Courtesy translation for the purpose of the consultation procedure – the final administrative rule will only be published in Dutch

Administrative rule on comparative assessment for plant protection products – version for public consultation

Preamble

Since the 1st of August 2015, Regulation (EC) No 1107/2009 requires competent authorities in the European Union to perform a comparative assessment whenever an application for authorisation is evaluated for a plant protection product containing at least one candidate for substitution. In the European Union, approved active substances are identified as candidates for substitution if they meet certain hazard criteria (see Annex II(4) of Regulation (EC) No 1107/2009). The comparative assessment's aim is to substitute plant protection products containing such substances with significantly safer alternatives – for example with non-chemical methods or products requiring less risk mitigation (see recital 19 of Regulation (EC) No 1107/2009) – whenever possible.

In the Netherlands, the current methodology for the comparative assessment entails two steps. The first step – the agronomic evaluation – identifies all available and adequate alternatives for the plant protection product containing the candidate(s) for substitution. Only if they are suitable and practically feasible under a wide range of circumstances they are considered to be adequate alternatives. In addition, the agronomic evaluation determines whether – if the product in question were to be substituted – the chemical diversity of the available products and methods would remain sufficient to minimise the development of resistance of pests or diseases. For the alternatives that fulfil these conditions a second step is performed: the comparative risk assessment. This step determines whether at least one of the alternatives is significantly safer than the product with the candidate for substitution. If this is the case, an authorisation for the product in question is rejected because it can be substituted with a safer alternative.

In practice, the comparative assessment rarely leads to rejection of an application for authorisation of a plant protection product. This is the case for the Netherlands as well as for other EU Member States. The REFIT evaluation of Regulation (EC) No 1107/2009 concluded that the comparative assessment as currently designed is not effective and efficient. The report concludes that – while the comparative assessment places a significant strain competent authorities' capacity – not a single product has yet been replaced (by 2020). There are a number of reasons for this, including the lack of sufficient available alternatives, concerns around resistance risk, the absence of public data on alternatives and the lack of an unambiguous method to compare the safety of plant protection products. With the currently proposed working method Ctgb mainly addresses the latter problem. The proposed method provides an unambiguous way to determine whether there are adequate and significantly safer alternatives.

When Ctgb's current methodology was adopted in 2015, a stepwise introduction was chosen in order to gain experience with the comparative assessment. After several years of experience, the current implementation is in need of revision. Moreover, the comparative risk assessment has proved to be impracticable with the current approach, thereby causing delays in the assessment process. Pending the outcome of the European process around the comparative assessment, Ctgb therefore wants to take a step towards an improved implementation. To arrive at an effective and efficient implementation of the comparative assessment in the short term and within the framework of current European legislation, this administrative rule defines an amended implementation for the Netherlands. Should the European legislation and/or Guidance for the comparative assessment be revised in the future, the Netherlands will bring its methodology in line with it.

The proposed administrative rule regulates the following amendments of the national methodology:

- The comparative assessment will be carried out for all applications for (extension or renewal of) product authorisation, including mutual recognition and non-professional use.
- The criterion for resistance management will be adjusted from *at least 5* to *at least 2, 3 or 4,* depending on the resistance risk of the relevant crop-pest combination. This is in line with the current EU Guidance for the comparative assessment (EPPO PP1/271(3))
- Products based on a candidate for substitution are no longer excluded a priori as alternatives (and thus count towards chemical diversity), but in the comparative risk assessment step they are, by definition, considered as not safer.
- Alternatives that cannot substitute the entire crop group of a use are no longer excluded; if an adequate and safer alternative exists for specific subgroups, they are removed from the candidate product authorisation (partial substitution).
- All non-chemical measures and methods that can be used as adequate alternatives are considered significantly safer within the context of the comparative assessment. These are measures and methods that are not plant protection products, such as mechanical methods or the use of natural (macro)predators. The European Sustainable Use Directive (Directive 2009/128/EC) requires that priority be given to non-chemical methods wherever possible because they pose the lowest risk to human health and the environment.
- The comparative risk assessment is carried out on the basis of a comparison between the risk mitigation measures of the candidate product and of the adequate alternatives. The premise is that the risk mitigation measures are indicative of the safety of a product: a product requiring less stringent risk mitigation measures is considered significantly safer within the context of the comparative assessment.

The details of the modified methodology are elaborated in articles 2 to 5 of this administrative rule.

The methodology described in this administrative rule allows for unambiguous and transparent identification of significantly safer alternatives. Several consequences are expected. First, introduction of this methodology will expedite performance of the comparative assessment. This leads to a more efficient authorisation procedure for applications for which no safer alternative exists (provided the product meets the other conditions required for authorisation). Second, the comparative assessment will be more effective. This means that products for which a safer alternative can be found are effectively substituted. Introducing this approach thus contributes to the comparative assessment's aim: substituting – if possible – products based on candidates for substitution by significantly safer alternatives.

With the current implementation, the comparative risk assessment is unworkable in practice. This causes a significant delay in the authorisation process if a comparative risk assessment must be performed. Ctgb therefore considers it necessary to implement the adjusted method for the comparative risk assessment (Articles 4 and 5 and Annex I) immediately upon adoption of this administrative rule, for on-going and new applications. The agronomic evaluation will be carried out with the method that is currently in place for these applications. Thus, there is a distinction between the entry into force of the adjustments to the comparative risk assessment and the adjustments to the scope and agronomic comparison. The immediate implementation of the adjusted comparative risk assessment applies only to pending applications for which a comparative assessment is carried out under the current methodology. The other changes (Articles 2 and 3) have implications for the data to be submitted by applicants and the application types for which the comparative assessment shall be carried out. To take these consequences into account, a transitional period of six months will be used for the other changes, after publication of this administrative rule in the Government Gazette.

Administrative rule of the Board for the authorisation of plant protection products and biocides of xxx, concerning the methodology for the comparative assessment of plant protection products

The Board for the authorisation of plant protection products and biocides,

Having regard to Article 50 of Regulation (EC) No 1107/2009, read in conjunction with Articles 4:81 to 4:84 of the General Administrative Law Act,

Decides:

Article 1. Definitions

For the purposes of this administrative rule, the following definitions shall apply:

a. *Ctgb*: Board for the authorisation of plant protection products and biocides;
b. *Regulation (EC) No 1107/2009*: Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJEU, L 309);
c. *Plant protection product*: plant protection product as referred to in Article 2(1) of Regulation (EC) No 1107/2009;
d. *Active substance*: active substance as referred to in Article 2(2) of Regulation (EC) No 1107/2009;
e. *Use*: use of a plant protection product according to Article 33(1) and Article 50(1) of Regulation (EC) No 1107/2009;
f. *Candidate for substitution*: an active substance that has been approved as a candidate for substitution in accordance with Article 24 of Regulation (EC) No 1107/2009;
g. *Non-chemical measure or method*: non-chemical control or prevention method which does not involve a plant protection product (e.g. a mechanical method such as hoeing or the use of natural predators).
h. *NVWA*: Netherlands Food and Consumer Product Safety Authority;
i. *Risk mitigation measure*: legally imposed measure that limits the adverse effects of the release of an active substance or plant protection product;
j. *Guidance SANCO/11507/2013*: guidance document for performance of the comparative assessment;
k. *Guidance EPPO PP 1/271 (3)*: guidance document for performance of the agronomic comparison;
l. *Guidance EPPO PP 1/213 (4)*: guidance document for analysis of the risk of resistance of target organisms to plant protection products;

Article 2. Scope

1. Ctgb performs a comparative assessment as referred to in Article 50(1) of Regulation (EC) No 1107/2009 when an application is submitted for authorisation of one or more uses of a plant protection product containing at least one candidate for substitution. This administrative rule defines how Ctgb performs the comparative assessment.
2. The comparative assessment is performed for the following types of applications, for both professional and non-professional users:
    a. A new authorisation, including a mutual recognition;
    b. A renewal of an authorisation;
    c. An extension of an authorisation (where the comparative evaluation will only be carried out for the additional uses applied for).

3. The comparative assessment shall not be carried out for any minor uses (as defined in Article 3(26) of Regulation (EC) No 1107/2009) of the product under evaluation.
4. The comparative assessment shall consist of an agronomic evaluation as described in article 3 of this administrative rule and – when applicable – a comparative risk assessment as described in articles 4 and 5 of this administrative rule.

Article 3. Methodology - the agronomic evaluation

1. The aim of the agronomic evaluation is to identify, in accordance with Article 50 and Annex IV of Regulation (EC) No 1107/2009, all available adequate alternatives to the use(s) of the product containing one or more candidates for substitution.
2. The NVWA carries out the agronomic evaluation on behalf of the Ctgb. In principle, the Ctgb follows the NVWA's advice. The NVWA assesses whether the available alternatives fulfil the conditions listed in the sixth paragraph of this article, using the relevant guidance documents (SANCO/11507/2013, EPPO PP 1/271 (3); EPPO PP 1/213 (4)).
3. Based on the information provided in the dossier submitted by the applicant and information from other sources (including the Ctgb's Authorised products database), the NVWA shall determine the adequacy of the available alternatives.
4. An adequate alternative may be another plant protection product or a non-chemical measure or method.
5. An adequate alternative may be an alternative for all of the uses, for part of the uses or for parts of individual uses that the application.
6. An alternative satisfies each of the following conditions for the relevant use (or part thereof) to be considered adequate:
    a. The alternative is usable and effective under different agricultural, plant health and environmental (including climatic) conditions (see recital 23 of Regulation (EC) No 1107/2009);
    b. If it is a plant protection product, it concerns a plant protection product for which an authorisation exists in the Netherlands;
    c. Where relevant, the chemical diversity of the available plant protection products remains sufficient to limit the risk of resistance development in the target organism (Annex IV, point 1b of Regulation (EC) No 1107/2009; EPPO PP 1/271 (3); EPPO PP 1/213 (4)) in case the alternative substitutes the product;
    d. According to Annex IV(3) of Regulation (EC) No 1107/2009, substituting the product with the alternative does not lead to significant practical or economic disadvantages for the user (EPPO PP 1/271 (3)).
7. The impact on any minor uses is taken into account (in accordance with Article 50(1)(d) and Annex IV(3) of Regulation (EC) No 1107/2009 and EPPO PP 1/271 (3)).
8. If one of the alternatives is a non-chemical measure that does not induce resistance development, this measure is considered to meet the criterion for chemical diversity.
9. The criterion for chemical diversity - in line with EPPO PP 1/271 (3) and EPPO PP 1/213 (4) - is that in the case of substitution:
    a. in the case of a crop-pest combination with a low risk of resistance, 2 modes of action should remain available;
    b. in the case of a crop-pest combination with a medium risk of resistance, 3 modes of action should remain available;
    c. in the case of a crop-pest combination with a high risk of resistance, 4 modes of action should remain available;
10. Authorised plant protection products containing one or more candidate(s) for substitution shall not be excluded a priori as adequate alternatives and thus count towards the number of available modes of action.

Article 4. Methodology - the comparative risk assessment

1. Pursuant to Article 50(1)(a) and Annex IV(2) of Regulation (EC) No 1107/2009, a comparative risk assessment shall be carried out. The comparative risk assessment shall determine whether one of the adequate alternatives is significantly safer.
2. If one of the adequate alternatives is significantly safer, the application in question shall be rejected.
3. All non-chemical measures or methods are considered to be significantly safer.
4. All low-risk products according to Article 47 of Regulation (EC) No 1107/2009 are considered to be significantly safer.
5. Products containing one or more candidate(s) for substitution shall not be assessed as significantly safer.
6. For all adequate alternatives for which the criteria set out in paragraphs 3 to 5 do not apply:
    a. none of the alternatives shall be considered as significantly safer if no risk mitigation measures are required for the requested use;
    b. an adequate alternative shall be considered as significantly safer if less stringent risk mitigation measures are prescribed for this alternative (see article 5 of this administrative rule for a clarification of the comparison of risk mitigation measures);
    c. if the application for authorisation concerns a product with a candidate for substitution that has a significantly lower ADI, AOEL or ARfD[1] than those of the majority of the approved active substances within relevant groups of substances/use categories (Annex II(4) of Regulation (EC) No 1107/2009), an adequate alternative shall be considered as significantly safer if both the following two criteria are met:
        - The exposure to ADI, AOEL and/or ARfD ratio of the adequate alternative is at least a factor 10 lower than that of the product with the candidate for substitution;
        - The risk mitigation measures for the adequate alternative are less stringent.'
7. Annex I elaborates on these criteria by outlining the steps taken during the comparative risk assessment.

Article 5. Methodology - risk mitigation measures

1. Risk mitigation measures refers to both the restriction phrases and the precautionary measures (P-statements) resulting from the risk assessment.
2. 'Less stringent risk mitigation measures' means the following:
    - The adequate alternative is not subject to the risk mitigation measures that apply to the product containing a candidate for substitution, or these risk mitigation measures are less stringent for the alternative; and
    - no additional risk mitigation measures (different to those required for the product containing a candidate for substitution) apply to the adequate alternative.
3. If the restriction statements or precautionary measures are included in national legislation at the time the comparative risk assessment is carried out, they shall not be taken into account.

Article 6. Entry into force

1. This administrative rule shall be published with explanatory notes in the Government Gazette.
2. This administrative rule shall enter into force from the day after the date of issue of the Government Gazette in which this administrative rule is published, with the exception of

[1] ADI: Acceptable Daily Intake; AOEL: Acceptable Operator Exposure Level; Acute Reference Dose.

Articles 2 and 3, which shall enter into force six months after the date of issue of the Government Gazette in which this administrative rule is published.

3. During the transitional period of six months, an application is allowed to be assessed on a voluntary basis under the administrative rule described in Articles 2 and 3. It is up to the applicant to indicate this.

Annex I. Methodology – the steps in the comparative risk assessment

1. Is one of the adequate alternatives a non-chemical measure or method?
    a. Yes → This alternative is assessed as significantly safer.
    b. No → Proceed to step 2.
2. Is one of the adequate alternatives a low-risk product?
    a. Yes → This alternative is assessed as significantly safer.
    b. No → Proceed to step 3.
3. Do all adequate alternatives contain a candidate for substitution?
    a. Yes → None of the adequate alternatives is assessed as significantly safer.
    b. No → For the adequate alternatives that do not contain a candidate for substitution, proceed to step 4.
4. Does the use for which the comparative assessment is performed require risk mitigation measures?
    a. Yes → Proceed to step 5.
    b. No → None of the adequate alternatives is assessed as significantly safer.
5. Was the active substance in question identified as a candidate for substitution because of its significantly lower ADI, AOEL or ARfD compared to the majority of approved active substances within the relevant groups of substances/use categories (Annex II(4) of Regulation (EC) No 1107/2009)?
    a. Yes → Proceed to step 6.
    b. No → Proceed to step 7.
6. Is the exposure to ADI, AOEL and/or ARfD ratio of any of the adequate alternatives at least a factor of 10 lower than that of the use it is compared to?
    a. Yes → Proceed to step 7.
    b. No → None of the adequate alternatives is assessed as significantly safer.
7. Do any of the adequate alternatives require less stringent mitigation measures than the use it is compared to?
    a. Yes → Alternatives to which this applies are assessed as significantly safer.
    b. No → None of the adequate alternatives are assessed as significantly safer.