Registration Manual Plant Protection Products – Comparative Assessment Article 50 of Regulation (EG) 1107/2009 – version October 2026

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1 Introduction – outline of the procedure

Article 50 of Regulation (EG) 1107/2009 states that applications for plant protection products (PPP) containing an active substance marked as Candidate for Substitution (CfS) should undergo a Comparative Assessment (CA) in addition to the risk assessment. **The aim of the Comparative Assessment is to eliminate use of products with a relatively high risk for health and environment, and substitute this with an alternative product or non-chemical method or measure for the same use with significantly lower risk.** The alternative may have no significant practical or economic disadvantages, and after substitution, sufficient variation in PPP or alternative non-chemical methods and measures should remain available for the intended use.

So, the information on these pages is only relevant to those applications based on an active substance that is marked as Candidate for substitution. For non-CfS active substances and low risk Active substances a CA is not part of the assessment (although Article 50.2 leaves an option for exceptions).

Whether an active substance is marked as Candidate for Substitution (CfS) (Article 24 of Regulation (EG) 1107/2009) can be retrieved from the starting page for each active substance in the EU pesticide database. A CfS is an approved active substance but with a relatively high-risk profile for health and environment; e.g. high persistence, high bioaccumulation, high toxicity, etc. See also Annex II (4) of Regulation (EG) 1107/2009.

The comparative assessment is performed for each individual major use intended for the candidate product (the product under application). A **use** is defined as application of the product in one specific crop (group) against a single specific disease/pest; e.g. for a claim against 3 different fungal diseases in a single crop; 3 comparative assessments must be performed. The same for a claim against a single disease in 3 different crops. The CA procedure consists of 2 main steps.

Step 1: Agronomical comparison

1a Which alternative products and non-chemical methods and measures are available for the applied-for use of the candidate product and do these alternatives represent sufficient variation in modes of action for the desired level of resistance management?

1b If so, can any alternatives without significant practical or economic disadvantages be identified?

Step 2: Comparison of risks

If 1A and 1B can both be answered with yes, can use of an alternative without significant practical or economic disadvantages be considered significantly safer than the candidate product for the specific crop-disease/pest combination?

If all 3 questions can be answered with yes, use of the candidate product will be substituted by that of the alternative (for the specific crop-disease/pest combination). If none of the alternatives without significant practical or economic disadvantages is considered significantly safer, the use of the candidate product is not substituted. If 1a or 1b is answered with no, this may directly lead to the conclusion to stop the CA without substitution.

2 Revised Ctgb policy decision for the comparative assessment (Staatscourant, 27 December 2023.)

In December 2023, Ctgb published a revised policy decision for the execution of a comparative assessment, that replaces the former. Please be referred to: Staatscourant 2023, 35333 | Overheid.nl > Officiële bekendmakingen – the text is only published in Dutch. The most important elements of the former and actual policy are summed up in the tables below.

2.1 General and step 1 agronomical comparison

Subject	Former policy	Revised policy -Dec 2023
Applicable to	Applications received before 1 July 2024	Applications received 1 July 2024 or later
Application types	All zonal applications Article 33 and Article 43 for a PPP based on a Candidate for Substitution with Ctgb as zRMS or cMS.	All zonal applications under Article 33 and Article 43 for a PPP based on a Candidate for Substitution with Ctgb as zRMS or cMS, **plus applications based on mutual recognition, under Article 40.**
Uses	Limited to professional use	For professional as well as **non-professional** use.
Format	Application form CA	**NL-addendum CA**; See also below.
Minor uses are excluded from CA	Article 50.1-d states that the consequences for minor uses should be taken into account. Ctgb therefore excludes any minor uses from the comparative assessment procedure. All uses included in the Ctgb list of minor uses plus 'special need uses' certified by NVWA (NPPO) qualify as minor for CA, whether applied for under Article 51 or not. So also uses included in the list of minor uses but applied for with a full dossier including efficacy are excluded from the CA. **Therefore, CA only applies to major uses.**	
Resistance management – substitution must not lead to a critical limitation of the options for resistance management	In case an alternative representing the same mode of action as the candidate product is available, substitution won't lead to loss of the mode of action. So, even if the collected alternatives do not represent the minimum 2,3 or 4 MoA's (see next line), there is no reason to not continue evaluating substitution. CA will therefore continue in this case.	
	After substitution minimum 5 Modes of Action remain for a specific use.	After substitution minimum **2, 3 or 4 Modes of Action remain,** depending on the risk of resistance development for a specific use.
	-	**Evaluation of the risk for resistance development** (EPPO PP 1/271 (3) and EPPO PP 1/213 (4)) is a new section in the agronomical comparison.

	-	In case **a non-chemical method or measure without risk for inducing resistance** (e.g. mechanical weeding) is identified as alternative without significant practical or economic disadvantages, this method/measure will substitute the use of the candidate product irrespective of how many modes of action are available.
Significant practical or economic disadvantages See paragraph; 2.5	Based on conditions for use, restrictions, and GAP details.	Conditions for use, restrictions, and GAP details have less weight. The applicant is required to actively submit argumentation and proof.
Alternatives based on a CfS	Are excluded as alternatives straight from the beginning of the CA procedure.	**Alternatives based on a CfS themselves are included** as alternatives for the number of available modes of action. However, alternatives based on a CfS are excluded from substituting the use of the candidate product. They are not considered significantly safer without performing the comparison of risks.

2.2 CA for new, amended or reassessed major uses based on a CfS active substance

For a new authorization (Articles 33 or 40), all major uses are subject to a comparative assessment. For an extension or amendment of use (Articles 33 or 40), the comparative assessment is limited to the new/amended major uses only. For any other changes of the authorization, e.g. significant formulation change, a comparative assessment will be part of the assessment for all major uses that need reassessment.

Comparative assessment for all major uses will be repeated with the Article 43 renewal reassessment of the product. In products containing 2 active substances, one of which is a CfS, the comparative assessment will be part of the Article 43 assessment for both active substances. So, even if the Article 43 renewal application is for the non-CfS in the product, comparative assessment is included.

2.3 NL-addendum CA

Comparative assessment is a national Member State-specific element, as authorized PPP and applicability of non-chemical methods and measures differ between Member States (MS). Ctgb developed a format NL addendum CA for national use only. Please be aware that other MS may have their own requirements for a CA.

The new format NL addendum CA guides the applicant through the Dutch CA assessment from A-Z. With a new application for products based on a CfS, the applicant is required to submit the filled-in NL addendum CA with the dossier for all applications based on Articles 33, 40 and 43. These web pages should be read in conjunction with the NL addendum CA. Applicants that need more information on the CA process can contact the Ctgb-Service Desk with their questions, or the project manager of the application once assigned.

Ctgb evaluates the NL addendum CA close to the decision phase for the application. First of all, this guarantees that CA is performed with the alternatives available at the time of the decision. Second, the final or at least the concept final WG with uses and the restriction sentences and the P-sentences from the assessment are needed for a valid CA. In case of applications that take more than 1 year to complete from submission, Ctgb may ask the applicant to provide an update of the NL addendum CA before Ctgb starts on the evaluation of this part. The same if during the application, the intended use was significantly changed or restricted in order to pass the risk assessment.

The agronomical comparison is evaluated by NVWA (NPPO) for Ctgb. If relevant, Ctgb will evaluate the comparison of risks. In the NL addendum CA, NVWA and Ctgb will work with commenting boxes for their evaluations.

2.4 Explanation on ‘’alternatives’’ versus ‘’alternatives without significant practical or economic disadvantages’’.

Often, quite a number of alternatives are available for major uses. Any authorized PPP or non-chemical method/measure directed at controlling the same disease/pest in the same crop is regarded as an alternative. They may not all be able to control the disease/pest under all circumstances, in all crop, pest, or disease stages or to the full extent. However, the alternatives all contribute to controlling the disease or pest and are therefore all considered for the number of available Modes of Action for resistance management.

Only ‘’alternatives without significant economic or practical disadvantages” are further considered as substitutes in the comparison of risks. The applicant should submit reasoning and proof for economic or practical disadvantages, subject to assessment by NPPO/NVWA, to disqualify a specific alternative as a possible substitute.

2.5 Elaboration on criteria for ‘’significant practical or economic disadvantages’’ as part of the agronomical comparison (Version: 1.3 by NPPO/NVWA)

Article 50.1-b of Regulation (EG) 1107/2009 states that PPP based on a CfS can only be substituted by an alternative without significant practical or economic disadvantages. This is part of the agronomical comparison, as elaborated in EPPO standard PP 1/271 (3). Underneath, this criterion is further detailed and explained.

A. Practical disadvantages

In Regulation (EC) No. 1107/2009 and the EPPO standard, the criterion ‘practical disadvantages’ is not described in quantitative terms but is explained with reference to several examples.

Appendix IV of Regulation (EG) 1107/2009 states:

- *…… where no technical facilities for the use of the alternative are available or economically feasible. …… This situation shall be substantiated.*

Examples from the EPPO Standard PP 1/271 (3):

- *lack of labour availability for hand weeding,*
- *insufficient land available to permit sufficiently long rotations,*
- *limited versatility of alternatives,*
- *consideration should be given to the control of additional pests and diseases.*

Additional examples

For the implementation of this criterion in the Netherlands, the above examples have been expanded with the following:

Non-chemical measures

- The majority of growers do not have access to the equipment required for this alternative, and acquisition of this equipment is not feasible in the short term.
- The alternative methods are not usable under common growing or weather conditions.

Chemical measures

- The versatility of the alternatives is limited because of additional conditions for use in the Legal Instructions for Use (Wettelijk Gebruiksvoorschrift or WG for short). The grower e.g. can not apply the product because of a restriction that excludes use of the product in groundwater protection areas or due to a restriction that excludes use in periods relevant to control of the disease/pest.
- The alternative is authorized but not available on the Dutch market.

Note: As matter of principle, additional conditions for use included on the WG (like e.g. prescribing higher drift reduction), are not regarded as practical disadvantage unless sufficiently corroborated by the applicant.

The above examples are not exhaustive. Over time, additional new examples (other situations) may become apparent.

B. Economic disadvantages

Controlling a pest or disease with an alternative product can be more expensive than with the candidate product under assessment.

Chemical measures

The examples in Regulation (EG) 1107/2009 and the de EPPO guidance do not concern alternative plant protection products, but only non-chemical methods.

Interpretation for the Netherlands

- If the alternative is a plant protection product, then we assume that use of the product is economically viable and thus there can be no question of significant economic disadvantages.

Non-chemical measures

Interpretation for the Netherlands

- In the UK, a list of non-chemical methods is available that was developed by DEFRA. For reasons of uniformity, this document forms the basis for the assessment. On top of that, other commonly known non-chemical measures in Dutch IPM systems will be assessed for effectiveness, availability and practical use.

2.6 Prevention of loss of minor uses

Ctgb interprets Article 50.1-d as: ''loss of minor uses due to a CA should be prevented''. Therefore, minor uses themselves are excluded from a CA. See also the entrée on minor uses in the table in chapter 2 of this Registration Manual.

However, minor uses may also be lost in case all the major uses are substituted. First of all, Ctgb cannot register an authorization with only minor uses authorized under article 51. Minimum 1 use should be authorized with a full assessment, before an extension with minor uses under article 51 can be registered. Second, if minor uses with a full assessment remain, the authorization can be continued but may no longer be economically viable for the authorization holder. In such case, the authorization holder may submit arguments and proof which major use is essential to keep the authorization available for the minor uses. If approved, this major use may be exempted from substitution based on preventing the loss of the minor uses of the product.

2.7 Step 2 Comparison of risks

Subject	**Former policy**	**Actual policy -Dec 2023**
Application date	All applications with a decision until and including 31 December 2023.	**All ongoing and new applications with a decision starting from 1 January 2024.**
Alternative product with low-risk status	-	Is considered **inherently safer** and will substitute the intended use of the candidate product.
Comparison of risks	**Based on the risk assessment, especially Ecotoxicology and Human toxicology.** Often such a comparison could not be made as the assessments differed too much in assessment framework and data to update the assessment of the alternative are not available.	**Based on restriction sentences on the WG (Legal Instructions for Use) and P sentences resulting from the assessment, it is determined if the alternative is significantly safer. See below.**

The comparison of risks of using the candidate product versus the risks of using the alternative (without significant practical or economic disadvantages) is based on a comparison of the restriction sentences included in the Legal instructions for Use (WG) and the P-sentences resulting from the assessment in the classification. P-sentences based on hazard or proposed by the applicant without need from the assessment are excluded from the comparison. **The concept final WG and concept**

final classification for the candidate product and the actual WG and classification of the alternative are compared to determine whether the alternative is significantly safer or not.

The Ctgb policy decision defines the alternative significantly safer when for at least one section it has less-heavy restrictions or P-classification compared to the candidate product provided that the alternative has no heavier restriction or P-sentence in any other section. Only then does the alternative without practical or economic disadvantages suit as a substitute for the candidate product.

For example, for a specific use the alternative has no prescription for P280 (operator protection), while the candidate product has as based on the assessment. This alone would lead to the conclusion that the alternative is significantly safer, and to substitution for this specific use. However, if at the same time the alternative is labelled DRT 95 for protection of NTP and the candidate product is not (the standard DRT 75 suffices), this leads to a conclusion that the alternative is not significantly safer. So various risks are not balanced against each other in nature nor in quantity. Neither is the underlying assessment framework or refinement level part of the comparison.

When the restrictions and P-sentences are equivalent for all sections, the use of the candidate product is not substituted.

The conclusions may vary among the major uses per product as the spectrum of alternatives is likely to vary, as well as the set of restrictions connected with each use. Also, the risk for resistance development may vary from use to use as characteristics of the crop as well as the target disease/pest vary.

2.8 Transitional period for the new Ctgb Policy on CA

The new policy decision for the comparison of risks applies to all new and ongoing applications for which a decision is taken starting from **1 January 2024**. For the agronomical comparison, the new policy decision applies for all applications received starting on **1 July 2024**. However, the new NL addendum format was not available until January 2026, due to challenges during the implementation.

Therefore, all applications for which a CA must be performed and that were received before 1 July 2024, NVWA (NPPO) evaluates the agronomical comparison based on the former criteria in a separate report. Ctgb then adds a comparison of risks according to Chapter 4 of the new format. For any applications received since 1 July 2024 for which the CA is not yet submitted in the new format, Ctgb will give the applicant the opportunity to fill up the new format before starting on the evaluation.

2.9 Decision on applications including a CA

Ctgb offers applicants a short period to react on the outcome of the comparative assessment before incorporating it in the final RR and in the decision on the application. The reaction of the applicant will be processed into the final versions.

The final decision on the application for each major use is based on the outcome of the risk assessment and the comparative assessment together:

	Conclusion risk assessment	**Conclusion comparative assessment**	**Decision**

a	No acceptable risk	-	Denial
b	Acceptable risk	Cannot be substituted	Authorization
c	Acceptable risk	Substitute with alternative	Denial
d	Acceptable risk	Agreement to delayed CA (Article 50.3)	Conditional authorization

Ad a: Denial based on the risk assessment.

In case the risk assessment concludes that acceptable risk cannot be proven, the use will be denied as usual. A subsequent comparative assessment is superfluous and will not be performed. This means that in case of a successful appeal procedure leading to acceptable risk, the comparative assessment still needs to be performed.

Ad b: Authorization

With a conclusion for safe use from the risk assessment plus a conclusion that the use cannot be substituted from the CA or CA is not relevant (minor uses), the use can be authorized. The use(s) will again be considered for a comparative assessment with the Article 43 renewal application or if an application for change of the authorization induces a reassessment of the use(s).

Ad c: Denial based on the CA – new uses and existing uses

In case the risk assessment concludes acceptable risk, but the CA concludes that the use can be substituted by a significantly safer alternative without critical effects on resistance management, this use will be denied. A **new use will simply not be authorized**.
When it concerns a **reassessment and substitution of existing uses**, the use is likewise denied, but Article 50.5 states that for existing uses this takes effect only after 3 years. Ctgb interprets this as a transitional period of 36 months instead of grace periods (Article 46) that apply when a use is withdrawn or restricted due to the reassessment of the risk. Within the transitional period of 36 months (Article 50.5), existing and new stock of the product with a label still including the substituted uses may be used and traded.

A decision on a reassessment of a product based on a CfS will address any changes due to the risk assessment in a new version of the WG (Legal Instructions for Use) that applies immediately after the decision, considering grace periods based on Article 46.
The uses denied based on the CA will still be included in that version of the WG, albeit their details may be amended based on the risk assessment. The expiration date 36 months ahead will be stated with these uses in the WG to inform users of their imminent finiteness.
The decision contains an explicit clause that uses denied based on the CA, will expire 36 months after the date of the decision irrespective* of any follow-up decisions and WG-changes during that period. Exactly 36 months after the original decision including the CA, Ctgb will publish a new version of the then actual WG without the uses substituted and denied based on the CA. No grace periods based on article 46 will apply with that WG-change. Neither will a new decision be published. It is the explicit responsibility of the authorization holder to manage his stocks and to timely inform users about the upcoming change of the WG.

*) Only in case the substituted use(s) is/are already withdrawn or otherwise terminated with another decision before the deadline 36 months after the primary decision for substitution, a WG change is

no longer needed. However, any grace period (Article 46) with this decision cannot exceed the deadline of 36 months after the primary decision for substitution.

Ad d-1: Delayed CA – request and decision to delay

Article 50.3 gives room for authorizing new uses of a product based on a CfS without CA. However, an authorization containing such uses is to be limited to a maximum duration of 5 years, for gaining experience with the new use in practice. To extend the authorization after 5 years, the comparative assessment should yet be performed. In practice this comes down to a postponed CA starting 4 years after the date of authorization.

For a claim to postpone the CA for a new use, the applicant must submit argumentation and proof. Such will be assessed by Ctgb. When Ctgb agrees and the applied-for uses pass the risk assessment, Ctgb will issue a conditional authorization for a maximum of 5 years. Condition is that the applicant yet submits a CA no later than 4 years after the date of the decision. This condition continues to apply irrespective of any follow-up decisions (e.g. administrative decisions, extension of use, renewal, etc) within the period of 5 years.
The duration of the initial authorisation may have to be set shorter than 5 years, because of a nearby date of expiry of the active substance. Any subsequent administrative extension of the authorization is then limited to a date of 5 years from the decision to postpone the CA at the original authorization.

Ad d-2: Delayed CA – postponed CA assessment and decision

In order to continue the authorization after 5 years, the authorization holder must submit an NL-addendum CA with a part A not later than 4 years after the date of the decision. Submission is under the scope of an NLWG application (Article 45) as CA concerns as a national specific element of the assessment and may be reason to amend the national label (WG). No other amendments can be included in this specific NLWG application, except for complete withdrawal of uses.
If no such application is received within 4 years after the authorization, the authorization will expire 5 years after the decision for authorization without grace periods.

No reassessment of the risk is needed. The assessment for a postponed CA is the same as for an ordinary CA. However, the assessment considers the valid Ctgb policy for CA and the alternatives available at the date of the evaluation, which may differ from the situation at the time of the decision for conditional authorization, 4 years earlier. Ctgb aims to process the evaluation of a postponed CA as quickly as possible, so that a decision can be taken about 6 months before the authorization expires. If then the conclusion is that none of the uses can be substituted; the authorization period will be extended until the ‘natural date of expiry’ as based on Regulation (EG) 1107/2009 and the expiration of the active substances.

When the conclusion is that all or part of the uses can be substituted, the decision will state that these uses are withdrawn. A new WG is published with the decision, but no grace period (Article 46) nor transitional period (Article 50.5) apply for the old WG. The new WG will only apply from the original date of expiry of the authorization. In practice, the authorization holder should have about 6 months to inform the market about the label change and to relabel stocks.