Efficacy

Under Regulation EC No 1107/2009[1] and 284/2013[2] (Section 6: Efficacy data), efficacy data must be provided. The data submitted are presented in an "Efficacy Package", composed of 3 documents:

- A **dRR (draft registration report, part B Section 7 Efficacy**): It is a document prepared by the applicant and written in accordance with the Guidance Document SANCO/6895/2009[3] and following all relevant EPPO PP standards. The purpose of the dRR for the Efficacy assessment is to provide an appropriate critical concise summary of the Biological Assessment Dossier (BAD), so that the zonal rapporteur member state (zRMS) can determine how the proposed uses(s) are supported, and whether each data requirement has been appropriately addressed (either by data or a justified reasoned case). The dRR should have sufficient detail such that the (z)RMS can largely refer to this document during the assessment, and use this as the basis of the final Registration Report (RR). dRR and RR should be standalone documents.

- A **BAD (Biological Assessment Dossier)** is a detailed summary: The data within the BAD should address the specific Efficacy data requirements detailed in EU Regulation. Useful historic guidance on how to write a BAD are available in Commission guidance 7600/VI/95[4] and OECD Guideline (SANCO/3989/2001). As for the dRR, applicants must also refer to all relevant EPPO PP standards. The BAD is classified as a 'K document' (non public document).

- **Annex**: Trials / study reports, trial series report (summaries), published papers, etc. They also belong to the "K document" (non public document).

Efficacy follows the layout of the requirements in "Section 6: Efficacy of the data requirements" in regulation 284/2013.

Where no data is provided for a chapter or a requirement, this should be explained / justified in the context of the product type, the type of demand, etc.

Zonal submissions are usually made to one of three **EU regulatory zones**. The dRR and the BAD must be adapted to each zone and not be a single all-encompassing dossier for the entire EU. Exceptions to this are for those uses, where the EU is considered as one regulatory zone (e.g. protected crops, products for stored produce, seed treatments).

Where there are particular National Requirements that may require further information and/or data, these could be addressed in accompanying National Addenda. This is explained more fully in Guidance Document SANCO 10055/2013, which describes the composition of the Efficacy core dossier and any accompanying National Addenda. Only limited additional data should be included in National addenda; the bulk of data / information should be presented in the core dossier. This guidance document should be referred to when drafting the dRR Section 7.

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1 REGULATION (EC) No 1107/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.

2 COMMISSION REGULATION (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (Section 6: Efficacy data).

3 SANCO/6895/2009: Guidance document on the presentation and evaluation of dossiers according to annex III of Directive 91/414/EEC in the format of a (draft) Registration Report.

4 Commission guidance 7600/VI/95: Guidelines and Criteria for the preparation and presentation of data concerning efficacy as provided in Annex III, parts A and B, section 6 of Directive 91/414/EEC concerning the placing of plant protection products on the market (biological assessment dossier).