COMPARATIVE ASSESSMENT AND SUBSTITUTION OF PLANT PROTECTION PRODUCTS IN SPAIN

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This document provides guidance for CA, in the authorization process of a PPP which contains an active substance that has been identified as a candidate for substitution (Regulation (EC) nº 1107/2009, art. 24 and 50).

It is based on the guidance document SANCO/11507/2013 (rev. 12), EPPO standard PP1/271 as well as guidance elaborated by other MSs.
**Step approach**

SANCO/11507/2013 (rev. 12), EPPO PP1/271 (2)

**Preliminary step**
- **General information** - candidate product, CfS active substance, type of application...
- Derogation **Art. 50(3)** -> No CA

**Agronomic aspects** (EPPO PP1/271):
- Define the uses of the candidate product- **major uses** to be considered in the CA.
- Identification of available **chemical** and **non-chemical alternatives** for each use.
- Assessing comparability regarding **efficacy** (aspects of efficacy and crop safety).
- Assessing **risk of resistance developing**.
- Consideration of **economic and practical disadvantages**.
- Assessing the impact on **minor uses** if the product is substituted for major uses.

**Risk for health and environment**
Identification and Comparability of **risk for health and environment**

**Steps 1-9**

**Step 10**

**STOP CA**
**NO SUBSTITUTION**

**SUBSTITUTION**

**Guidance for the CA in Spain**

**Preliminary step**
The outcome of the comparative assessments performed by Spain

- 23 CAs of candidate products (Label extensions, New Products, and renewals):
  - 14 CAs - proposed for Authorisation:
    The conclusion of the CA is not suitable for substitution because (1 or several):
    - **Resistance management** - There is **not enough chemical diversity**, less than four modes of action (< 4 MoA) available for each of the uses.
    - **Substitution of major uses** of the product would have a negative impact on minor uses.
    - **Loss of specific pest control tools**.
    - **Non-chemical preventive or control methods cannot supplant chemical control**.

- 9 CAs - Pending:
  - Additional **information on health and environmental risk assessment**.
  - Additional MoAs were found so **CA is to be continued**.
  - Disagreements with using the derogation in **Art 50 (3)**.
  - Cat 4 studies. (RR)
  - RR.

• **Substitution** - No yet
• **Change in the label** - No Yet
**Preliminary step**

- **General information:**
  zRMS, Trade name of the Product, National registration number, Formulation, Preparation type (EU Code), Type of application (Art. 43, new PPP and extension of use), Candidate for Substitution (active substance name), Reason(s) for approval as candidate for substitution.

- **Derogation according to Art. 50 (3):**

<table>
<thead>
<tr>
<th>Do you wish to use the derogation stated in Article 50(3) to gain experience with this product?</th>
</tr>
</thead>
<tbody>
<tr>
<td>YES    □ Stop CA (*). No further information necessary.</td>
</tr>
<tr>
<td>*Explain why practical experience with the active is necessary.</td>
</tr>
<tr>
<td>NO     □ Go to Step 1</td>
</tr>
</tbody>
</table>

By way of derogation, a candidate PPP shall be authorised without CA in cases where it is necessary to **acquire experience** first through using that product in practice. Such authorisations shall be granted once for a period **not exceeding five years**.

* **Disagreement with using Art 50 (3).** E.g. case: The candidate product and similar PPPs have been registered in Italy around 10 years ago. Due to comparable agroclimatic conditions, it would not be necessary to acquire experience first and CA should be made.
Agronomic aspects

**Step 1 Application details to be considered in the comparative assessment:**

<table>
<thead>
<tr>
<th>Label extension</th>
<th>□ → Go to Step 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Art. 43 (Renewals)</td>
<td>□ → Go to Step 3 (*) Identification of claimed uses</td>
</tr>
<tr>
<td>New product</td>
<td>□ → Go to Step 3 (*) Identification of claimed uses</td>
</tr>
</tbody>
</table>

**Step 2 Is at least one major use included in the label extension?**

| YES □ → (*) Identification of claimed uses |
| NO □ → Stop CA. No further information necessary. |

All uses are to be considered at renewal and new products, but only the proposed new uses will be considered in applications of label extension.

(*) Identification of claimed uses (crop/target)

<table>
<thead>
<tr>
<th>Crop (EPPO code)</th>
<th>Pest name (EPPO code)</th>
<th>Major/minor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crop 1 ....</td>
<td>Target 1 ....</td>
<td>Minor □ → Stop CA for this use</td>
</tr>
</tbody>
</table>

Major □ → Go to Step 3

**Step 3 Major uses to be considered in the CA**

- If the application contains only minor uses, a CA is not required.
- If major uses are included in the application, the CA will focus on these.
- If the major uses under consideration were to be replaced by an alternative then it is permitted to explain the consequences on minor uses (see step 6).
**Agronomic aspects**

Step 4 Alternatives to be considered in the comparative assessment:

Do chemical or non-chemical alternatives exist for controlling the target pest (or regulating plant growth) in the target uses?

<table>
<thead>
<tr>
<th>Crop 1 * Target1</th>
<th>Chemical □</th>
<th>Chemical □ → Go to table a) and provide details. Then, go to step 5.</th>
<th>Non-Chemical □</th>
<th>Non-Chemical □ → Go to table a) and provide details. Then, go to step 5.</th>
<th>Non-alternative □</th>
<th>Non-alternative □ → Stop CA for this use.</th>
</tr>
</thead>
</table>

*Table of alternative uses*

<table>
<thead>
<tr>
<th>Chemical alternatives</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Crop</strong></td>
</tr>
<tr>
<td>---------------------</td>
</tr>
<tr>
<td>Crop 1</td>
</tr>
</tbody>
</table>

Consideration of alternative control measures in a comparative assessment is required for major uses of the product. "If there are many uses, focus specifically on the uses where the diversity of alternatives is not sufficient to reduce the emergence of resistance."
Agronomic aspects

Alternative chemical products per use:

• Relevant information on alternative chemical products is available in National Register of PPPs (MAPA, Ministry of Agriculture, Fish and Food database)


• Information about the chemical MoA of the a.s of the alternative product can be found in information published by the relevant resistance action committees and groups:

HRAC https://www.hracglobal.com/
IRAC www.irac-online.org/
FRAC www.frac.info/
Agronomic aspects

Details of the non-chemical alternatives per use:

• A **non-chemical method** (or methods), including a preventative method (e.g. a resistant variety), **can only be considered as a potential alternative** when it is a practical method which is already used by growers for the same target pest, or when the method has been assessed by research and shown to be suitable for use in the particular environmental and agronomic situation over a number of years.

• Relevant information on **Non-chemical alternatives are available in Integrated Pest Management national guidelines**. For a wide range of crops.  

  IPM national guidelines in grapevine, olive, citrus, stone fruit, pome fruit, cereals, maize, rice, potato, cotton, sunflower, beet, brassicas, lettuce, ...

• If information is not available in **IPM guidelines**, **regional guidelines** and **scientific articles** are also consulted.
**Agronomic aspects**

Information regarding:
- Major pests
- Monitoring and risk estimate
- Preventive and cultural control
- Threshold/intervention timing
- Non-chemical Alternatives
- Chemical Alternatives (National Register of PPP)

<table>
<thead>
<tr>
<th>Plagas principales</th>
<th>Seguimiento y estimación del riesgo para el cultivo</th>
<th>Medidas de prevención y/o culturales</th>
<th>Umbral/Momento de intervención</th>
<th>Medidas alternativas al control químico (*)</th>
<th>Medios químicos</th>
</tr>
</thead>
</table>
| Mosca del olivo (Bactrocera oleae) | Muestreo de fruto  
Se realizará en 20 árboles por parcela de muestreo  
Olivar de almazara | A la hora de realizar una nueva plantación, tener en cuenta que las variedades más sensibles son “oordal” y “manzanilla” | ACEITUNA DE ALMAZARA  
Para tratamientos de pareja  
Primer tratamiento cuando se supere alguno de los siguientes umbrales:  
- 1 adultos/trampa McPhail y día  
- 5 adultos/trampa comitóptera y se observe 1% de aceituna picada | Medios biotecnológicos  
Trampa masiva de atracción y muerte  
En lugares con alta incidencia | Se podrán utilizar los productos fitosanitarios autorizados en el Registro |

* Difficulty in checking the efficacy level reached by non-chemical alternatives (solo or in combination) or as a part of a programme of Integrated Pest Management (with alternative PPP).
**Agronomic aspects**

**Step 5 Diversity of alternative chemical substitutes to support resistance management practices:**

<table>
<thead>
<tr>
<th>Is the number of available modes of action equal or higher than 4?:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crop 1 * Target 1</td>
</tr>
<tr>
<td>YES □ → Go to step 6</td>
</tr>
<tr>
<td>NO □ → Stop CA for this use.</td>
</tr>
</tbody>
</table>

Information about the current situation of resistances for each use. Especially, information published by the relevant resistance action committees and groups (HRAC, IRAC and FRAC) is considered. Other published sources of information such as specific factsheets and scientific data can be also consulted.

For each use considered, specify how many different modes of action are available (see step 4).

EPPO standard PP1/271 (2) requires at least four modes of action to manage a high resistance risk. Therefore, where equal or higher than 4 MoAs are available, is considered the chemical diversity sufficient to minimize the occurrence of resistance.

If < 4 MoAs - substitution will not be appropriate.
Step 6 Consequences for the minor uses if the product in question is substituted for the major uses subject to the comparative assessment:

It is permitted to explain the consequences on minor uses if the major uses under consideration were to be replaced by an alternative.

Commercial information can be used to justify the consequences on minor uses.

* We assess the information provided by the applicant and check other alternatives on these minor uses. Commercial aspects can be included. However, no source of information is available. Difficulty to check this information.
**Agronomic aspects**

**Step 7 Assessing comparability regarding effectiveness:**

Identify any distinctive assets of the candidate PPP which are absent in the alternatives and can lead to higher or more consistent/sustainable control of the pest.

<table>
<thead>
<tr>
<th>Crop 1</th>
<th>NO □ → Go to Step 8</th>
<th>YES □ → Stop CA (*). No further information necessary.</th>
</tr>
</thead>
</table>

Distinctive assets of the candidate product can be: **restrictions** on the product in terms of **time of application**, effects on **quality or yield**, **phytotoxic effects on adjacent crops**, effects on succeeding crops, **propagating material effects** or effects on **transformation processes**.

* Difficulty for comparison with alternatives in each aspect regarding effectiveness such as the effects on yield, phytotoxic effects on adjacent crops, effects on succeeding crops, propagating material effects or effects on transformation processes.
Is the product an integral component of an established IPM strategy in Spain?

<table>
<thead>
<tr>
<th>Cultivo 1</th>
<th>NO □ → Go to Step 9</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>SI □ → Stop CA (*)</td>
</tr>
</tbody>
</table>

(*) Relevant information/Justification:

Substitution of a candidate product by an alternative should not lead to disruption of established IPM systems, prohibit establishment of new IPM systems or have a negative impact on organisms beneficial to crop protection for which there are no possibilities for acceptable mitigation measures.

* It is considered that non-chemical alternatives for an use in a specific situation is usually part of a programme in combination with chemical PPP. However, the use of a specific PPP containing a CfS active substance, as part of IPM is not reflected in these guidelines.
Step 9 Consideration of economic and practical disadvantages of alternatives for the user:

Significant disadvantages are defined as ‘quantifiable impairment of working practices or business activity leading to an inability to maintain sufficient control of the target organism’.

Information that might provide useful evidence includes the need for and availability of specialist application equipment or techniques for some alternative products where these would result in such a disadvantage, the availability of necessary infrastructure such as specialist storage facilities, restrictions on flexibility in the timing of treatments to respond to environmental and other conditions. Applicant might also hold specific commercial information useful in addressing this consideration that would support each case.

* No reliable source to confirm information provided by the applicant is available (regional plant health information, fact sheet, applicant’s internet website, National Register of PPP… can be consulted). Economic aspects are difficult to assess. This information is not adequately checked.
### Risk for health and environment

**Step 10** Comparability of risk for health and environment, and identification of the alternatives that are likely to provide significant safer options for pest control:

**Hazard classification**

<table>
<thead>
<tr>
<th>Product</th>
<th>Human health classification</th>
<th>Environmental classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product 1</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Risk mitigation measures**

| Product 1 | Human health mitigations | Environmental mitigation |

Are there any alternative products that require significantly less risk mitigation measures?

YES □ → Go to Step 11
NO □ → Stop CA. No further information necessary.

Risk for health and environment are assessed by experts in these matters.

**Step 11** If this step is reached, this application may require a specialist comparative assessment
Any other relevant information to avoid withdrawal of the authorization not considered in previous steps
The most significant knowledge gaps

- Effectiveness of non-chemical alternatives is not always well established and quantified - Mostly, these alternatives should be applied together with conventional PPPs. Actually, in the majority of the cases, there are not optimum alternatives to conventional products due to low efficacy, poor knowledge, practical disadvantages..., etc.

- Management Resistance - If CA is stopped due to < 4 MoAs for a particular use but additional MoAs (alternative PPPs) for that use are found and no further information to continue CA is provided.

- Reliable information to assess/check practical and economical aspects.
Thank you for your attention

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