



Netherlands Food and Consumer
Product Safety Authority
*Ministry of Agriculture,
Nature and Food Quality*

EPPO Standard PP 1/271 Guidance on Comparative Assessment (CA): history of the concept



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REASON FOR COMPARATIVE ASSESSMENT

- Replacement of EU **Directive** 91/414 by **EU Regulation** 1107/2009
- In **Article 50** of Regulation 1107/2009 the concept of **Comparative Assessment** was introduced



ARTICLE 50:

- ✓ ...alternatives are significantly safer for human or animal health or the environment
- ✓ ..alternatives do not present significant economic or practical disadvantages
- ✓ ...minimize the occurrence of resistance in the target organism
- ✓ ...consequences for minor use authorizations are taken into account

Article 50

Comparative assessment of plant protection products containing candidates for substitution

1. A comparative assessment shall be performed by Member States when evaluating an application for authorisation for a plant protection product containing an active substance approved as a candidate for substitution. Member States shall not authorise or shall restrict the use of a plant protection product containing a candidate for substitution for use on a particular crop where the comparative assessment weighing up the risks and benefits, as set out in Annex IV, demonstrates that:
 - (a) for the uses specified in the application an authorised plant protection product, or a non-chemical control or prevention method, already exists which is significantly safer for human or animal health or the environment;
 - (b) the substitution by plant protection products or non-chemical control or prevention methods referred to in point (a) does not present significant economic or practical disadvantages;
 - (c) the chemical diversity of the active substances, where relevant, or methods and practices of crop management and pest prevention are adequate to minimise the occurrence of resistance in the target organism; and
 - (d) the consequences on minor use authorisations are taken into account.



HISTORY OF THE CONCEPT (1)

- In January 2008 a proposal from the **EPPO resistance panel** for EPPO action on this topic was written
- 'Resistance strategy aspects are likely to be the **most important factor** in comparative risk assessment'



HISTORY OF THE CONCEPT (2)

- Because no guidance on how to perform CA was available it was expected that **wide differences** between MS would develop
- These differences would **disturb resistance management** (pests do not recognise borders), would disturb the **level EU economic playing field**, and would **increase illegal use**



PROPOSAL FROM THE RESISTANCE PANEL

Organize an **EPPO Workshop** that should:

- be held in 2008
- address a wide audience
- formulate the terms of reference of the guidance document
- formulate the basic principles for the guidance document



TIMELINE

- March 2008: EPPO **General Standards Panel** was supportive of the proposal
- May 2008: **Working Party on PPP** was supportive but concluded that **all agronomic aspects** of CA should be considered
- September 2008: Organizing Committee was formed
- May 2009: EPPO Workshop CA in Brussels



WORKSHOP CA 2009

61 participants:

- ✓ 18 Member States
- ✓ EPPO
- ✓ ECPA
- ✓ European Commission
- ✓ COPA-COGECA



GENERAL ASPECTS WORKSHOP CA - 2009

- Principles should be **simple** and **not overly prescriptive**
- Work sharing?
- Tiered schematic approach, with **review steps**



MAIN CONCLUSIONS WORKSHOP CA - 2009

- EPPO will produce a general Standard, based on a scheme organized into review steps
- Guidance on resistance issues with respect to CA will be provided in EPPO standard PP1/213



RECOMMENDATIONS WORKSHOP CA 2009 (1)

Guidance/clarification on:

- **Efficacy**
 - ✓ Data requirements for comparison of control methods?
 - ✓ Similarity in terms of efficacy?
 - ✓ How to compare products which contain more a.s.
 - ✓ Levels of control used by MS



RECOMMENDATIONS WORKSHOP CA 2009 (2)

Guidance/clarification on:

- Practical/economic considerations
 - ✓ No simple, defined guidance available
 - ✓ How should information be collected?



RECOMMENDATIONS WORKSHOP CA 2009 (2)

Guidance/clarification on:

- **Minor uses**
 - ✓ Comparing different cropping systems
 - ✓ General principles for comparison between chemical and non-chemical control methods



RECOMMENDATIONS WORKSHOP CA 2009 (2)

Guidance/clarification on:

- Resistance
- Clear definition of what constitutes sufficient phytosanitary measures



CONTINUATION AFTER THE WORKSHOP

- October 2009: Combined meeting of General Standards Panel and Resistance Panel, first draft was discussed.
- March 2010: Draft was tested and commented by different MS and industry
- September 2011: First approval of Standard PP 1/271 Guidance on comparative assessment



TODAY and TOMORROW..

- Follow up **workshop** on CA
- ✓ **Share experiences** of applicants and EPPO countries on the implementation of EPPO Standard PP 1/271 as different approaches may have been developed at national level
- ✓ Reconsider the **conclusions** and **recommendations** from the previous Workshop



TODAY and TOMORROW..

- ✓ **Identify** whether there are areas where **further work** or guidance in relation to the EPPO Standard is needed
- ✓ Work hard and enjoy the workshop