# Evaluation Manual for the Authorisation of plant protection products according to Regulation (EC) No 1107/2009

## NL part

## Plant protection products

## Chapter 1 General Introduction and Generic Aspects

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**Board for the Authorisation of plant protection products and biocides**

# Chapter 1 General Introduction and Generic aspects

Category: Plant Protection Products

**GENERAL INTRODUCTION**

Substances that are approved under Regulation (EC) No 1107/2009 and were approved under Directive 91/414/EEC are included in Commission Implementing Regulation (EU) No 540/2011. The EU aspects, data requirements, zonal and interzonal approaches are described in the EU part.

The NL evaluation manual describes the procedures followed as Dutch specific aspects and Dutch specific agricultural conditions and practices. The Dutch specific aspects are related to the agricultural and environmental conditions specific for the NL.

Drift, groundwater and drinking water are considered as Dutch specific aspects related to specific Dutch environmental conditions. These should be addressed in national addenda.

Additionally, some Dutch agricultural conditions and practice are described in this chapter in the appendixes, together with the Dutch definition list application areas plant protection products (Definitielijst toepassingsgebieden gewasbeschermingsmiddelen, DTG) and list of definitions of terminology in the legal conditions (Definitielijst Termen Wettelijke ge Definitielijst Termen Wettelijke gebruiksvoorschriften, DTW).

The NL part of the evaluation manual describes, Dutch data requirement and the Dutch risk assessment approaches that are used for a national authorisation. Additionally, the generic part how the comparative assessment is conducted is described below for toxicology, residues, fate and behaviour and ecotoxicology.

## 1. COMPARATIVE ASSESSMENT NL APPROACH

In the evaluation manual EU part General Introduction the concept for candidates for substitution and the tiered approach of comparative assessment is described. Since the comparative assessment is NL approach because the plant protection product containing a candidate for substitution can be replaced with a national authorised products. Step 3 and step 4 the tired approach of comparative assessment are described in this part of the NL evaluation manual. How the scientific assessment for comparative assessment is conducted will be described for the different aspects, toxicology, residues and environment.

### Toxicology

The aspect Mammalian Toxicology requires a comparative assessment (CA) in the following cases:

- its AOEL is significantly lower than those of the majority of the approved active substances within groups of substances/use categories
- there are reasons for concern linked to the nature of the critical effects (such as developmental neurotoxic or -immunotoxic effects) which, in combination with the use/exposure patterns, amount to situations of use that could still cause concern, for example, high potential of risk to groundwater; even with very restrictive risk management measures (such as extensive personal protective equipment or very large buffer zones)
- it is or is to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as carcinogen category 1A or 1B, if the substance has not been excluded in accordance with the criteria laid down in point 3.6.3
- it is or is to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as toxic for reproduction category 1A or 1B if the substance has not been excluded in accordance with the criteria laid down in point 3.6.4
- if, on the basis of the assessment of Community or internationally agreed test guidelines or other available data and information, reviewed by the Authority, it is considered to have endocrine disrupting properties that may cause adverse effects in humans if the substance has not been excluded in accordance with the criteria laid down in point 3.6.5

Two separate approaches are applied, one for CfS which are based on intrinsic properties and the other when they are based on a significantly lower AOEL. When the product contains a CfS which is based on intrinsic properties (e.g. reproductive toxicity category 1) than the CA will be based on the intrinsic properties. For products containing a CfS based on a significantly lower AOEL than the CA will be based on a comparison of the risk assessment.

*Comparison based on intrinsic properties:*

For the comparison based on intrinsic properties an overview should be given on the intrinsic properties of the alternative formulation (Table 1). If one of the alternative formulations is not classified for reproductive toxicity, carcinogenicity and is not considered to be an endocrine disruptor than it will be concluded that the alternative formulation provides a lower risk.

**Table 1: Overview of the intrinsic properties of the alternative formulations:**

| Formulation | Classification | | |
|---|---|---|---|
| | Carcinogenic Y/N | Reproductive toxicity Y/N | Endocrine disruptor |
| Y | Y (H350/H351) | | |
| Z | | | |

Step b – conclusion:
Option 1: alternative formulation is available:
Unlike the Candidate for Substitution formulation X the alternative formulation(s) Y,Z are not classified for carcinogenicity, reproductive toxicity and does not contain an active substances which is considered to be an endocrine disruptor. Therefore, it is concluded that suitable alternative formulations are available which provide a lower risk. It should be specified for which crops from the GAP table listed in section 2.6 of part A of the dRR this applies.

Option 2: no alternative formulation is available:
No alternative formulation is available which is not classified for carcinogenicity, reproductive toxicity or does not contain an active substances which is considered to be an endocrine disruptor. Therefore, it is concluded that not suitable alternative formulation is available which provides a lower risk. It should be specified for which crops from the GAP table listed in section 2.6 of part A of the dRR this applies.

*Comparison for CfS based on significantly lower AOEL:*
For the risk assessment it should be evaluated if the identified alternatives from step 1 provide a lower risk. For the aspect Mammalian Toxicology is has been decided to use a factor of 10 difference to be able to conclude that there is a significantly lower risk. The factor 10 was based on a pilot study with a limited number of products. As more experience is gained with comparative assessments this value may change in the future.

The comparison will be carried out for the operator, bystander, resident and worker. One of these exposure groups should give a 10 fold difference. If this is the case then at the same time it should not give a higher risk for the other exposure groups.

Step a:
Provide a short overview of the risk assessment of the product with the CfS (both with and without PPE if PPE is required). Full details are not required as they are provided in Part B.6 of the dRR. Only the outcome should be given.

**Table 2: Overview of the risk assessment of product X**

| **Crops** | **Application type** | **% AOEL** | | | | |
|---|---|---|---|---|---|---|
| | | **Operator** | | **Resident** | **Worker** | |
| | | **- PPE** | **+PPE** | **- PPE** | **- PPE** | **+PPE** |
| X | Tractor mounted low crops | | | | | |
| | Tractor mounted high crops | | | | | |
| | Handheld low crops | | | | | |
| | Handheld high crops | | | | | |
| | Greenhouse | | | | | |

Step b
Give an overview of the risk assessment of the alternative formulations. There can be different alternatives available for each crop. Therefore, it should be indicated for which crop the assessment is relevant.

Alternative products also containing a CfS substance are not included in the risk assessment since it was found in the pilot study that they are unlikely to provide a lower significant risk.

Use the Risk Index/% AOEL which was calculated for the original authorization of the alternative product. Put an overview of the Risk Index of the alternative formulation in Table 3.

Detailed information on the original authorization of the alternative formulations can be found in the authorization registry on our website.

**Table 3: Overview of the risk assessment for the alternative products based on the original authorization**

| Crops | Application type | Same exposure model used as the assessment for CfS substance (Y/N) | Risk index | | | | | | Remarks (e.g. if application rate in risk envelope for assessment was higher than for the specific crop) |
|---|---|---|---|---|---|---|---|---|---|
| | | | Toepasser | | Omstander | Omwonenden | Werker | | |
| | | | - PPE | +PPE | - PPE | - PPE | - PPE | +PPE | |
| **Formulation X** | | | | | | | | | |
| | Tractor mounted low crops | | | | | | | | |
| | Tractor mounted high crops | | | | | | | | |
| | Handheld low crops | | | | | | | | |
| | Handheld high crops | | | | | | | | |
| **Formulation Y** | | | | | | | | | |
| | Tractor mounted low crops | | | | | | | | |
| | Tractor mounted high crops | | | | | | | | |
| | Handheld low crops | | | | | | | | |
| | Handheld high crops | | | | | | | | |

Since January 1st 2016 the new EFSA Opex Guidance is used which in most cases will not have been applied for the alternative formulations. This means that if a significant difference in risk assessment is found this could be due to a difference in exposure model and not due to a difference in the risk as such. It should be made clear that the significant difference in risk is not due to the exposure models before it can be concluded that the proposed alternative is indeed an appropriate alternative. Due to time constraints it is not possible to re-evaluate each alternative formulation. A pragmatic approach is to select the formulation(s) which gives the lowest risk index based on the old exposure models and to carry out an exposure assessment with the EFSA Opex model for this formulation. If a NL-AOEL was used for the alternative method for the original assessment this should not be applied in the reassessment. The formulation(s) which gives the lowest risk index with the EU-AOEL should be selected to reassess with the EFSA Opex model.

If a re-evaluation is required the following table can be used:

**Table 4: Overview of the risk assessment for the alternative products based on EFSA OPEX**

| Crops | Application type | Risk index | | | | |
|---|---|---|---|---|---|---|
| | | Toepasser | | Omwonenden | Werker | |
| | | -PPE | +PPE | - PPE | -PPE | +PPE |
| **Formulation X** | | | | | | |
| | Tractor mounted low crops | | | | | |
| | Tractor mounted high crops | | | | | |
| | Handheld low crops | | | | | |
| | Handheld high crops | | | | | |

Step c – conclusion

Option 1: There is an alternative with a significantly lower risk (factor 10) than the CfS product. It should be specified for which crops from the GAP table listed in section 2.6 of part A of the dRR this applies.

Option 2: There are no alternatives with a significantly lower risk (factor 10) than the CfS product. It should be specified for which crops from the GAP table listed in section 2.6 of part A of the dRR this applies.

**Residues**

The aspect Residues only needs to conduct a comparative assessment (CA) when the active substance is indicated as a CfS for the first criteria, i.e. its ADI, ARfD or AOEL is significantly lower than those of the majority of the approved active substances within groups of substances/use categories. For all other criteria, at this stage, no assessment is required for the aspect Residues.

The comparison needs to be conducted regarding the percentage usage of the ADI or the percentage usage of the ARfD for every requested crop separately. If the substance is considered as a CfS for its low ADI, then the comparison will be conducted for the percentage usage of the ADI. If the substance is considered as a CfS for its low ARfD, then the comparison concerns the percentage usage of the ARfD.

The percentages should be compared between the requested product containing the CfS and the possible alternatives. For comparison, the percentages ADI or ARfD will be calculated in the same way as EFSA calculates them, i.e. by using STMRs and HRs. No comparison will be made regarding the percentage usage of the ADI and ARfD for rotational crops and animal products.

*Step a*

Provide a short overview of the risk assessment of the product with the CfS. Full details are not required as they are provided in Part B.7 of the dRR. Only the outcome should be given here. No CA is required for minor crops.

**Table 5: Overview of the risk assessment of product X**

| Crops | % ADI | % ARfD |
|---|---|---|
| | | |
| | | |
| | | |

| | | |
|---|---|---|
| | | |

*Step b*
Give an overview of the risk assessment of the alternative formulations. There can be different alternatives available for each crop. The risk assessment for the alternative products is available from the published evaluation of the latest product approval.

If there is no ARfD allocated for an alternative formulation, the alternative product is likely to provide a lower acute risk (>factor of 10) than the formulation containing the CfS.

Alternative products also containing a CfS substance are not included in the risk assessment since it was found in the pilot that they are unlikely to provide a lower significant risk.

**Table 6: Overview of the risk assessment for the alternative products**

| | **Product y** | | **Product …** | | **Product …** | | **Product …** | | **Product …** | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Crops** | **% ADI** | **% ARfD** | **% ADI** | **% ARfD** | **% ADI** | **% ARfD** | **% ADI** | **% ARfD** | **% ADI** | **% ARfD** |
| | | | | | | | | | | |
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| | | | | | | | | | | |
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*Step c – conclusion*
For the aspect Residues it has been decided to use a factor of 10 difference to be able to conclude that there is a significantly lower risk. As more experience is gained with CA this value may change in the future.

The percentages in Table 6 should be compared with the percentage of the requested product in Table 5. Cells containing percentages in table 2 which are (more than) 10 times lower than the corresponding percentage in Table 5 can be marked green to give a clear overview. If an alternative formulation has a 10 times lower percentage usage of the ADI, then the % usage of the ARfD will be checked as well (and the other way around). When a 10 times higher percentage usage of the ARfD is observed (or the other way around) than the product containing the CfS, the alternative is not considered as an acceptable alternative.

Option 1: There is an alternative with a significantly lower risk (factor 10) than the CfS product. It should be specified for which crops this applies. More alternatives can be possible for each crop. The following text can be used for the conclusion.

Product x contains active substance which is approved as a candidate for substitution because it has a low ADI/ ARfD. As a conclusion of the comparative assessment, the use on crops is/are suitable for substitution because product is a significant safer alternative.

Option 2: There are no alternatives with a significantly lower risk (factor 10) than the CfS product. It should be specified for which crops this applies. The following text can be used for the conclusion.

Product x contains active substance which is approved as a candidate for substitution because it has a low ADI/ ARfD. As a conclusion of the comparative assessment the use on crops is not/are not suitable for substitution because there are no products with a significantly safer alternative.

## Environment

The aspects Environmental Fate and Behaviour and Ecotoxicology a comparative assessment (CA) is required in the following cases:

- It meets two of the criteria to be considered as a PBT substance.

For the risk assessment it should be evaluated if the identified alternative(s) provide a lower risk. Although a factor of 10 is used in the toxicological assessment to determine a lower risk, it is not possible to use this in the environmental fate and eco-toxicological risk assessments. The decision will instead be based upon weight of evidence and expert judgement.

The comparative assessment for fate and behaviour and ecotoxicology is performed per individual proposed use, as follows and consists of the following steps:

1. Alternatives that are (also) Candidates for Substitution are excluded;
2. ***How to compare persistence***: Calculate PEC and/or $PEC_{plateau}$ for the newly proposed use which is based on the Candidate for Substitution - perform a risk assessment with the calculated PECs and compare to existing risk assessments from alternative products;

**Comparison of soil organisms risk assessment for the active substance (CfS) and active substance(s) for the alternative existing plant protection products**

| Use | Substance | $NOEC_{corr}$ or $EC10_{corr}$ (mg/kg) | PIECsoil or PECplateau [mg a.s./kg] | TER | Trigger value |
|---|---|---|---|---|---|
| | CfS | | | | 5 |
| | Alternative 1 | | use X from existing r.a. | | 5 |
| | Alternative 2 | | use X from existing r.a. | | 5 |
| | Alternative 3 | | use X from existing r.a. | | 5 |

***How to compare bioaccumulation***: Check whether secondary poisoning and/or food chain biomagnification are likely in the existing alternative - If neither secondary poisoning nor food chain biomagnification will occur for the alternative, the alternative should be assessed further to determine whether it is a fully acceptable alternative;

***How to compare toxicity***: Check whether the alternative shows a lower risk to aquatic organisms (including risk reducing measures where appropriate) - if there is a lower risk to aquatic organisms from the alternative it should be assessed further to determine whether it is a fully acceptable alternative;

**Comparison of aquatic organisms risk assessment for the active substance (CfS) and active substance(s) for the alternative existing plant protection products**

| **Group** | | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | **Sed. dwell. prolonged** | **Higher-tier information** | | **group** | | **Sed. dwell. prolonged** |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchn. subcapitata*** | ***Chironomus riparius*** | ***Species sp.*** | | ***Species sp.*** | | ***Chironomus riparius*** |
| **Endpoint (µg/L)** | | $LC_{50}$ xxx | NOEC xxx | $EC_{50}$ xxx | NOEC xxx | $E_rC_{50}/E_YC_{50}$ xxx | NOEC xxx | xxx xxx | | xxx xxx | | NOEC xxx |
| **AF** | | 100 | 10 | 100 | 10 | 10 | 10 | xxx | | xxx | | 10 |
| **RAC (µg/L)** | | xxx | xxx | xxx | xxx | xxx | xxx | xxx | | xxx | | xxx |
| **Worst – case use** | **$PEC_{gl-max}$ (µg/L)** | | | | | | | | **xx-d $PEC_{twa}$ (µg/L)** | | **$PEC_{gl-max}$ (µg/kg)** | |
| **CfS** | | | | | | | | | | | | |

| **Group** | | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | **Sed. dwell. prolonged** | **Higher-tier information** | | **group** | | **Sed. dwell. prolonged** |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Ex. potato | | | | | | | | | | | | |
| **Alternative 1** | | | | | | | | | | | | |
| | | | | | | | | | | | | |
| Alternative 2 | | | | | | | | | | | | |
| | | | | | | | | | | | | |
| Alternative 3 | | | | | | | | | | | | |
| | | | | | | | | | | | | |
| Alternative 4 | | | | | | | | | | | | |
| | | | | | | | | | | | | |

3. Current Guidances and Evaluation Manual should be used in all assessments (for viable alternatives).

Furthermore it is of importance that the alternative plant protection product shows an overall lower or similar risk on all aspects (it is not desirable that an improvement on one part of the risk assessment results in a deterioration in another part of the risk assessment (but this is an overall decision).

As the process of comparative assessment is still under development, this method may be updated once more experience is gained in assessing alternatives.