Written comments by the Netherlands to the Draft proposal for amendment of REGULATION (EC) No 1107/2009 – Annex IV

We welcome the Commission's initiative to simplify the procedure for the comparative assessment (CA) and hope that the feedback below will contribute to achieving this goal.

We consider the proposed amendment of Annex IV as a significant step forward in the process of increasing the efficiency and effectiveness of CA. In particular, we welcome the text about the procedure (section 1), which puts the burden of proof unequivocally with the applicant. Furthermore, the proposed amendment addresses the role of non-chemical alternatives more clearly than the original text. The proposed adjustment of the chemical diversity criterion could increase efficiency of the identification of potential alternatives, and decreasing the required TER factor may improve the effectiveness of the CA procedure.

While we view the proposed amendment as an overall improvement, there are some concerns which we would like to address.

The proposed text on the procedure (section 1) puts the responsibility for CA clearly with the applicant. However, the following sections (2-4) highlight the role of the MS Authority in the assessment, inviting confusion about the delineation of roles and responsibilities. We would like the text to be unambiguous about the role of the MS Authority as the *assessor* of the analysis and the data provided by the applicant.

We also want to share our concern about the suggested public consultation. We worry that this would make the procedure much more complicated and time consuming, with questionable results. In our view it does not contribute to a more efficient and effective comparative assessment. What we propose instead is development of a publicly available database of alternative measures and products, which can be used during the CA process by all MS. Development of such a database may involve public consultation without needlessly complicating each individual CA procedure. This EFSA call for proposals, which includes a request for an inventory of all alternatives for pest control (p. 6), could be helpful in the development process.

Lastly, section 3 (on risk assessment) suggests a more in-depth analysis of the broader sustainability aspects of a potential substitution. While such an analysis could be theoretically ideal, we fear that this is too ambitious to aim for at this stage, given the issues MS are already facing with the current comparison of potential alternatives and the CfS and the broad and multi-interpretable scope of sustainability. It would increase complexity and therefore we cannot support this point.

The Netherlands adhere to the ultimate goal of Article 50, which is to reduce the use of plant protection products (PPP) containing one or more Candidates for Substitution (CfS) by replacing these products with non-chemical measures or alternative PPP that present a lower risk for humans, animals and the environment. Since its introduction in 2015, the Netherlands have assessed approximately 40 cases to which CA was applicable. While significant time and effort has gone into the assessment, the PPP was substituted in none of these cases.

The main issue is therefore not with the goal of CA, but with the means to achieve it. In our reaction to the Member State Competent Authority Survey on CA issued by COM in 2021, we suggested several potential solutions for making CA more efficient and effective, such as a tool for quantitative comparison and a harmonised database of alternative measures. We look forward to hearing the Commission's ideas about these suggestions.

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Currently, NL is also working on amending the national procedures for the CA to increase its efficiency and effectiveness. We are still in the process of finetuning this approach, and we hope to inform the WG of its progress in an upcoming meeting.

You can find our specific feedback and textual suggestions in the comments below. Many thanks for the proposal and the work of processing our written comments. We look forward to the next WG meeting.

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Draft proposal for amendment

REGULATION (EC) No 1107/2009 – Annex IV

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REPRESENT THE VIEW OF THE COMMISION SERVICES

ORIGINAL

ANNEX IV

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Comparative assessment pursuant to Article 50

1. Conditions for comparative assessment

Where refusal or withdrawal of an authorisation of a plant protection product in favour of an alternative plant protection product or a non-chemical control or prevention method is considered, referred to as 'substitution', the alternative must, in the light of scientific and technical knowledge, show significantly lower risk to health or the environment. An assessment of the alternative shall be performed to demonstrate whether it can be used with similar effect on the target organism and without significant economic and practical disadvantages to the user or not.

Further conditions for refusal or withdrawal of an authorisation are as follows:

(a) substitution shall be applied only where other methods or the chemical diversity of the active substances is sufficient to minimise the occurrence of resistance in the target organism;

(b) substitution shall be applied only to plant protection products where their use presents a significantly higher level of risk to human health or the environment; and

(c) substitution shall be applied only after allowing for the possibility, where necessary, of acquiring experience from use in practice, where not already available.

2. Significant difference in risk

A significant difference in risk shall be identified on a case-by-case basis by the competent authorities. The properties of the active substance and the plant protection product, and the possibility of exposure of different population subgroups (professional or non-professional users, bystanders, workers, residents, specific vulnerable groups or consumers) directly or indirectly through food, feed, drinking water or the environment shall be taken into account. Other factors such as the stringency of imposed restrictions on use and prescribed personal protective equipment shall also be considered.

For the environment, if relevant, a factor of at least 10 for the toxicity/exposure ratio (TER) of different plant protection products is considered a significant difference in risk.

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(s). 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.

The comparative assessment shall take authorised minor uses into account.

PROPOSAL

ANNEX IV

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Comparative assessment pursuant to Article 50

1. Procedure for comparative assessment

In order to perform a comparative assessment, Member States shall request from the applicant who wishes to obtain or renew an authorisation for a plant protection product containing an active substance approved as candidate for substitution:

- an overview of other plant protection products authorised for the same use in that Member State and of non-chemical control or prevention methods; and
- an analysis following the principles in sections 2 to 4 below to demonstrate that the identified alternatives to the plant protection product for which the applicant is seeking authorisation are not sufficient to minimise occurrence of resistance, are not significantly safer for human or animal health or the environment, cannot be used with similar effect on crop systems or result in economic and practical disadvantages to the user.

Member States shall perform the comparative assessment on the basis of the information provided by the applicant and from their own sources to verify whether the applicant has identified all plant protection products authorised by them for the crop/pest combination(s) concerned by the application.

At each step of the comparative assessment as set out below, the consequences for minor uses of a refusal of the authorisation for some or all of the uses applied for shall be considered.

The outcome of the comparative assessment must be a substantiated reasoning for the granting of total or partial refusal of the authorisation applied for, taking into account whether:

- the chemical diversity of active substances in the other identified authorised plant protection products and non-chemical control or prevention methods is sufficient to minimise the occurrence of resistance of the target organism(s);
- the other identified authorised plant protection products or non-chemical control or prevention methods pose a significantly lower level of risk to human or animal health or to the environment;
- and the other identified authorised plant protection products or non-chemical control or prevention methods do not present significant economic or practical disadvantages.

2. Minimise the occurrence of resistance

For assessing whether the chemical diversity of the identified alternative authorised products is sufficient, Member States shall consider the mode of action against the target pest(s) of the active substances contained therein. Each strain of a micro-organism efficacious against a target pest shall be considered as a different mode of action.

At least three different and independent modes of action should remain available among the authorised plant protection products for the given crop/pest combinations, depending on the resistance risk associated. Special attention should be given to priority pests as defined pursuant Article 6(2) of Regulation (EU) 2016/2031 and listed in Commission delegated regulation (EU) 2019/1702, and for minor uses, for which more different and independent modes of action should remain available.

Broadly used alternative methods to chemical pesticides for plant protection and pest management, based on agronomic techniques such as those referred to in point 1 of Annex III to Directive

Commented [5.1.2.e]: *COM: Shall we add that MS must run a public consultation on the analysis so that other authorisation holders, or NGOs, academia or research institutes can provide further information, especially on the non-chemical alternatives?* To guarantee that the reasoning is sufficiently substained…

Commented [5.1.2.e]: NL believes that a public consultation at this stage will lead to a more complex procedure and is therefore counterproductive to the ambition of encouraging replacement. As a counter-proposal, NL proposes that the European Commission develops a public database in which (feasible and effective) alternative measures and products are collected and which can be used during the CA process by all MS. Such a public database is in line with the work of the COM and EFSA to collect alternatives and IPM best practices and can be complemented by alternative measures and products that are available nationally.

Commented [5.1.2.e]: NL: Needs elaboration to make clear that the MS authority will not only need to check the potential alternatives but also perform a comparative risk assessment.

Proposal to replace with:

"Member States shall review the information provided by the applicant and from their own sources to verify whether the applicant has identified all relevant alternative non-chemical measures and plant protection products authorised by them for the crop/pest combination(s)

Commented [5.1.2.e]: NL: This section must include that a substantiated reasoning is not only necessary for refusal, but for approval as well. Propose to replace by:

Commented [5.1.2.e]: NL: Please change to:

"non-chemical control or prevention methods and when relevant the chemical diversity of active substances in the

Commented [5.1.2.e]: NL: Replace with " identified alternative"

Commented [5.1.2.e]: NL: Replace with " identified alternative"

Commented [5.1.2.e]: NL: Reference to EPPO PP 1/271 (3) 'Guidance on efficacy aspects of comparative assessment' is missing. Stage B of this standard describes how comparability regarding the risk of developing resistance

Commented [5.1.2.e]: NL: This doesn't hold for all species of MO (e.g., Bt). Propose to remove this sentence in its entirety.

Commented [5.1.2.e]: NL: What is the basis for the number three here? And what is the difference between 'different' and 'independent' MoA?

Commented [5.1.2.e]: NL: Why more MOA for minor uses?

Commented [5.1.2.e]: NL: this text is unclear: are there also cases where less than three MoA suffice (or more specifically: what is the intention of the wording: 'depending on the resistance risk associated')? Also, why are more MoA

2009/128/EC or physical, mechanical or biological pest control methods or a combination of those, shall be considered sufficient to minimise occurrence of resistance.

If the identified alternatives are insufficient to minimise occurrence of resistance in the target organism(s) for some or all of the intended use(s) of the product for which authorisation is applied for, the comparative assessment can be terminated and the product authorised for the relevant uses.

3. Significant difference in risk

Member States shall consider the properties of the active substance and the plant protection product for which an application is submitted and those of the identified alternative active substances and authorised products, and for each of these the possibility of exposure. Other factors such as the stringency of imposed restrictions on use and prescribed risk mitigation measures shall also be considered.

For the environment, if relevant, a factor of at least 5 for the risks calculated with the relevant applicable guidance document for the different plant protection products is considered a significant difference in risk.

A more in-depth assessment of the trade-offs related to hazard, risk, possible risk mitigation measures that can be put in place and broader sustainability aspects may need to be performed to make an informed choice on the preferred alternative.

Broadly used alternative methods to chemical pesticides for plant protection and pest management, based on agronomic techniques such as those referred to in point 1 of Annex III to Directive 2009/128/EC or physical, mechanical or biological pest control methods or a combination of those, shall be considered as of significantly lower level of risk. .

If none of the identified alternative plant protection products or non-chemical control or prevention methods presents significantly lower level of risk, or those who do present a significant lower level of risk are insufficient to minimise occurrence of resistance as set out in point 2 for some or of the uses, the comparative assessment can be terminated and the product authorised for the relevant uses.

4. Significant practical or economic disadvantages

To determine whether the use of identified alternative authorised plant protection products or non-chemical control or prevention methods leads to a significant disadvantage compared to the product for which authorisation is applied for, Member States shall assess whether the alternatives from a practical or economic point of view cause a quantifiable major impairment of working practices or business leading to:

- Inability to maintain sufficient control of the potential damage in crop production (insufficient efficacy) or
- The control of the pest for the intended crops leads to significantly higher costs than for the product for which authorisation is applied for.

The assessment of the practical and economic disadvantages shall focus on the user level and not consider wider socio-economic impacts.

If some or all of the identified alternative plant protection products or non-chemical control or prevention methods resulting from the application of section 3 present significant economic or practical disadvantages compared to the product for which authorisation is applied for, or if those

Commented [5.1.2.e]: NL: What is the definition of biological pest control methods? Would a definition be needed in the PPPR?

Commented [5.1.2.e]: NL: Agree.

Commented [A15]: NL: What is the reasoning behind the change from 10 to 5?

Commented [5.1.2.e]: NL: Please clarify. Does this imply a full life-cycle analysis of the alternatives?

This would increase the time needed for the CA. Also, expertise outside the scope of the PPPR would be needed to perform such an assessment. We would not consider this to contribute to the simplification of the CA.

Commented [5.1.2.e]: NL: Agree.

Commented [5.1.2.e]: NL: So no risk assessment needed?

Commented [5.1.2.e]: NL: what is meant here with "some of the uses"?

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Commented [5.1.2.e]: NL: The assessment on significant practical or economic disadvantages takes place before the assessment on significant difference in risk. Maybe good to change the order here as well?

Commented [5.1.2.e]: NL: Reference to EPPO PP 1/271 (3) 'Guidance on efficacy aspects of comparative assessment' is missing. Stage D of this standard describes how practical and economic disadvantages can be assed.

Commented [5.1.2.e]: NL: This is unclear – 'on user level' might suggest that no single grower can have an economic or practical disadvantage. (Consider rephrasing – 'shall only take into consideration the disadvantages to the end users of the PPP')

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which do not present such disadvantages are insufficient to minimise occurrence of resistance as set out in section 2 for some or all of the uses, the product can be authorised for the relevant uses.

Commented [512e]: NL: Delete?