



## EUROPEAN AND MEDITERRANEAN PLANT PROTECTION ORGANIZATION

### EPPO Workshop on Comparative Assessment of Plant Protection Products Lisbon, 2018-10-24/25

## CONCLUSIONS AND RECOMMENDATIONS

### ***Revision of EPPO Standard PP 1/271 Guidance on comparative assessment***

The Workshop concluded that, based on the experience of using EPPO Standard PP 1/271 *Guidance on comparative assessment*, the Standard could now be revised to provide further guidance and clarity. The following areas were proposed to be considered for revision of the Standard by the EPPO Panel on General Standards for Efficacy Evaluation:

#### Order of the steps

The feedback from the questionnaire and the Workshop discussions noted, that often assessing comparability regarding the risk of developing resistance and assessing the effects on minor uses are steps which are considered early in the stepwise process for Comparative Assessment (CA). These steps are considered as an efficient filter and a means to reduce or avoid the workload imposed by the other steps, and by having to consider human health and environmental aspects. It should be therefore considered whether these sections should be moved to become earlier steps. The current Standard does already note that it is possible to assess the relevant steps earlier in the CA process, as experience is gained in the process. However, the Workshop concluded that the steps could be presented as a ‘circular’ decision making scheme, allowing applicants to start at the point that is relevant to individual country guidance and procedures.

#### Missing steps in the decision-making scheme

The Workshop noted that some steps are missing in the recommended process for CA:

- The stepwise process does not provide guidance on how to compare PPP containing an active substance approved as Candidates for Substitutions (CfS) when they are in mixtures and the Standard could cover both resistance and efficacy considerations when comparing with authorized mixtures;
- The provision in Article 50(3) of Regulation (EC) 1107/2009<sup>1</sup> permits a 5-year authorization to ‘gain experience of a new use’. This provision is missing in the Standard and should be considered in the Standard. While considering this aspect, there were two points raised that should be clarified with relevant regulatory bodies. The first is the interpretation of whether the experience of a ‘new use’ is a) country specific, with the proposed ‘new’ use not yet authorized in that country or b) if the ‘new use’ is already authorized in another country considered to be directly comparable (regarding all relevant agronomic, climatic conditions), and relevant ‘experience’ has already been gained. It is noted that the latter interpretation would potentially be more complex for both regulators and applicants. The second point was noted as a direct regulatory concern, with a number of attendees being unclear what happened at the end of that 5-year authorization period, for example would a CA need to be submitted and assessed at that point.

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<sup>1</sup> Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market.

### Steps where further clarification is needed

- Step 3 (on assessing crop safety aspects): In practice, this could be addressed by comparing any general warnings/restrictions on phytotoxicity. For herbicides in particular, any restrictions relating to succeeding/following crops are valid comparisons. The step should be re-worded to be more relevant to practical situations.
- Step 4 and Note c (in relation to a possible ‘broader’ spectrum of activity beyond the authorized uses): it was noted that this is not a valid and practical criterion and the comparison of efficacy should focus on authorized uses, for which there are underlying and assessed supporting data. This aspect does not concern the extension of authorizations for minor uses (Article 51 of Regulation 1107/2009) for which there may be some grower evidence on the use of the authorized product.
- Step 11 and Note g (on ‘assessing practical or economical disadvantages’): Further explanation, beyond what is already stated in the Note, could be given for herbicides considering the importance of weed control in crop rotations.
- Step 13 and Note h (about the unsustainable control for minor crops in case of substitution). This step was considered difficult to assess in practice, and relevant only when CA is not stopped at an earlier stage because of Article 51 (Extension of authorizations for minor uses). In the Note, the possible consequences refer to ‘the product supply’ chain and were considered difficult to address or anticipate. The Note could further explain the impacts related to whether the loss of a major use may lead to the product being commercially unviable if only minor uses remain.
- Step 15 (assessing any wider consequences): the non-food crop uses and some of the wider value of PPP could be mentioned as other examples, rather than focussing only on crops. For example, the value of herbicides in vegetation management for airfields or railways or the importance of fungicides in reducing mycotoxins to acceptable levels.
- As part of any general revision of the Standard, all the wording and accompanying explanatory notes should be reviewed

### Resistance (covered in the Standard by steps 6-10)

Resistance related aspects should be reconsidered by the EPPO Panel while revising EPPO Standard PP 1/271 as the Workshop concluded that further resistance advice could be provided to:

- Clarify how to address mixtures where the basis of the mixture is resistance management.
- remove identified discrepancies between this Standard and EPPO Standard PP 1/213 *Resistance risk analysis*

### ***Sharing information on Comparative Assessment***

The Workshop concluded that information on how CA is conducted by different countries could be provided on the EPPO website for the use of registration authorities and applicants. Relevant existing documents and useful references to carry out the process could be provided. This would include:

- Links to any available published national guidance on CA and Integrated Pest Management (IPM) national guidelines
- Results of the EPPO CA questionnaire should be summarized and disseminated;
- Links to the Minor Uses database of solutions (EUMUDA) which includes information on PPP and non-chemical alternative solutions;
- Provision of useful examples of how Comparative Assessment is carried out by countries. Some of the country presentations given at the Workshop may assist in this;
- Information on emerging and quarantine pests: links to relevant EPPO plant health information could be made e.g. named quarantine pests / alert lists as useful source for applicants if they have evidence of efficacy against these pests, and as part of considering possible future impacts.

### ***Further recommendations***

- Updating and sharing of research information on non-chemical alternatives should be encouraged;
- The UK (DEFRA) published study on non-chemical pest control methods<sup>2</sup> which is useful in the comparative assessment process and widely referenced could be updated and widened to other EPPO countries. Further consideration is required on the mechanisms for doing this and finding willing volunteers.
- There are a number of EU funded projects relating to IPM and the outputs of their activities should be made more readily available to registration authorities and applicants. This point is related also the DEFRA study, in that the outcomes of these projects could form the basis of a wider based guidance.;
- The Workshop noted that the SANCO Guidance document<sup>3</sup> could be clearer:
  - on the recommendations provided in the section ‘Compare candidates with candidates?’ as it is interpreted very differently between country regulators,
  - on how to address comparisons of mixtures when each mixture has a Cfs (in addition to possible recommendations in the revised EPPO Standard PP 1/271),
  - on the regulatory procedure at the end of the Article 50(3) of Regulation (EC) 1107 on the five-year derogation (to gain experience of a new use for a PPP containing a Cfs).

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<sup>2</sup> *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*, ADAS, DEFRA (2013)

<sup>3</sup> SANCO/11507/2013 rev. 12 *Draft guidance document on Comparative Assessment and Substitution of Plant Protection Products in accordance with Regulation (EC) N.1107/2009*