chapter 4 of part A. Filling the NL addendum CA below is **not needed**.

Explanation

The NL addendum CA is only designed by Ctgb for use in NL. Applicants are advised to check with individual CMSs how they wish to receive information concerning a CA procedure. Applicants are requested to fill in this template in case a comparative assessment is relevant for their application. Ctgb will evaluate the NL addendum CA as part of the assessment.

When filling in the NL addendum CA, the applicant is free to copy tables or sections when needed.

This template is designed to be self-explanatory. In case of questions, please contact Ctgb via the Ctgb Service Desk (before application is submitted) or the Ctgb project manager assigned to the application (after the application is submitted). Questions and answers will be monitored, and if necessary, additional explanation may be added to this form over time.

Comparative Assessment and Substitution of Plant Protection Products in accordance with article 50 of Regulation (EC) No 1107/2009

Product code:

Product name(s):

Active substance(s) approved as CfS:

Other active substances:

National Addendum The Netherlands

Application type:

Ctgb application number:

Applicant:

Submission date:

MS Finalization date:

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1. General introduction of the product under assessment.

Product name	
Product formulation code	
Product formulation type	
Target of product	*Insecticide/acaricide/fungicide/herbicide/……..*
Working mechanism	*e.g. contact, systemic, behavior in/on plant*

Active substance with CfS (Candidate for Substitution) status	
Reasons for approval as CfS *(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*
Content in the formulation	
Mode of action	
IRAC/FRAC/HRAC-code	

Other active substances	
Content in the formulation	
Mode of action	
IRAC/FRAC/HRAC-code	

Application type	
Summary of uses under assessment	

Ctgb will ask the applicant to update the NL addendum CA when the comparative assessment is performed near the end of the risk assessment and preferably when a concept final WG is available.

2. Initial steps to determine if a comparative assessment (CA) applies.

It is assumed that the application concerns a plant protection product based on an active substance approved as Candidate for Substitution (CfS) with an application for authorization in The Netherlands (NL). If not, this NL addendum does not need to be filled. The Comparative assessment (CA) is a member state-specific part of the assessment.

Step 1. Is this application intended for:

- A new zonal authorization (Article 33) or new authorization via mutual recognition (Article 40) – application type ZTG, NLTG, NLWERGZ; **Yes; go to step 2**
  OR
- Renewal of an existing authorization (Article 43) – application type ZRG, NLRG; **Yes; go to step 2**
  OR
- Extension or amendment via zonal authorization (Article 33) or via mutual recognition (Article 40) – application type ZWTG, NLWTG, NLWERGZ. In that case, only the new or amended uses are subject to the comparative assessment. In this respect a major/significant change of the formulation is seen as an amendment of all uses. **Yes; go to step 2**
- **No to all 3 options above;** (e.g. national applications for NLKUG, NLWG, various administrative applications), no further information is needed > **stop CA and stop filling this national addendum CA any further. Please, fill in the conclusion in chapter 4 of part A.**

Step 2. Does this application concern only (new) minor uses as defined in the Dutch list of Minor Uses (in English and Dutch) or as recognized by Loket Kleine Toepassingen of NPPO (NPPO agreement needs to be submitted)?

- **Yes;** no further information is needed as Ctgb does not consider comparative assessment nor substitution for minor uses. **Stop CA. Please fill the conclusion in chapter 4 of part A.**
- **No,** there are relevant major uses; **continue to step 3**.

*Ctgb does consider all uses included in the Dutch list of minor uses or specific uses recognized as minor by Loket Kleine Toepassingen as **minor uses**, irrespective from whether they are authorized with efficacy data (major authorization) or under article 51 without efficacy data (minor authorization).*

Step 3. Do you want to make use of the derogation of Article 50(3) for all or part of new uses to acquire experience first by using the product in practice?

- **If yes for all uses;** please motivate your case below. S**top CA. Please fill the conclusion in chapter 4 of part A.**
- **If yes for part of the uses;** please motivate your case below. Then go to **chapter 3** for the remaining uses.
- **No;** go to **chapter 3**

Applicant's motivation for derogation according to article 50.3.

3. Agronomic aspects of Comparative Assessment

This part of the assessment will be evaluated for Ctgb by NPPO (NVWA).

3.1 Introduction

For this assessment a stepwise approach which contains three stages (see chapters 3.3.1, 3.3.2 and 3.3.3) should be followed. As described in EPPO PP 1/271 (3) on efficacy aspects of comparative assessment, the process may be terminated after completion of an individual stage, and it may not be necessary to continue through the whole scheme. In that case the CA-process, in view of agronomic considerations, can be finalized by filling in the final conclusions (chapter 3.4). If the CA process cannot be stopped after completion of an individual stage, the next stage must be completed.
The order in which the stages are considered is left to the applicant and may be based on considering the key issues likely to stop CA early in the process.

3.2 Determining the alternatives to consider as substitute(s) for the uses of the candidate product

Alternatives for the uses should be identified against which CA will be performed. Alternatives may be other authorized PPPs (including products containing an active substance approved as a candidate for substitution), a basic substance, or a measure to prevent the occurrence of the pest or to control the pest.

Per use, an overview of all alternative authorized plant protection products in the Netherlands, the active substance(s) and the associated mode of action codes (according to IRAC, FRAC or HRAC), should be given in Appendix 1. If an authorized product with the same use is not seen as an alternative this should be motivated (with trial results) by the applicant. Per use, an overview of all alternative non-chemical methods (not PPP but including basic substances) should be given in Appendix 2, including an assessment of the effectiveness and practical or economic disadvantages.

3.3 Conduct of comparative assessment process

3.3.1 Assessing comparability regarding the risk of developing resistance

An overview of all available PPPs with their modes of action (MoA) (regardless possible practical or economic disadvantages) for the proposed major uses of the product with their resistance codes (FRAC group code, HRAC/WSSA code, IRAC mode of action classification code) is given in Appendix 1.

In case there is an alternative non-chemical method (or a combination of various such methods) with a comparable or higher effectiveness, which does not induce development of resistance and without practical or economic disadvantages, the comparative assessment leads to substitution without further analyses of alternatives. A non-chemical method is regarded significantly safer than use of a chemical PPP. Please fill the conclusion tot substitute in table 3.4.1.

When substitution does not change the number of available MoAs, there is no adverse effect on resistance management and therefore CA is to be continued for this use. This occurs when an alternative product(s) with the same MoA(s) as that of the product under assessment is authorized.

The conclusion of the assessment on comparability regarding the risk of developing resistance for that use is that substitution is possible from a resistance management perspective.

If the number of resistance groups does decrease when the product under assessment based on the CfS is replaced, it should be checked whether a sufficient number of resistance groups remain to minimize the risk of developing resistance in the target organism. The number is modes of actions that should remain available is, in accordance with EPPO PP 1/271 (3) and EPPO PP 1/213 (4), as follows:

a. for a crop-pest combination with a low risk of resistance[1], at least two modes of action must remain available;
b. for a crop-pest combination with an average risk of resistance, at least three modes of action must remain available;
c. for a crop-pest combination with a high risk of resistance, at least four modes of action must remain available.

Table 3.3.1: Evaluation of resistance management strategy based on Appendix 1 and 2.

Crop	Pest	Necessary number of available MoAs[1]	RAC code(s) of alternatives[2]	Total number of available MoAs	Conclusion*

[1)] based on the resistance risk of the crop-pest combination (see Appendix 1).

[2)] Non-chemical method is indicated by NCM (number of methods)

**) Options for conclusion:*

1. *There is an alternative with the same RAC code as the candidate for substitution. CA is continued with a comparative risk assessment in chapter 4.*
2. *There are sufficient different modes of action available. CA is continued with a comparative risk assessment in chapter 04.*
3. *There are insufficient different modes of action available. Stop CA.*
4. *Assessment regarding resistance management is not considered because the CA-process was stopped in chapter 3.3.2*
5. *Assessment regarding resistance management is not considered because the CA-process was stopped in chapter 3.3.3.*

3.3.2 Assessing practical and economic disadvantages of the available alternative(s) based on Appendix 1 and 2

An overview of all alternatives, both chemical and non-chemical, for the proposed major uses of the product is given in appendices I and II. An assessment of possible practical and economic disadvantages should be performed, and results should be added to appendices I and II. Results of the assessment of possible practical and economic disadvantages should be summarised in Table 3.3.2.

Table 3.3.2: Conclusion on practical or economic disadvantages of the available alternative(s) for each use

Crop	Pest/disease/weed	Conclusion *

[1] See EPPO standard PP 1/213 (4) 'Resistance risk analysis' for guidance on the inherent and agronomic resistance risk.

**) Options for conclusion:*
1. Alternatives (chemical and/or non-chemical) without practical or economic disadvantages available: [names of products and/or non-chemical methods]; CA is continued with a comparative risk assessment in chapter 4.
2. No chemical and/or non-chemical alternatives without practical or economic disadvantages available: stop CA
3. Assessment regarding practical or economic disadvantages is not considered because the CA-process was stopped in chapter 3.3.1.
4. Assessment regarding practical or economic disadvantages is not considered because the CA-process was stopped in chapter 3.3.3.

3.3.3 Assessing effects of CA on authorizations with existing minor uses.

Authorizations may contain **major uses**, **minor uses with a major (complete) assessment**, and **minor uses with a minor assessment under Article 51**. **Minor use** is here defined as any use included on the Dutch list of minor uses*, so without discriminating between applications supported by a major assessment or a minor article 51 assessment. However, please keep in mind that this difference is relevant for the rest of this paragraph. A **major use** is defined as not included in the list of minor uses and supported by a complete major assessment.

Art 50.1-d of Directive (EG) 1107/2009 states that for substitution through comparative assessment ''the consequences for minor uses are taken into account" as stated above in step 2 of chapter 2. Therefore, loss of any minor uses through Comparative Assessment should be prevented. The Ctgb policy decision therefore exempts all minor uses as defined by the Dutch list of minor uses from comparative assessment itself. However, this paragraph deals with the situations in which substitution of major uses affects the minor uses in the application. The authorization holder may submit arguments and evidence to maintain a major use and thereby prevent the loss of minor uses.

- In case the application does not contain any minor uses with a major assessment, substitution of all major uses leads to denial of the authorization including any minor uses applied for via article 51. An authorization based on only minor uses authorized via article 51 is not possible. So in such a case, the consequence for minor uses applied for via article 51 is evident and the authorization holder may submit arguments and evidence which major use should be exempted from substitution in order to maintain the minor article 51 uses and commercial viability of the authorization.
- In case the application/authorization contains minor uses supported by a major assessment, such uses remain minor and are exempted from comparative assessment. As they were authorized through a major assessment, one such use suffices to continue the authorization, including any minor uses applied for via article 51, if relevant. No major uses are needed for an authorization. However, in case the commercial viability of the product is jeopardized by the loss of the major uses, the applicant may still submit arguments and evidence which major use is essential to continue the authorization.
- Ctgb considers 1 major use sufficient for commercial viability of a product containing minor uses, but authorization holders may submit arguments and commercial evidence to support the need for more than 1 major use. (This does not apply when only a single major use without minor uses is remaining after CA).

Of course, in order to consider uses for authorization, the first requirement remains that the risk assessment for these uses must be considered acceptable.

*) For the applicable version of the list for minor uses, please follow the link in this webpage Kleine toepassingen | College

voor de toelating van gewasbeschermingsmiddelen en biociden).

Options for conclusion:
1: There are no minor use applications, so substitution will have no consequences for minor uses.
2: Assessment regarding consequences for minor uses is not considered, because substitution is not possible for 1 or more major uses.
3: Because of the consequences for minor uses, substitution for the use in …… is not possible. [Please specify and give further explanation]. Stop CA.

3.4 Overall conclusion agronomic aspects of Comparative Assessment

Table 3.4.1: Uses of [*Name of Product + active substance*] that can be substituted in view of agronomic considerations. CA is continued with a comparative risk assessment in chapter 4.

Crop	Pest/disease/weed	Alternative PPP(s) *or method*(s)	Active substance	Registration number

Table 3.4.2: Uses of [*Name of Product*] that cannot be substituted in view of agronomic considerations

Crop	Pest/disease/weed	Conclusion *

**Options for conclusion:*

1. *Based on all available alternatives, a good resistance management is not possible.*
2. *No chemical and/or non-chemical alternatives without practical or economic disadvantages available.*
3. *Because of the consequences for minor uses, substitution is not possible.*

Appendix 1 to chapter 3: Alternative authorised plant protection products in the Netherlands

Overview of alternatives (other authorized PPPs (including products containing an active substance approved as a candidate for substitution) (Based on the Ctgb-authorization database [LINK} date: *xx-xx-202x*), for the proposed major uses of <name CfS product> according Ctgb database.

Remarks:

- Do not include products based on a parallel or derived authorization.
- Include all PPPs authorized for the same crop-disease/pest combination irrespective of application type, application timing, conditions for use, GAP details, etc.
- An assessment of possible practical and economic disadvantages should be performed. When the alternative has practical or economic disadvantages, this must be motivated in column 3.
- Alternatives that cannot replace an entire crop group of a use are not excluded. The use will be further split up to underlying crop groups or to single crops.

Use 1: Crop/pest combination: <name crop or crop group>, <name pest>

Risk on resistance of crop-pest combination: low/average/high

FRAC/HRAC/IRAC code(s) of the product under assessment:

		Practical or economic disadvantages		**Resistance risk**
Product	Active substance	Significant practical or economic disadvantages	Alternative without significant practical or economic disadvantages (Y/N)	FRAC/HRAC/IRAC code

Use 2: Crop/pest combination: <name crop or crop group>, <name pest>

Risk on resistance of crop-pest combination: low/average/high

FRAC/HRAC/IRAC code(s) of the product under assessment:

		Practical or economic disadvantages		**Resistance risk**
Product	Active substance	Practical or economic disadvantages	Alternative without practical or economic disadvantages (Y/N)	FRAC/HRAC/IRAC code

Appendix 2 to chapter 3: Non-chemical alternatives

An overview of non-chemical alternatives and basic substances (date: *dd-mm-yyyy*), for the proposed major uses of [*name product*].

Remarks:

- An assessment of possible practical and economic disadvantages should be performed. When the alternative has practical or economic disadvantages, this must be motivated in column 3.

Use 1: Crop/pest combination: <name crop or crop group>, <name pest>

Name non-chemical alternative	Description	Assessment of effectiveness and practical or economic disadvantages [2]	Alternative without practical or economic disadvantages (Y/N)	Alternative regarding resistance risk (Y/N) [3]

[2] See DEFRA document *'Non-chemical pest control methods: A review of the literature to establish their efficacy and safety to workers, to inform the process of comparative assessment required by new pesticide legislation'*. Defra Project Code: PS2809/348656.

[3] When the alternative has practical or economic disadvantages it is not included as an alternative regarding resistance risk. When the alternative has no practical or economic disadvantages it is included as an alternative regarding resistance risk. The resistance code is NCM. Every suitable non-chemical method counts as one resistance group.

Use 2: Crop/pest combination: <name crop or crop group>, <name pest>

Name non-chemical alternative	Description	Assessment of effectiveness and practical or economic disadvantages	Alternative without practical or economic disadvantages (Y/N)	Alternative regarding resistance risk (Y/N)

4. Comparison of risks

When the agronomical evaluation (chapter 3) for one or more crop-pest combination(s) concluded that there is sufficient ground to further investigate substitution, a comparison of risks between the product under evaluation and the **alternatives without practical or economic disadvantages** as identified in table 3 needs to be performed. When the use of at least one alternative is evaluated to be **significantly safer** than the use of the product under evaluation, it will be concluded to substitute the product under evaluation for that specific crop-pest combination. In all other situations, the product under evaluation will not be substituted for the specific crop-pest combination.

For the comparison of risks, it is necessary to categorize alternatives without practical or economic disadvantages from table 3 as in table 5.

Table 5 Categorization of alternatives (method/product names) per crop-pest combination as identified in chapter 3.

Crop	Pest/disease/weed	All alternatives				CA is stopped	Proceed to step 4.1
		Non-chemical method*	LR PPP	Non-LR PPP	PPP based on CfS		

The following steps need to be repeated for each individual crop-pest combination for which a comparison of risks needs to be performed.

[Crop-pest combination]

Step 4.1 Non-chemical measure or method as alternative.

- If an **alternative non-chemical measure or method that is expected to not induce any resistance in the target organism** (e.g. mechanical control, precautionary measures,

sanitation, biological control) was identified as alternative without practical nor economic disadvantages, this leads to substitution of the product under evaluation for the proposed crop-pest combination. The non-chemical measure or method is considered inherently safer than using a chemical PPP, while resistance management is not relevant in such a case. **CA for that crop-pest combination can be stopped with a conclusion to substitute.** Comparison of further alternatives for that crop-pest combination is not needed. Fill in table 6a, the sections 6b and 6c may be removed for conciseness. Proceed to conclusions in chapter 5 for that crop-pest combination.

Step 4.2 Alternatives based on CfS can be excluded as substitutes.

Any alternative PPP based on a CfS is not considered significantly safer irrespective of any prescribed risk mitigation. Alternatives based on a CfS are to be excluded from further comparison of risks and are scratched through in the table 5 above.

Do any non-CfS-based alternatives remain?

- **No;** CA **is stopped** for that crop-pest combination and proceed to the conclusion in chapter 5 for this crop-pest combination.
- **Yes;** Proceed to **step 4.3**.

Step 4.3 LR PPP

Does any of the alternatives in table 5 qualify as Low-Risk PPP product or non-chemical method with a risk to induce resistance in the target organism?

- **Yes:** Such an alternative is considered inherently safer. **CA can be stopped for that crop-pest combination with a conclusion to substitute** without further comparison of risk mitigation measures**.** Comparison of further alternatives for that crop-pest combination is not needed. Fill in table 6a, but there is no need to further fill in the section 6b and 6c and these may be removed for conciseness. Proceed to conclusions in chapter 5 for that crop-pest combination.
- **No:** Strike trough table 6a. **Proceed to 4.4 and table 6b followed by 6c**

Step 4.4 Comparison of risks for the proposed crop-pest combination between the product under evaluation and the alternatives.

The risk of using the remaining alternatives for the specific crop-pest combination from table 5 need to be assessed against the risk of using the product under assessment in steps 6b and 6c and by filling in table 6. Repeat filling in table 6 for the next alternative until

- either one of the alternatives is considered significantly safer and comparison of further alternatives can be stopped with a conclusion to substitute the product under assessment for that crop-pest combination
- or all alternatives have been tested to **not** be significantly safer – the CA will not lead to substitution of the product under assessment for that crop-pest combination

Alternatives are most efficiently tested in order of increasing levels/numbers of restrictions (aanvullende toepassingsvoorwaarden) mentioned on the Legal Instructions for Use (in Dutch Wettelijk Gebruiksvoorschrift, WG) relevant for the specific use.

Product under evaluation without risk mitigation

- In case, no risk mitigation nor P-sentences are triggered by the crop-pest combination for the product under assessment no alternative can be considered significantly safer. In that case the product under evaluation will not be substituted for the specific crop-pest combination. There is no need to compare alternatives. The CA can be stopped and the conclusion in chapter 5 can be filled in.
- If not; Proceed below.

Comparison of ADI, AOEL, ARfD

Was the AS in the product under evaluation classified as CfS for reason of relatively low values for ADI, AOEL or ARfD compared to active substances from the same group? Fill in table 6b

- **No:** The comparison of risk continues in **step 6c** straight away**.**
- **Yes: Is the covered percentage of the ADI, AOEL and/or ARfD of the alternative at least 10-fold lower than that of the product under evaluation?**
    - **Yes:** The risk is considered significantly less but proceed to table **6b** as this also needs to prove that the alternative has no higher restriction for other aspects of risk.
    - **No; stop CA**. The product under evaluation will not be substituted for that specific crop-pest combination by this alternative. **Continue with the next alternative or if there aren't any more untested alternatives** proceed to conclusions in chapter 5 for this crop-pest combination.

Comparison of risk mitigation measures and P-sentences

A comparison is made between the **risk mitigations** relevant for the specific use as stated in 'aanvullende toepassingsvoorwaarden' on the concept final WG for the proposed use of the product under assessment, versus those on the most actual WG for the current authorization of the alternative product. It cannot be excluded that relevant restrictions of use are part of the WG table itself, its caption or the footnotes. Warning sentences starting with 'LET OP' are generally not considered risk mitigations.

- Neither differences in **assessment framework nor in refinement level** underlying the restrictions are taken into consideration.
- Restrictions and conditions for the alternative that are recently covered by **general law** are not taken into consideration for the comparison, e.g. drift reduction of 75% is covered in the general law of the Environmental Activities Decree (EAD), where using minimum DRT 75 is prescribed for all applications. In older authorizations, 75 drift reduction may still be

specified in the Legal Instructions for Use (WG), but this will not be considered a restriction relevant for this comparison.

- **The reason underlying combined or generic restrictions or restrictions for a specific period or crop stage**, is at first not taken into consideration. Only if such restrictions become decisive for the outcome of the comparison of risks, the relevance of the restriction for the crop-pest combination under evaluation will be further analyzed based on the existing risk assessments of the product under evaluation and that of the alternative.
  Explanation: Some restrictions or classification can be triggered by one or a few specific uses but will be prescribed in a general way and thereby apply to all uses on the label, e.g. operator and worker protection. It may thus well be that the restriction is not needed to mitigate a risk for the specific crop-pest combination under comparative assessment. Some restrictions might be combined, most notably drift mitigation prescribed for the protection of aquatic organisms, NTA and/or NTP, and specific details may get lost in favor of readability or compactness.

- Relevance of restriction sentences is based on the following list with standard sentences [Restrictie+en+attenderingszinnen professioneel+gebruik+2025]. When restrictions are not included in the list, expert judgement will be applied to assess the relevance for risk mitigation.

Next to risk mitigation measures, the comparison also **involves P-sentences** triggered by the risk assessment for the product as identified by the comments below the classification table in part A. P-sentences voluntarily proposed by the applicant are not taken into consideration for the comparison of risks.

No weighing of risks

To conclude that use of an alternative carries significantly lower risk, the risk mitigation/P-sentence for the alternative must be less strict than that for the product under evaluation, for at least 1 aspect. This will lead to substitution.
However, if at the same time for at least one other aspect the risk mitigation or P-sentence for the alternative is stricter than that for the product under evaluation, the alternative is not anymore considered to be significantly safer. This will prevent substitution, even though this might be beneficial for one or more other aspects of the risk. Risks are therefore not weighed against each other. Neither are dose rates considered. Comparison of risks is based on restrictions for the worst-case dose rates (for the crop-pest combination) at both sides of the comparison.
If no difference is found between levels of restriction for any aspect, the alternative is not regarded significantly safer, and thus the alternative will not substitute the product under evaluation for this crop-pest combination.

Table 6: Comparison of risks for each alternative per crop-pest combination

Aspect		Product under evaluation [Product NAME or CODE]	Alternative (Alt.) [PRODUCT – N-code]	Use of Alt. less restricted than that of Cand.*
6a Alternative is a non-chemical method or LR PPP				
Non-chemical method or LR PPP			Use of non-chemical method or LR PPP is considered inherently safer than use of a PPP based on a CfS AS.	Substitute the product under evaluation for this crop-pest combination
6b Percentage of Tox. Reference values (only relevant if CfS for relatively low ADI, AOEL and/or ARfD)				
	ADI			**
	AOEL			**
	ARfD			**
6c Comparison of risk mitigation and P-sentences				
General				
	Restriction in application period/crop stages			
Mammalian Toxicology				
	Operator			
	Worker			
	Resident			
	Other			
Residues				
	Human consumption			
	Feeding restriction			
	Plant back interval			
	Other			
Efate				
	Ground water			
	Other			
Ecotox				

	Birds and mammals			
	Aquatic			
	Bees			
	NTA			
	Soil organisms			
	NTP			
	Other			
Efficacy				
	Resistance			
P-sentences classification				
SCORE		.. * +	..*=	..*-
CONCLUSION#				

**) fill in + when use in product under assessment is more restricted than the use in the alternative; Fill in - when use in product under assessment is less restricted than the use in the alternative; fill in = when restrictions are identical/equivalent (also when no restrictions apply on both sides).*

***) Percentage covered of toxicological reference values of the product under evaluation should be minimum 10-fold higher than for the alternative to include +; otherwise fill =. Only relevant for AS classified as CfS for significantly lower toxicological reference values. See 6b above. Only if minimum 1 + is scored, continue with 6c.*

#) Guideline for conclusion of comparison of risks.

Category	**Percentage ADI, AOEL, ARfD**	**Restrictions and P-sentences scores (#)**			**To substitute or not**
		+	**=**	**-**	
Alternative based on non-chemical method or LR PPP available.	n.r.	n.r.	n.r.	n.r.	Yes
Product under assessment is based on CfS with relatively low ADI, AOEL and/or ARfD	All three score =	n.r.	n.r.	n.r.	No
	Score of alternative at least 10-fold lower	≥1	≥0	None	Yes
		≥1	≥0	≥1	No
		None	≥0	≥1	No
		None	≥1	None	No

Product under assessment is based on CfS for other reasons • **No risk mitigations and/or P-sentences apply** for product, use and claim under assessment. • **Risk mitigations and/or P-sentences do apply** for product, use and claim under assessment.					
	n.r.	n.r.	n.r.	n.r.	No
	n.r.	**≥1**	**≥0**	**None**	**Yes**
		≥1	≥0	≥1	No
		None	≥0	≥1	No
		None	≥1	None	No

≥0 means any number 0 or higher; ≥1 means minimum 1. n.r. means 'not relevant'.

Once a conclusion is reached to substitute the product under assessment for a certain crop-pest combination, no further alternatives have to be investigated for that use. Please proceed to the next crop-pest combination (if relevant).

Explanation

Table 6 should be repeated in case a next alternative for the same crop-pest combination needs to be compared. The comparison for different claims within the same use may be combined in the same table, in case the same product was identified as alternative, as usually the same set of restrictions and conditions apply.

For situations in which several alternatives for the same crop-pest combination need to be compared, the table with restrictions for the product under evaluation can be copied, but the column for the next alternative contains a new set of restrictions.

When changing to a new crop-pest combination, please be aware that restrictions and conditions for both the product under evaluation and the alternative may be use-specific. Copy-paste may still be most efficient but should be carefully checked.

5. Conclusion of CA

Table 7: The product under assessment [NAME PRODUCT] contains the CfS [name AS]. Overall conclusions of the comparative assessment per crop-pest combination are presented in the last column. Please copy this conclusion in chapter 4 of part A.

Crop	Pest/disease/weed	Conclusion agronomical comparison	Conclusion comparison of risks (mention name of identified significantly safer substitute if relevant)	Substitute (Yes/No)
