

Elaboration of criteria for 'practical or economic disadvantages' and 'consequences for minor uses' as part of the agronomic comparison

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Introduction

In Regulation (EC) No. 1107/2009, comparative assessment (CA) is described in Article 5, which states that a product which is a Candidate for Substitution (CfS) can be replaced only if the alternative product or method 'does not pose significant economic or practical disadvantages'. Moreover, 'the impact on minor uses' must be assessed. Both aspects are part of the agronomic comparison, which has been elaborated in the EPPO guidance PP 1/271.

Below, these criteria are specified based on the above-mentioned Regulation and the EPPO guidance.

This policy memorandum has been submitted to industry representatives and environmental groups. The latter have suggested that CA should be regarded as a means for promoting innovation (compulsory or otherwise). However, based on the list of CfS, alternatives can be used only if they comply with strict, measurable conditions. Another consideration is whether an alternative is actually available and not whether it can be developed. The overall movement towards more innovation is already taking place in the context of low-risk products and the 'greening' that has been initiated by the government departments; in cooperation with the Ctgb, concrete implementation of green products and methods is being tested in pilot projects.

A. Practical disadvantages

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

Examples from Regulation 1107/2009:

- *where no technical facilities for the use of the alternative are available or economically feasible.*
 - *and restrictions on and/or prohibitions of use of a plant protection product could cause such disadvantage.*
- This situation shall be substantiated.*

Examples from the EPPO guidance:

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

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

Non-chemical measures

1. The majority of the growers do not have access to the equipment¹ required for this alternative, and acquisition of this equipment is not feasible in the short-term.
2. The alternative methods are not usable in all conditions (including weather conditions);

Chemical measures

3. The versatility of the alternatives is more limited because:

¹ By means of ownership, rental or subcontracting

- a. additional restrictions on the label may be severe (for example, do not use before 1 May);
- b. the alternative product is not on the market.

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 for substitution.

Chemical measures

The examples in Regulation (EC) No. 1107/2009 and the de EPPO guidance (see Appendix 1) do not concern alternative plant protection products, but only non-chemical methods.

Implementation in the Netherlands:

If the alternative is a plant protection product, then we assume in principle that this can be used without significant economic disadvantage. A significant economic disadvantage occurs only if the alternative plant protection product is so much more expensive that the crop can no longer be grown profitably, or if different equipment is required for applying the product that the majority of growers do not have access to.

Non-chemical measures

In the UK, a list of non-chemical methods is available that was developed by DEFRA. Only the methods on this list are considered as alternatives. This benefits the uniformity of assessments of various products and saves time for the authorisation holders (they no longer have to collect this information themselves). Such a list is not available in the Netherlands. The preparation and updating of such a list takes a great deal of time (and is therefore costly) because the measures differ for each crop-pest combination.

Implementation in the Netherlands:

Initially, the existing UK document will be used. Following the evaluation, it will be determined whether a document focusing specifically on the Netherlands is required.

C. Minor uses

The Ctgb has decided to conduct a CA only for major uses. The CA will not be conducted for minor uses.

According to the approved method, 'When a minor use is likely to no longer be supported because a major use is a candidate for substitution (in which case it is no longer feasible to continue to support the authorisation of the minor use), the applicant may substantiate this circumstance. After a case-by-case review, the Ctgb will determine whether the major use(s) can be maintained to preserve the product range for minor uses.'

This case-by-approach takes place as follows:

If a major use of the product can be substituted, then the applicant can indicate (with substantiation) whether disadvantages can be expected for minor uses. If this is the case, then the applicant can indicate which continued major use of the product is required to maintain the availability of these minor uses. We assume that if at least one major use remains on the label, it will be economically feasible for the authorisation holder to keep the product on the market. In this case, there will be no disadvantages for the

associated minor uses. If the authorisation holder nevertheless believes that maintaining a single major use (and all minor uses) on the label offers insufficient economic perspective for continuing to support the authorisation of the product, then the applicant can substantiate this (for example based on sales figures, crop production area, number of users per crop/year).

The information on the legal instructions for use will be used as the basis. For example, if 'grain' is listed on the label, then only the alternatives which also have this on the label will be assessed, and therefore not all underlying crops. If sufficient alternatives for grain are available, then this also applies to the underlying crops, unless the applicant indicates that there are practical or economic disadvantages with the alternatives in specific underlying crops. However, if it is evident that there are logical alternatives for these uses, then this can be included in the comparative assessment.

Appendix 1: relevant passages on ‘significant practical or economic disadvantages’

- **Regulation (EC) No. 1107/2009 (Annex IV)**

Significant practical or economic disadvantage.

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.

- **EPPO guidance**

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

- No, go to 12.
- Yes, stop CA

Note g: Practical or other disadvantages including, for example, lack of labour availability for hand weeding, insufficient land available to permit sufficiently long rotations to enable pest, weed or disease management through crop rotation, versatility of alternatives, etc. The windows of application of other methods may differ considerably from the application of the candidate and limit the feasibility of the alternative. Consideration should be given to the need and acceptability of the use of additional PPPs or alternative measures to control additional pest problems.

- **Consultation on the Comparative Assessment method in the Netherlands (04-09-2015)**

How are economic disadvantages taken into account?

If an alternative product is authorised or if a non-chemical alternative is commonly used (by the majority of growers), in principle it will be assumed that these alternatives are economically viable. Indeed, a non-chemical method is now commonly being used in practice for plant protection. If a chemical alternative has economic disadvantages, then the applicant must substantiate this assertion, which will then be assessed on a case-by-case basis. This will differ for each situation and will depend partly on factors such as crop yield and costs for plant protection. If it turns out that the alternative has significant economic disadvantages (to be assessed by the Netherlands Food and Consumer Product Safety Authority), then the alternative must be considered as unsuitable.

In addition, it is doubtful whether a farmer/grower can be reasonably expected take preventative or non-chemical measures if this requires significant investment. In this regard, if the majority of the growers have a specific apparatus or technical installation, it will be assumed that this is the normal situation. If a crop is grown on various types of growing operations, then each type will be assessed separately.