

COMPARATIVE ASSESSMENT AND SUBSTITUTION OF PLANT PROTECTION PRODUCTS IN SPAIN

Elena Gutiérrez Martín

Unit of Plant Protection Products (UPF-DTEVPP).

National Institute for Agricultural and Food Research and
Technology (INIA), Madrid. Spain.



***EPPO Workshop on Comparative
Assessment
Lisbon, 2018-10-24/25***

Guidance for the Comparative Assessment and Substitution of Plant Protection Products in Spain



<https://www.mapa.gob.es/agricultura/pags/fitos/registro/fichas/pdf/Guía+complementaria+de+evaluación+comparativa+en+España.pdf>

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) n° 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)

Guidance for the
CA in Spain

Preliminary step

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

Preliminary
step

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.

Steps 1-9

STOP CA
NO SUBSTITUTION

Risk for health and environment

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

Step 10

SUBSTITUTION



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):**

Do you wish to use the derogation stated in Article 50(3) to gain experience with this product?

YES Stop CA (*). No further information necessary.

*Explain why practical experience with the active is necessary.

NO Go to Step 1

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:

Label extension Art. 43 (Renewals) New product	<input type="checkbox"/> → Go to Step 2 <input type="checkbox"/> → Go to Step 3 (*) Identification of claimed uses <input type="checkbox"/> → Go to Step 3 (*) Identification of claimed uses
<u>Step 2</u> Is at least one major use included in the label extension?	YES <input type="checkbox"/> → (*) Identification of claimed uses NO <input type="checkbox"/> → 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)*

Crop (EPPO code)	Pest name (EPPO code)	Major/minor
Crop 1	Target 1 ...	Minor <input type="checkbox"/> → Stop CA for this use Major <input type="checkbox"/> → Go to Step 3 <i>Step 3 Major uses to be considered in the CA</i>

- 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?	
Crop 1 * Target1	Chemical ☐ → Go to table a) and provide details. Then, go to step 5. Non-Chemical ☐ → Go to table a) and provide details. Then, go to step 5. Non-alternative ☐ → Stop CA for this use.

a) Table of alternative uses

Crop	Target	Chemical alternatives			Non-chemical alternatives
		Product	Active Substance (s)	Mode of action (s)	
Crop 1	Target 1	Product 1	a.s 1	MoA 1
		

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)

<https://www.mapa.gob.es/es/agricultura/temas/sanidad-vegetal/productos-fitosanitarios/registro/menu.asp>



A screenshot of the 'Registro de Productos Fitosanitarios' website. The page title is 'Registro de Productos Fitosanitarios'. Below the title, there is a section titled 'Productos fitosanitarios' with a list of menu items: 'Consultas por nº registro y/o nombre', 'Consultas por sustancia activa', 'Consultas por plagas', 'Consultas por aplicación/plagas', 'Otras denominaciones comunes', 'Importaciones paralelas', and 'Listado de Productos Autorizados (Excel)'. Each item is preceded by a small icon representing a document or list.

- 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/>

International Survey of Herbicide Resistant Weeds www.weedscience.org/

IRAC www.irc-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. <https://www.mapa.gob.es/es/agricultura/temas/sanidad-vegetal/productos-fitosanitarios/guias-gestion-plagas/>



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

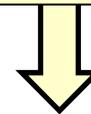
GUÍA DE GESTIÓN INTEGRADA DE PLAGAS OLIVAR



e.g. IPM national guideline in olive crops

Information regarding:

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



Plagas principales	Seguimiento y estimación del riesgo para el cultivo	Medidas de prevención y/o culturales	Umbral/Momento de intervención	Medidas alternativas al control químico (*)	Medios químicos
Mosca del olivo (<i>Bactrocera oleae</i>)	<i>Muestreo de fruto</i> 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 "cordal", "manzanilla"	ACEITUNA DE ALMAZARA <i>Para tratamientos de parcheo</i> Primer tratamiento cuando se supere alguno de los siguientes umbrales: - 1 adultos/trampa McPhail y día y se observe 1% de aceituna picada - 5 adultos/trampa cromotrópica/día y se observe 1% de aceituna picada	Medios biotecnológicos Trampeo masivo de atracción y muerte En lugares con alta	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:

Is the number of available modes of action equal or higher than 4?:

Crop 1 * Target 1

YES → Go to step 6

NO → Stop CA for this use.

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.



Agronomic aspects

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.

Crop 1	NO <input type="checkbox"/> → Go to Step 8 YES <input type="checkbox"/> → Stop CA (*).No further information necessary. (*) Relevant information/Justification:
--------	--

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.**



Agronomic aspects

Step 8 Assessing necessity in Integrated Pest Management Systems:

Is the product an integral component of an established IPM strategy in Spain?

Cultivo 1

NO → Go to Step 9

SI → Stop CA (*). No further information necessary.

(*) 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.**



Agronomic aspects

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

Product	Human health classification	Environmental classification
Product 1		

Risk mitigation measures

Product	Human health mitigations	Environmental mitigation
Product 1		

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

Elena Gutiérrez Martín.

UPF-DTEVPF.

INIA. Madrid. Spain.



*EPPO Workshop on Comparative
Assessment
Lisbon, 2018-10-24/25*