

## Efficacy in Plant Protection



### Efficacy testing in Plant Protection

Since the establishment of the company in 1989, efficacy work was a key activity at SCC. This is to summarise actual developments and to give a short review of the developments in the area of efficacy evaluation.

### Efficacy enters the international agenda

Since the start of the zonal registration procedures on 14 June 2011, triggered by Regulation (EC) No 1107/2009, **efficacy requirements**, which always were an important issue for national product registration procedures, entered the agenda of international conferences on Plant Protection Product (PPP) registrations. Various contributions of authority representatives mention the problems associated with Section 7 of the **draft Registration Report (dRR)**. Often national data requirements were not followed and sometimes even complete **Biological Assessment Dossiers (BADs)** and dRRs had to be re-written by applicants as they did not fit official requirements. In order to understand the current problems one has to take a brief look into the past.

### Late start of EU harmonisation

In the last decades of the 20th century and in the first years of the new millennium the efficacy assessment was a purely national enterprise and the work of the efficacy specialists restricted to national dossiers, following national rules. Unlike other dossier sections where national models were compared with each other and adjusted to harmonized models in long lasting processes, the efficacy experts worked in splendid isolation until recently, despite the first attempt of international legislators to harmonize efficacy guidelines and criteria EU-wide with Guidance document SANCO 7600/VI/95 in 1995. The main reason for the procrastination of international harmonisation in the efficacy section was that the efficacy evaluation had not been a part of the Annex I listing process of Council Directive 91/414/EEC. Due to the lack of legal pressure, the harmonization process in the efficacy section started about 15 years after the other sections.

“In fact it is stated in document 1663/VI/94 that for the purpose of inclusion of an active substance in Annex I, the consideration of efficacy or of unacceptable effects on plants or plant products does not arise and therefore Annex III dossiers submitted need not include efficacy study reports” (7600/VI/95

rev.6 dated 14 July 1997). Each authority had its preferences how efficacy dossiers should be written. Therefore, the same set of data had sometimes to be re-organized if an application to a neighboring country was foreseen, and the authority specialist in charge was known to dislike the way the neighbors made their assessment. However, at that time this was not a great disadvantage as member states hardly took into consideration study results from across the border.

Before the introduction of GEP in 1999 it was also very difficult to judge the credibility of the test results generated outside of the own territory, especially if the results were reported in the local language, only.

## Mutual recognition:

### First steps to harmonisation

The real wind of change arose when the first companies dared to apply for product re-registrations according to articles 10 and 11 of Council Directive 91/414/EEC. The difficulties for mutual recognition applications were so enormous in several countries that in 2008 the commission issued the Guidance document SANCO/00298/2006 rev 9b dated 2 December 2008 on mutual recognition of PPPs which aimed “to clarify the conditions to be met and the procedures to be followed in order to pave the way to a more frequent application of the principle of mutual recognition, and hence to work-saving for all Member States.” The guidance document stated that “National conditions in the test area ‘efficacy’ are often comparable in various countries of the EC, particularly if conditions are similar in respect to cultivation/storage conditions and climate. The international European plant protection organization EPPO has now submitted a study on comparability based on comparable regions for efficacy.” This EPPO Guidance on comparable climates (PP 1/241(1) from 2005) was in fact a very important precondition for international harmonisation. Even though it restricts its validation to climatic aspects, it is now common sense to aggregate data according to the zonal classification made in this document.

### Efficacy: EPPO is in the lead

It is impossible to summarize in a few sentences the various actors and their initiatives which lead to a much better understanding between the efficacy experts within the EU. However, one should mention that the Commission leaves it “up to EPPO”, to determine the technical rules of the efficacy evaluations. After a long process several new or revised EPPO guidelines were issued in 2012 which lead the way to zonal registration procedures, also in the efficacy section. Most important in this context is **EPPO Standard PP1/278(1)** ‘Principles of zonal data production and evaluation’ which describes the general rules according to which EU-wide efficacy programs have to be set up and evaluations to be carried out and **EPPO Standard PP1/276(1)** ‘Principles of efficacy evaluation for microbial plant protection products’ which confirms that the rules set up for chemical products are, with few variations, also valid for “biopesticides”. Workshops organized by EPPO allow to participate in the process of guideline development and are a unique chance to meet many of the evaluators in one place.

In the ‘EPPO Workshop on Experiences with implementation of zonal evaluation of PPPs’, which was held in Sofia in October 2013, workgroup sessions discussed efficacy requirements in the context of formulation changes, the registration of co-formulated products, the relations of dRR and BAD and the data requirements in the case of applications which cover all EU zones (protected crops, seed treatments and stored products). A blueprint how to achieve harmonised zonal guidance as requested by Regulation (EC) 1107/2009 has been provided by the Nordic States who implemented a clear guidance for the Northern Zone already on 01 June 2011.

### New Efficacy Guidance Document

Since 3 April 2014 the new requirements of **SANCO/10055/2013 rev.4** on efficacy composition of core dossier and national addenda are valid. This new guidance describes the efficacy composition of core dossier and national addenda. The most important improvement from the aspect of dossier writing is the combination of the previous annex points “minimum effective dose tests” and “efficacy tests” into one annex point “Testing Effectiveness”. This allows a much more straight forward presentation and discussion of results. Especially in the case of very complex BADs or BADs with a high number of uses

this will lead to time and cost savings.

## Active substance renewal and product re-authorisations

Whereas in the active substance renewal the presentation of efficacy data plays only a minor role (for details of the requested type of presentation see SANCO/2012/11251 rev. 1.2), the subsequent re-authorisation applications need to carefully consider the scope of requirements to be fulfilled. In case of a smooth renewal process, i.E. no changes of intended uses (GAPs) were needed the efficacy sections of the re-authorisation dossiers only need to give an update in the area of resistance following the requirements of EPPO General Standard PP 1/213(3). However, often some adaptations of the GAP are needed and in such cases it should be clarified in direct contact with the zonal Rapporteur Member State (zRMS) if some or significantly more work has to be invested into the BAD and the (current) dRR Section 7 (OECD table of contents). As of January 2016 the efficacy data are presented in MCP Section 6 (according to the new EU table of contents (for crosswalks between the two systems see **SANCO/10181/2013 rev. 2.1**).

## IPM compatibility in focus

Compatibility with IPM programs is getting increasingly important and if specific label claims are made, these have to be backed by data. "In addition, the Sustainable Use Directive (2009/128/EC) requires Member States to establish or support the establishment of the necessary conditions for the implementation of Integrated Pest Management (IPM)." According to SANCO/10055/2013 applicants therefore have to take into consideration the national action plans for individual member state requirements and "may need to provide further information and/or data in the national addenda, including national labeling policies."

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