



Comparative Assessment: Industry Experience to date

Beth Hall

ECPA, Efficacy Expert Group chair 2018

What is Comparative Assessment

(GD SANCO/11507/2013 rev.6)



- **Replacement of a product**, which contains a **candidate for substitution** by methods and products of plant protection of lesser concern in order to **benefit the protection of human or animal health and the environment while minimising the economic and practical disadvantages for agriculture**



Factors relevant to Comparative Assessment:

Article 50 (1) of Regulation (EC) 1107/2009



Member State shall not authorise the respective PPP or restrict its use in the following cases:

- (a) For the intended uses in the application there are **chemical or non-chemical control or preventive methods available which are significantly safer** for health or animal health or the environment,
- (b) The **substitution with chemical, non-chemical or preventive method** would not present significant **economic or practical disadvantages.**



Factors relevant to Comparative Assessment:

Article 50 (1) of Regulation (EC) 1107/2009



- (c) The **chemical diversity** of active substances, where relevant, or other available methods for plant protection are adequate to **minimise the occurrence of the resistance** in the target organisms
- (d) **The impact on minor use** authorisations has been taken into consideration



Product Evaluation Candidates for Substitution



77 ASs listed as candidates for substitution

- Application date from August 2015

Additional ASs likely to be included after review

- Based on criteria in Annex II, point 4 :
 - Significantly lower ADI, ARfD or AOEL
 - 2 of 3 PBT properties
 - Remaining concerns
 - Significant proportion of inactive isomer(s)
 - Approved by derogation to cut-off(s)

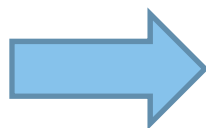


Number of AS lost in EU28 in last 18 years

(IPOL | Policy Department for Economic, Scientific and Quality of Life Policies)



2000 >900 AS



2008 = 425 AS



**2018 = 352 AS
(including 75 biocontrol)**

Since 2011:

- **Applications for approval of 22 new ASs**, of which **12 have been approved**, 2 not approved and **8 are pending** a decision on approval.
- **Applications for the renewal of 148 ASs**, of which **32 have been approved**, 8 not approved, 20 withdrawn and **88 are still pending** a decision on renewal of approval.
- **Candidates for Substitution** have undergone the same stringent evaluation and have been approved for use in the EU

Experience to date: CA Submissions made.

- ▶ Limited experience of the process end to end
- ▶ submissions made at New product & PR timing:
- ▶ Example from one company:

Member States involved	14
Number of CA submission	101
Number of CA outcomes	12
Number of Product (or use) losses	0



Comparative Assessment

Experience to date - Guidance



Across the EU28 we see a range of situations:

Member states either:

 **Follow EPPO Standard PP1/271(2)**

 **National Guidance based on EPPO standard**

- Alternative chemical / non chemical solutions,
- Derogation
- Number of available MoA
- Minor uses

All covered but with different priorities

 **No Experience to date**

- Process and guidance in development

Comparative Assessment

Experience to Date



- ▶ Most MS provide clear templates for applicants to present their benefit case.
- ▶ Some MS conduct the Comparative Assessment without requirement of applicant input but will allow consultation during the process.
- ▶ Example where MS conduct CA with consideration of Efficacy in parallel with analysis by Tox, Ecotox ,E-fate.



Variability in process

Timing of CA submission.

Process - MS require the National docs at point of country submission (either ZRMS or CMS)

- But some CMS are requiring the national document at the time of zRMS submission.

Derogation (5 year experience)

- Number of derogations have been granted but no experience of what to do next? What is the regulatory process to follow?
- Some MS allow derogation where a known AS is used on a New crop for first time, other MS only allow for New AS.

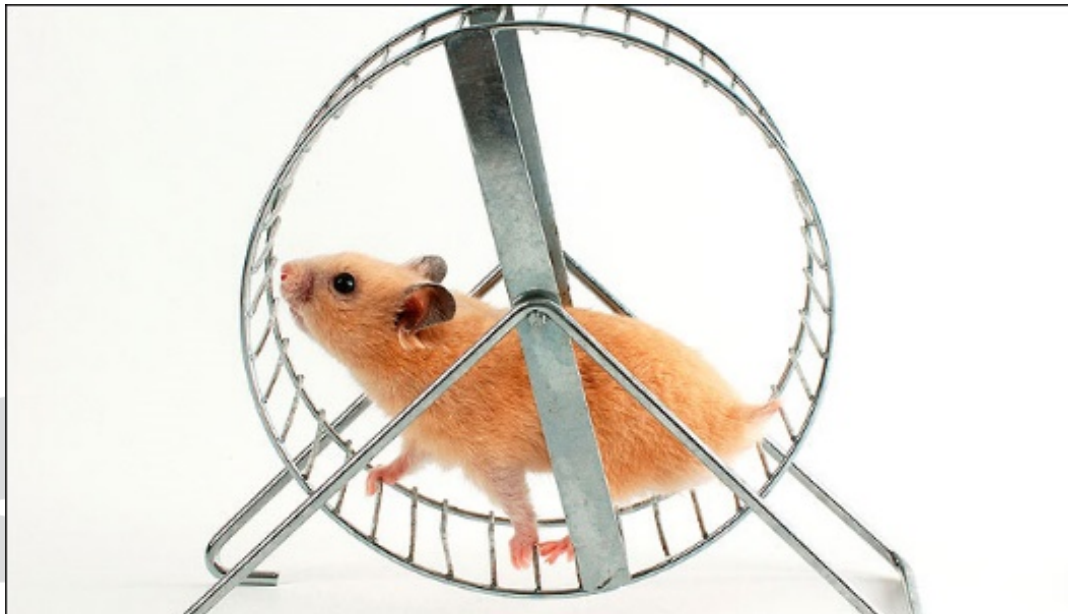
Visibility of CA outcome

- Made public in some MS (UK, NL, DK, FI, SE, FR)
- Other MS report not accessible.

Process Challenge:

Example product (2 way mix of know AS) :

- New product submission
- 2 years later PR driven by AS1
- 3 year later the PR driven by AS2
- Label Extension - addition of new use
- in 5-6 years up to 4 CA benefit cases are submitted for the same product!
- Consider fast track approach when PPP already reviewed?



Industry Experience: EPPO Guidance



- Step-wise pragmatic approach is appreciated
- Key biological / agronomic factors considered

Bulletin OEPP/EPPO Bulletin (2015) **45** (3), 388-391

ISSN 0250-8052. DOI: 10.1111/epp.12247

European and Mediterranean Plant Protection Organization
Organisation Européenne et Méditerranéenne pour la Protection des Plantes

PP 1/271 (2)

Efficacy evaluation of plant protection products
Evaluation biologique des produits phytosanitaires

PP 1/271 (2) Guidance on comparative assessment

Specific scope

This Standard provides guidance for comparative assessment (CA) to determine whether the substitution of a plant protection product (PPP) is appropriate in view of agronomic considerations. However, this Standard does not address comparative safety from the human and environmental perspective. It covers comparison with chemical and non-chemical pest control alternatives. The Standard provides a scheme to support decision-making. Expert judg-

ment is required in answering the questions (which may include the need to seek specialist advice).

Specific approval and amendment

First approved in 2011-09.

Minor revision approved in 2015-09 (to harmonize requirements with the DG SANCO 11507/2013)¹.



Comparing Product with Alternative Chemical and Non chemical solutions;



Challenging as difficult to objectively compare efficacy without data.

- Applicants can only describe the benefits of their product
- Inconsistency in pest terminology on labels

Comparing with products which contain CfS AS.

- Some MS do not allow this.



Non Chemical Alternatives

- Difficult to find details on non-chemical methodologies
- Little information about the economic viability of non chemical alternatives



Non Chemical control methods



Heavily Reliant on Defra report as source of info

ADAS

Non-chemical pest control methods:

A review of the literature to establish their efficacy and safety to workers, to inform the process of comparative assessment required by new pesticide legislation.

Defra Project Code: PS2809/348656



Date
24th Jan 2013

Submitted to:
Sally Wood

Report Authors :
Jonathan Blake, Tim O'Neill, Peter Gladders,
Mike Lole, Jessica Sparkes, Jude Bennison,
Gemma Gillies, and Sarah Cook.



Consideration of Minor uses



MS have dealt with this in highly variable ways:

- ▶ if one minor uses is on the label then the product will not be substituted.
- ▶ Up to 5 Minor uses needed or 50% of label as Minor uses to stop CA process
- ▶ Minor uses are not considered for CA, but the major uses in a product are considered
- ▶ Some MS consider each major use separately



Realistically, if important major uses are lost from labels then Industry are unlikely to maintain the minor uses.

Economics always prevail!!

Looking forward

Does CA today take into account the considerable regulatory risk associated with the products commercially available?





**Security of future pest control?
What AS will be left?**

Industry Experience: Conclusions

- Industry experience to date has been positive
- National level - Some variability on process and priorities
- Process is repetitive for each submission- labour intensive and inefficient
- EPPO standard PP1/271(2) has been valuable
 - focus on efficacy / agronomic / economic factors
 - pragmatic step-wise approach
 - basis for many National Guidance documents
- Important to consider future challenges to product authorisation when conducting CA.