

Draft proposal for amendment

REGULATION (EC) No 1107/2009 – Annex IV

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ORIGINAL

ANNEX IV

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.

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PROPOSAL

ANNEX IV

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)

Commented [5.1.2.e (1)]: 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 substantiated...

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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 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.

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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 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.

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