# Results from the questionnaire on the reporting of efficacy evaluation trials

## Introduction

The EPPO Standard PP 1/181 *Conduct and reporting of efficacy evaluation trials, including good experimental practice* should be followed if the results of efficacy evaluation trials are to be used for registration purposes. The use of this Standard provides the basis for recognition of efficacy data between countries.

This Standard (first approved in 1992-9, last revision mainly to reflect zonal assessment approved in 2012-09) is the "*basis for recognition of efficacy data between countries. Thus, registration of a product in one country can be based on results obtained in one or several other countries, provided the Standard has been followed*."
It implies that the recognition of the efficacy data between countries, but also of the Biological Assessment Dossiers (BAD) submitted by the applicants, and of the Registration Reports and Good Agricultural Practice and authorizations proposals of the rapporteur Member State, can only be achieved if the GEP institutions, the applicants and the regulatory authorities follow this standard.

Each trial report should possess two main qualities. It should be:
1) comprehensive and readable, and 2) traceable.

### *Comprehensive and readable reports*

EPPO Standard PP 1/181: *The trial report should include all relevant information from the trial notebook presented according to the same plan. The report should include an assessment and discussion, which will first concern the validity of the trial (with particular reference to the results in untreated and reference plots), and draw attention to any special conditions which have arisen. It will then include a systematic appraisal of the efficacy of the test product(s) in relation to the reference product(s) and the untreated control, and/or of any other variables (dose, application time, application type) included in the design. Finally, it will include a systematic appraisal of any side-effects, especially phytotoxicity (for herbicides, this appraisal will concern selectivity trials). This appraisal is often done at the trial series report stage.*

The assessment and discussion that has been prepared by the experimenter himself on the basis of his/her notebook and his/her own observations (or the observations of field technicians) is a key point for the regulatory authorities. They demonstrate that the pest was present, that the test conditions allowed comparison of the products in an appropriate manner (for example, conditions that are too favorable for the crop may mask possible phytotoxic effects, etc.).

A few trials that are well conducted and reported can be more valuable than huge number of trials that are poorly reported, or that are summarized in an 'administrative' way.

### *Traceable reports*

The steps leading to the preparation of a trial report should be traceable at the level of the GEP institution
EPPO Standard PP 1/181: *The managers and operators of the organization, whose responsibilities are clearly assigned, should be able to check at their level that GEP is being followed, and thus to validate the trial throughout its course.*

EPPO Standard PP 1/181*: The information recorded during the trial is generally held in an individual dossier known as the 'trial notebook'. Since recording is often now computerized, this notebook does not necessarily exist in hard copy. For example, data on the execution of treatments, recording and measurements is often captured in a computer system directly in the field, or immediately on return to the office, for electronic transmission to headquarters where it will be used in drafting the trial report and trial series report. The organization needs the same data, however it is stored, and for convenience the text supposes that the trial notebook is drawn up in hard copy.*

The EU regulatory evaluators and the GEP auditors were asked to evaluate the quality of 40 trial reports with very different layout in order to get a clearer view on their approach.

**Questionnaire**

A series of study reports that have been submitted to the Belgian evaluators within the last two years has been chosen, considering the various modes of presentation of the information. Since the same or very similar dossiers are sent to each Member State, these study reports can be considered as a representative batch of the reports that are submitted to the EU regulatory authorities.
The trials have been performed by the agrochemical companies themselves, by GEP contractors or by official organizations.

The evaluators were asked to give their evaluation on the acceptability of the studies and their layout in terms of:

1. General evaluation of the report (Table 1)
2. GEP status (Table 2)
3. Experimental conditions, basic information, treatments, meteorological and edaphic data (Table 3)
4. Raw data, results, statistical analysis, conclusions (Table 4)

The following scale was used to classify the answers to the first four questions:

1: fully unacceptable
2: unacceptable
3: acceptable (with some deficiencies)
4: fully acceptable

The fifth question was related to the elements that should be improved in the trial report, according to the evaluator.

**Results**

Nineteen questionnaires from 9 Member States (Austria, Belgium, the Czech Republic, Germany, Hungary, the Netherlands, Poland, Slovakia, the United Kingdom) have been filled in by around 25 experts. The experts were regulatory evaluators (for a majority of them), GEP auditors, and scientists in the field of plant protection products.

**Table 1. General evaluation of the trial**

| Study number | Study name | Eval. BE-1 | Eval. BE-2 | Eval. NL | Eval. HU | Eval. AT-1 | Eval. AT-2 | Eval. CZ-1 | Eval. CZ-2 | Eval. CZ-3 | Eval. DE-1 | Eval. DE-2 | Eval. DE-3 | Eval. DE-4 | Eval. DE-5 | Eval. DE-6 | Eval. DE-7 | Eval. SL | Eval. UK | Eval. PO | Mean (report) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | | 2 | 4 | | 3 | | | 3 | 3 | 4 | | | | 3 | | 1 | 2 | 4 | | 3 | 2.9 |
| 2 | x | 2 | 3 | 4 | 3 | 4 | 3 | 4 | 3 | 4 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 2 | 3.2 |
| 3 | | 2 | 3 | 4 | 1 | 2 | 2 | 2 | 2 | 1 | | | | 2 | | 1 | 1 | 1 | | 1 | 1.8 |
| 4 | | 1 | 1 | 1 | 2 | | | 2 | 2 | 3 | 2 | 2 | 1 | 2 | 2 | 2 | 1 | 1 | 2 | 2 | 1.7 |
| 5 | | 1 | 1 | 1 | 3 | 3 | 2 | 2 | 2 | 1 | 3 | 3 | 3 | 3 | 2 | 3 | 3 | 3 | 2 | 2 | 2.3 |
| 6 | | 1 | 1 | 3 | 1 | 1 | | 3 | 3 | 4 | 4 | 4 | 3 | 3 | 3 | 3 | 3 | 4 | 3 | 3 | 2.8 |
| 7 | x | 3 | 4 | 4 | 4 | 4 | 4 | 3 | 4 | 4 | 3 | 4 | 3 | 4 | 3 | 4 | 3 | 4 | 3 | 4 | 3.6 |
| 8 | | 1 | 1 | 1 | 1 | 1 | | 2 | 3 | 1 | | | | 1 | | 1 | 1 | 2 | | 1 | 1.3 |
| 9 | | 1 | 1 | 2 | 1 | 2 | | 2 | 1 | 2 | | | | 2 | | 1 | 3 | 1 | | 1 | 1.5 |
| 10 | x | 3 | 4 | 4 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 3.7 |
| 11 | | 2 | 4 | | 1 | 3 | | 2 | 3 | 3 | | | | 3 | | 1 | 3 | 1 | | 1 | 2.3 |
| 12 | | 1 | 3 | | 4 | 3 | | 3 | 3 | 4 | 3 | 3 | 2 | 3 | 3 | 3 | 3 | 2 | 4 | 3 | 2.9 |
| 13 | | 1 | 1 | | 4 | 1 | | 3 | 3 | 4 | 3 | 3 | 2 | 2 | 3 | 3 | 3 | 2 | 3 | 3 | 2.6 |
| 14 | x | 3 | 3 | | | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 3 | 3 | 4 | 3 | 4 | 4 | 4 | 3.5 |
| 15 | x | 3 | 4 | | 3 | 3 | 4 | 4 | 3 | 4 | 2 | 4 | 4 | 3 | 3 | 2 | 3 | 4 | 4 | 4 | 3.4 |
| 16 | | 1 | 1 | | 3 | | | 2 | 3 | 3 | 3 | 3 | 4 | 2 | 3 | 3 | 3 | 2 | 3 | 3 | 2.6 |
| 17 | x | 3 | 4 | | 4 | | | 3 | 3 | 4 | 3 | 4 | 2 | 2 | 3 | 4 | 3 | 2 | 3 | 3 | 3.1 |
| 18 | | 2 | 1 | | | 1 | | 2 | 3 | 3 | | | | 2 | | 1 | 3 | 1 | | 1 | 1.8 |
| 19 | | 1 | 1 | | 4 | 1 | | 3 | 3 | 3 | 3 | 4 | 2 | 2 | 3 | 3 | 3 | 2 | 3 | 3 | 2.6 |
| 20 | x | 4 | 4 | | 4 | 3 | | 3 | 3 | 4 | 3 | 4 | 3 | 4 | 3 | 4 | 2 | 2 | 4 | 3 | 3.4 |
| 21 | x | 4 | 4 | | 4 | 3 | | 4 | 3 | 4 | 3 | 4 | 2 | 3 | 3 | 4 | 3 | 3 | 4 | 3 | 3.4 |
| 22 | x | 4 | 4 | | 4 | 3 | | 3 | 4 | 4 | 3 | 3 | 4 | 3 | 3 | 3 | 4 | 3 | 4 | 3 | 3.5 |
| 23 | | 2 | 2 | | 4 | 3 | | 3 | 3 | 4 | 3 | 3 | 2 | 2 | 2 | 3 | 3 | 1 | 3 | 3 | 2.7 |
| 24 | x | 4 | 4 | | 4 | | | 3 | 3 | 4 | 3 | 3 | 3 | 4 | 3 | 4 | 4 | 4 | 3 | 3 | 3.5 |
| 25 | | 4 | 4 | | 1 | | | 3 | 3 | 4 | 3 | 3 | 1 | 2 | 2 | 2 | 3 | 2 | | 3 | 2.7 |
| 26 | | 1 | 1 | | 3 | 2 | | 3 | 3 | 3 | 3 | 3 | 1 | 2 | 2 | 2 | 1 | 1 | 2 | 2 | 2.1 |
| 27 | | 2 | 4 | | 1 | 1 | | 2 | 3 | 1 | | | | 2 | | 1 | 1 | 2 | | 1 | 1.8 |
| 28 | | 2 | 3 | | 3 | 3 | | 3 | 4 | 4 | 3 | 4 | 3 | 3 | 3 | 3 | 3 | 2 | 2 | 3 | 3 |
| 29 | x | 3 | 3 | | 4 | 4 | | 3 | 4 | 4 | 4 | 4 | 4 | 3 | 4 | 3 | 3 | 3 | 4 | 3 | 3.5 |
| 30 | x | 3 | 4 | | 3 | | | 3 | 4 | 4 | 4 | 4 | 3 | 3 | 3 | 4 | 3 | 3 | 4 | 4 | 3.5 |
| 31 | x | 4 | 3 | | 4 | | | 4 | 4 | 4 | 3 | 4 | 3 | 3 | 3 | 4 | 3 | 2 | 4 | 4 | 3.5 |
| 32 | | 1 | 2 | | | | | 3 | 3 | 4 | | | | 2 | | 1 | 1 | 4 | | 1 | 2.2 |
| 33 | x | 3 | 3 | | 4 | | | 3 | 4 | 4 | 3 | 3 | 4 | 3 | 3 | 4 | 3 | 4 | 3 | 3 | 3.4 |
| 34 | x | 3 | 4 | | 4 | 3 | 3 | 3 | 4 | 4 | 3 | 4 | 4 | 4 | 3 | 3 | 3 | 2 | 3 | 4 | 3.4 |
| 35 | x | 4 | 4 | | 4 | | | 3 | 4 | 4 | 2 | 3 | 3 | 4 | 4 | 3 | 3 | 3 | 4 | 3 | 3.4 |
| 36 | | 2 | 3 | | | 1 | 2 | 2 | 2 | 1 | | | | 2 | | 1 | 2 | 1 | | 1 | 1.7 |
| 37 | | 1 | 1 | 1 | | 1 | 3 | 2 | 2 | 3 | | | | 2 | | 1 | 3 | 1 | | 1 | 1.7 |
| 38 | | 1 | 1 | | 4 | | | 2 | 3 | 4 | 3 | 3 | 1 | 3 | 2 | 3 | 3 | 2 | 2 | 2 | 2.4 |
| 39 | | 3 | 3 | | 4 | | | 3 | 3 | 4 | 2 | 3 | 2 | 3 | 3 | 2 | 3 | 2 | 3 | 4 | 2.9 |
| 40 | | 2 | 2 | | | | | 3 | 3 | 4 | 3 | 2 | 1 | 3 | 2 | 2 | 2 | 1 | 2 | 1 | 2.2 |
| | Mean (assessor) | 2.3 | 2.7 | 2.5 | 3.1 | 2.4 | 3 | 2.8 | 3.1 | 3.4 | 3 | 3.4 | 2.7 | 2.7 | 2.8 | 2.6 | 2.7 | 2.4 | 3.2 | 2.6 | |

**Table 2. GEP status**

| Study number | Study name | Eval. BE-1 | Eval. BE-2 | Eval. NL | Eval. HU | Eval. AT-1 | Eval. AT-2 | Eval. CZ-1 | Eval. CZ-2 | Eval. CZ-3 | Eval. DE-1 | Eval. DE-2 | Eval. DE-3 | Eval. DE-4 | Eval. DE-5 | Eval. DE-6 | Eval. DE-7 | Eval. SL | Eval. UK | Eval. PO | Mean (report) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | | 4 | 4 | | 4 | | | 4 | 4 | 4 | | | | 4 | | | 3 | 4 | | 2 | 3.7 |
| 2 | x | 3 | 3 | 3 | 4 | 4 | 3 | 3 | 4 | 2 | 2 | 1 | 3 | 2 | 2 | 3 | 2 | 2 | 3 | 1 | 2.6 |
| 3 | | 1 | 3 | 2 | 1 | | | 2 | 1 | 1 | | | | 2 | | | 1 | 1 | | 1 | 1.5 |
| 4 | | 1 | 1 | 1 | 3 | | | 2 | 1 | 1 | 2 | 1 | 1 | 2 | 1 | 2 | 1 | 1 | 1 | 1 | 1.4 |
| 5 | | 1 | 1 | 1 | 4 | 2 | | 2 | 1 | 1 | 2 | 1 | 3 | 2 | 1 | 2 | 3 | 1 | 1 | 1 | 1.7 |
| 6 | | 1 | 1 | 4 | 1 | 2 | | 3 | 2 | 2 | 4 | 4 | 4 | 4 | 3 | 4 | 3 | 4 | 3 | 3 | 2.9 |
| 7 | x | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 2 | 4 | 3 | 4 | 3 | 4 | 3 | 4 | 3 | 4 | 3.7 |
| 8 | | 1 | 1 | 1 | 1 | 1 | | 2 | 1 | 1 | | | | 1 | | | 1 | 1 | | 1 | 1.1 |
| 9 | | 1 | 1 | 3 | 1 | 1 | | 2 | 1 | 1 | | | | 2 | | | | 1 | | 1 | 1.4 |
| 10 | x | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 3 | 4 | 3 | 4 | 3 | 4 | 3 | 3 | 3 | 4 | 3.7 |
| 11 | | 2 | 3 | | 1 | 4 | | 2 | 1 | 2 | | | | 1 | | | | 1 | | 1 | 1.8 |
| 12 | | 1 | 2 | | 4 | 2 | | 2 | 1 | 1 | 2 | 1 | 1 | 3 | 2 | 2 | 2 | 1 | 3 | 2 | 1.9 |
| 13 | | 1 | 1 | | 3 | 2 | | 3 | 2 | 2 | 4 | 4 | 3 | 4 | 3 | 4 | 3 | 1 | 3 | 3 | 2.7 |
| 14 | x | 4 | 4 | | | 3 | 4 | 4 | 4 | 4 | 3 | 4 | 3 | 4 | 4 | 4 | 3 | 4 | 4 | 4 | 3.8 |
| 15 | x | 2 | 4 | | 4 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 3 | 4 | 4 | 4 | 3 | 4 | 4 | 4 | 3.7 |
| 16 | | 1 | 1 | | 4 | | | 3 | 2 | 2 | 4 | 4 | 4 | 4 | 3 | 4 | 3 | 1 | 3 | 3 | 2.9 |
| 17 | x | 3 | 3 | | 4 | | | 3 | 2 | 2 | 4 | 4 | 3 | 4 | 3 | 4 | 3 | 1 | 3 | 3 | 3.1 |
| 18 | | 1 | 1 | | | 1 | | 3 | 2 | 2 | | | | 4 | | | 3 | 1 | | 1 | 1.9 |
| 19 | | 1 | 1 | | 4 | 1 | | 3 | 2 | 2 | 4 | 4 | 3 | 4 | 2 | 4 | 3 | 2 | 2 | 3 | 2.6 |
| 20 | x | 4 | 4 | | 4 | 4 | | 4 | 4 | 4 | 4 | 4 | 1 | 4 | 4 | 4 | 3 | 2 | 3 | 4 | 3.6 |
| 21 | x | 4 | 4 | | 4 | 3 | | 4 | 4 | 4 | 3 | 4 | 1 | 4 | 4 | 4 | 3 | 3 | 3 | 4 | 3.5 |
| 22 | x | 4 | 4 | | 4 | 4 | | 3 | 4 | 4 | 3 | 4 | 3 | 4 | 4 | 4 | 4 | 3 | 3 | 4 | 3.7 |
| 23 | | 2 | 1 | | 4 | 2 | | 3 | 2 | 2 | 4 | 3 | 4 | 4 | 3 | 4 | 3 | 1 | 3 | 3 | 2.8 |
| 24 | x | 4 | 4 | | 4 | | | 4 | 4 | 4 | 4 | 3 | 4 | 4 | 3 | 4 | 4 | 4 | 3 | 4 | 3.8 |
| 25 | | 4 | 4 | | 1 | | | 3 | 4 | 4 | 4 | 3 | 3 | 4 | 2 | 4 | 3 | 4 | | 4 | 3.4 |
| 26 | | 1 | 1 | | 3 | 1 | | 2 | 1 | 1 | 2 | 1 | 1 | 2 | 1 | 2 | 1 | 1 | 1 | 1 | 1.4 |
| 27 | | 1 | 4 | | 1 | 1 | | 2 | 1 | 1 | | | | 2 | | | 1 | 1 | | 1 | 1.5 |
| 28 | | 3 | 4 | | 2 | 3 | | 4 | 4 | 4 | 3 | 4 | 4 | 4 | 3 | 4 | 3 | 2 | 3 | 3 | 3.4 |
| 29 | x | 4 | 4 | | 4 | 4 | | 3 | 4 | 4 | 3 | 3 | 1 | 4 | 4 | 4 | 3 | 3 | 4 | 2 | 3.4 |
| 30 | x | 4 | 4 | | 4 | | | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 3 | 4 | 3 | 3 | 4 | 4 | 3.8 |
| 31 | x | 4 | 4 | | 4 | | | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 3 | 4 | 3 | 2 | 4 | 4 | 3.8 |
| 32 | | 1 | 2 | | | | | 2 | 1 | 1 | | | | 2 | | | 1 | 1 | | 1 | 1.3 |
| 33 | x | 4 | 4 | | 4 | | | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 3 | 4 | 3 | 4 | 4 | 4 | 3.9 |
| 34 | x | 3 | 4 | | 4 | 1 | 2 | 3 | 2 | 2 | 4 | 4 | 3 | 4 | 3 | 4 | 3 | 1 | 4 | 2 | 2.9 |
| 35 | x | 4 | 4 | | 4 | | | 4 | 4 | 4 | 2 | 4 | 2 | 4 | 4 | 4 | 3 | 3 | 4 | 4 | 3.6 |
| 36 | | 1 | 3 | | | 1 | 2 | 2 | 1 | 1 | | | | 2 | | | 2 | 1 | | 1 | 1.5 |
| 37 | | 1 | 1 | 1 | | 1 | 2 | 2 | 1 | 2 | | | | 4 | | | 3 | 1 | | 1 | 1.7 |
| 38 | | 1 | 1 | | 4 | | | 3 | 1 | 2 | 4 | 3 | 1 | 4 | 3 | 3 | 3 | 1 | 3 | 1 | 2.4 |
| 39 | | 2 | 2 | | 4 | | | 2 | 1 | 1 | 2 | 1 | 1 | 2 | 4 | 2 | 2 | 1 | 3 | 1 | 1.9 |
| 40 | | 2 | 2 | | | | | 2 | 1 | 1 | 2 | 1 | 1 | 2 | 2 | 2 | 2 | 1 | 2 | 1 | 1.6 |
| | Mean (assessor) | 2.4 | 2.7 | 2.4 | 3.2 | 2.4 | 3.1 | 3 | 2.5 | 2.5 | 3.2 | 3.1 | 2.6 | 3.3 | 2.9 | 3.5 | 2.6 | 2 | 3 | 2.4 | |

**Table 3. Experimental conditions, treatments, meteorological and edaphic data**

| Study number | Study name | Eval. BE-1 | Eval. BE-2 | Eval. NL | Eval. HU | Eval. AT-1 | Eval. AT-2 | Eval. CZ-1 | Eval. CZ-2 | Eval. CZ-3 | Eval. DE-1 | Eval. DE-2 | Eval. DE-3 | Eval. DE-4 | Eval. DE-5 | Eval. DE-6 | Eval. DE-7 | Eval. SL | Eval. UK | Eval. POL. | Mean (report) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | | 2 | 4 | | 4 | | | 4 | 3 | 3 | | | | 3 | | | 3 | 4 | | 3 | 3.3 |
| 2 | x | 2 | 4 | 4 | 4 | 3 | 3 | 4 | 4 | 3 | 3 | 3 | 4 | 3 | 3 | 3 | 3 | 4 | 4 | 3 | 3.4 |
| 3 | | 2 | 4 | 4 | 1 | | | 3 | 3 | 1 | | | | 2 | | | 1 | 1 | | 1 | 2.1 |
| 4 | | 1 | 1 | 1 | 3 | | | 3 | 2 | 3 | 2 | 3 | 2 | 2 | 2 | 3 | 1 | 3 | 2 | 2 | 2.1 |
| 5 | | 1 | 1 | 1 | 4 | 3 | | 3 | 1 | 2 | 3 | 1 | 4 | 3 | 2 | 2 | 2 | 1 | 2 | 1 | 2.1 |
| 6 | | 1 | 1 | 3 | 1 | 3 | | 4 | 3 | 3 | 4 | 4 | 4 | 3 | 3 | 3 | 3 | 4 | 3 | 3 | 2.9 |
| 7 | x | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 3 | 4 | 3 | 4 | 3 | 4 | 3.8 |
| 8 | | 1 | 1 | 1 | 1 | 1 | | 2 | 2 | 1 | | | | 1 | | | 1 | 1 | | 1 | 1.2 |
| 9 | | 1 | 1 | 1 | 1 | 2 | | 3 | 2 | 2 | | | | 2 | | | 3 | 2 | | 1 | 1.8 |
| 10 | x | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 3 | 3 | 3 | 4 | 4 | 4 | 3.8 |
| 11 | | 3 | 4 | | 1 | 4 | | 3 | 4 | 3 | | | | 3 | | | 3 | 1 | | 1 | 2.7 |
| 12 | | 1 | 4 | | 4 | 3 | | 3 | 2 | 3 | 4 | 2 | 2 | 3 | 2 | 3 | 3 | 1 | 4 | 3 | 2.8 |
| 13 | | 1 | 1 | | 3 | 3 | | 4 | 4 | 3 | 3 | 4 | 3 | 3 | 3 | 3 | 2 | 4 | 3 | 3 | 2.9 |
| 14 | x | 3 | 3 | | | 4 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 3 | 3 | 4 | 3 | 4 | 4 | 4 | 3.6 |
| 15 | x | 3 | 4 | | 4 | 4 | 4 | 4 | 4 | 4 | 2 | 4 | 4 | 3 | 3 | 2 | 3 | 4 | 4 | 4 | 3.6 |
| 16 | | 1 | 1 | | 4 | | | 4 | 3 | 3 | 3 | 3 | 3 | 3 | 2 | 4 | 3 | 3 | 3 | 4 | 2.9 |
| 17 | x | 4 | 4 | | 4 | | | 4 | 4 | 4 | 4 | 4 | 2 | 3 | 3 | 4 | 3 | 4 | 3 | 3 | 3.6 |
| 18 | | 1 | 1 | | | 1 | | 3 | 3 | 3 | | | | 3 | | | 3 | 1 | | 1 | 2 |
| 19 | | 1 | 1 | | 4 | 1 | | 3 | 3 | 3 | 4 | 4 | 1 | 3 | 3 | 3 | 2 | 3 | 3 | 3 | 2.6 |
| 20 | x | 4 | 4 | | 4 | 3 | | 4 | 4 | 4 | 3 | 4 | 2 | 4 | 3 | 4 | 2 | 4 | 4 | 4 | 3.6 |
| 21 | x | 4 | 4 | | 4 | 3 | | 4 | 4 | 4 | 3 | 4 | 3 | 3 | 3 | 4 | 3 | 3 | 4 | 4 | 3.6 |
| 22 | x | 4 | 4 | | 4 | 3 | | 2 | 3 | 4 | 3 | 4 | 4 | 3 | 3 | 3 | 4 | 3 | 4 | 3 | 3.4 |
| 23 | | 2 | 2 | | 4 | 3 | | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 2 | 3 | 3 | 2.9 |
| 24 | x | 4 | 4 | | 4 | | | 4 | 4 | 4 | 3 | 3 | 3 | 4 | 3 | 4 | 4 | 4 | 3 | 4 | 3.7 |
| 25 | | 4 | 4 | | 1 | | | 3 | 4 | 4 | 3 | 4 | 2 | 3 | 2 | 2 | 2 | 4 | | 3 | 3 |
| 26 | | 1 | 1 | | 4 | 3 | | 3 | 3 | 3 | 3 | 3 | 1 | 2 | 2 | 3 | 1 | 3 | 2 | 3 | 2.4 |
| 27 | | 3 | 4 | | 1 | - | | 2 | 3 | 1 | | | | 2 | | | 1 | 3 | | 1 | 2.1 |
| 28 | | 3 | 4 | | 4 | 4 | | 4 | 4 | 4 | 3 | 4 | 4 | 3 | 3 | 3 | 3 | 3 | 2 | 4 | 3.5 |
| 29 | x | 2 | 4 | | 4 | 4 | | 4 | 4 | 4 | 3 | 4 | 4 | 3 | 3 | 4 | 3 | 4 | 4 | 4 | 3.6 |
| 30 | x | 4 | 4 | | 4 | | | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 3 | 4 | 3 | 4 | 4 | 4 | 3.9 |
| 31 | x | 4 | 4 | | 4 | | | 3 | 4 | 4 | 3 | 4 | 4 | 3 | 3 | 4 | 3 | 4 | 4 | 3 | 3.6 |
| 32 | | 1 | 4 | | | | | 4 | 4 | 4 | | | | 2 | | | 1 | 4 | | 1 | 2.8 |
| 33 | x | 3 | 4 | | 4 | | | 3 | 3 | 4 | 3 | 4 | 4 | 3 | 3 | 4 | 3 | 4 | 3 | 4 | 3.5 |
| 34 | x | 4 | 4 | | 4 | 4 | 4 | 3 | 4 | 4 | 3 | 4 | 4 | 4 | 3 | 3 | 3 | 4 | 3 | 4 | 3.7 |
| 35 | x | 4 | 4 | | 4 | | | 4 | 4 | 4 | 2 | 3 | 4 | 4 | 4 | 4 | 3 | 4 | 4 | 4 | 3.8 |
| 36 | | 2 | 3 | | | 2 | 2 | 3 | 2 | 1 | | | | 2 | | | 2 | 1 | | 1 | 1.9 |
| 37 | | 1 | 1 | 1 | | 1 | 3 | 3 | 2 | 2 | | | | 3 | | | 3 | 1 | | 1 | 1.8 |
| 38 | | 1 | 1 | | 4 | | | 3 | 3 | 3 | 2 | 3 | 4 | 3 | 2 | 3 | 3 | 4 | 2 | 3 | 2.8 |
| 39 | | 4 | 4 | | 4 | | | 4 | 3 | 3 | 3 | 3 | 2 | 3 | 2 | 3 | 2 | 4 | 3 | 4 | 3.2 |
| 40 | | 3 | 3 | | | | | 3 | 3 | 3 | 3 | 2 | 1 | 3 | 2 | 2 | 2 | 1 | 2 | 1 | 2.3 |
| | Mean (assessor) | 2.5 | 3 | 2.4 | 3.3 | 2.9 | 3.4 | 3.4 | 3.3 | 3.2 | 3.1 | 3.5 | 3.1 | 3 | 2.7 | 3.3 | 2.6 | 3 | 3.2 | 2.8 | |

**Table 4. Raw data, results, statistical analysis, conclusions**

| Study number | Study name | Eval. BE-1 | Eval. BE-2 | Eval. NL | Eval. HU | Eval. AT-1 | Eval. AT-2 | Eval. CZ-1 | Eval. CZ-2 | Eval. CZ-3 | Eval. DE-1 | Eval. DE-2 | Eval. DE-3 | Eval. DE-4 | Eval. DE-5 | Eval. DE-6 | Eval. DE-7 | Eval. SL | Eval. UK | Eval. POL. | Mean (report) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | | 1 | 4 | | 4 | | | 4 | 3 | 3 | | | | 3 | | | 2 | 4 | | 4 | 3.2 |
| 2 | x | 2 | 3 | | 4 | 3 | 3 | 3 | 3 | 4 | 3 | 3 | 4 | 3 | 3 | 3 | 3 | 4 | 3 | 2 | 3.1 |
| 3 | | 1 | 3 | 2 | 1 | 3 | | 2 | 2 | 1 | | | | 2 | | | 1 | 1 | | 1 | 1.7 |
| 4 | | 1 | 1 | 1 | 3 | | | 3 | 2 | 3 | 3 | 3 | 2 | 2 | 2 | 2 | 1 | 4 | 2 | 2 | 2.2 |
| 5 | | 1 | 1 | 1 | 4 | 3 | | 3 | 2 | 2 | 3 | 4 | 4 | 3 | 2 | 2 | 3 | 4 | 2 | 1 | 2.5 |
| 6 | | 1 | 1 | 3 | 1 | 3 | | 4 | 3 | 3 | 3 | 4 | 4 | 3 | 3 | 3 | 3 | 4 | 3 | 3 | 2.9 |
| 7 | x | 4 | 4 | 4 | 4 | 4 | 4 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 3 | 3 | 3 | 4 | 3 | 4 | 3.7 |
| 8 | | 1 | 1 | 1 | 1 | 1 | | 3 | 3 | 1 | | | | 1 | | | 1 | 3 | | 1 | 1.5 |
| 9 | | 1 | 1 | 1 | 1 | 2 | | 3 | 2 | 2 | | | | 3 | | | 3 | 2 | | 1 | 1.8 |
| 10 | x | 4 | 4 | 4 | 4 | 4 | 4 | 3 | 4 | 4 | 4 | 4 | 4 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 3.7 |
| 11 | | 3 | 4 | | 1 | 4 | | 3 | 2 | 3 | | | | 3 | | | 3 | 1 | | 1 | 2.5 |
| 12 | | 1 | 3 | | 4 | 3 | | 3 | 3 | 3 | 4 | 3 | 3 | 3 | 3 | 2 | 2 | 4 | 3 | 4 | 3 |
| 13 | | 1 | 1 | | 2 | 1 | | 3 | 3 | 3 | 3 | 4 | 2 | 3 | 3 | 3 | 3 | 4 | 3 | 3 | 2.6 |
| 14 | x | 4 | 4 | | | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 3 | 4 | 3 | 3 | 4 | 3 | 3 | 3.6 |
| 15 | x | 2 | 4 | | 4 | 4 | 4 | 4 | 3 | 4 | 3 | 4 | 4 | 3 | 3 | 3 | 3 | 4 | 3 | 3 | 3.4 |
| 16 | | 2 | 1 | | 3 | | | 3 | 3 | 3 | 3 | 4 | 4 | 3 | 2 | 3 | 3 | 4 | 3 | 2 | 2.9 |
| 17 | x | 4 | 4 | | 4 | | | 3 | 3 | 4 | 3 | 4 | 3 | 3 | 3 | 3 | 3 | 4 | 3 | 4 | 3.4 |
| 18 | | 2 | 1 | | | 1 | | 3 | 3 | 3 | | | | 3 | | | 3 | 1 | | 1 | 2.1 |
| 19 | | 1 | 1 | | 4 | 1 | | 3 | 3 | 3 | 3 | 4 | 3 | 3 | 2 | 4 | 3 | 4 | 3 | 3 | 2.8 |
| 20 | x | 4 | 4 | | 4 | 4 | | 4 | 3 | 4 | 3 | 4 | 3 | 3 | 3 | 4 | 3 | 4 | 4 | 4 | 3.6 |
| 21 | x | 4 | 4 | | 4 | 4 | | 4 | 4 | 4 | 3 | 4 | 3 | 4 | 3 | 4 | 3 | 3 | 4 | 3 | 3.6 |
| 22 | x | 4 | 4 | | 4 | 4 | | 4 | 4 | 4 | 3 | 4 | 4 | 3 | 3 | 3 | 4 | 4 | 4 | 3 | 3.7 |
| 23 | | 3 | 2 | | 3 | 3 | | 4 | 3 | 3 | 3 | 3 | 4 | 3 | 2 | 3 | 3 | 4 | 2 | 4 | 3.1 |
| 24 | x | 4 | 4 | | 4 | | | 4 | 4 | 4 | 3 | 3 | 3 | 4 | 3 | 4 | 4 | 4 | 3 | 3 | 3.6 |
| 25 | | 4 | 4 | | 1 | | | 3 | 3 | 4 | 3 | 4 | 2 | 2 | 2 | 2 | 2 | 4 | | 2 | 2.8 |
| 26 | | 1 | 1 | | 3 | 1 | | 3 | 2 | 2 | 3 | 3 | 1 | 2 | 2 | 3 | 1 | 2 | 2 | 2 | 2 |
| 27 | | 3 | 4 | | 1 | - | | 3 | 3 | 1 | | | | 2 | | | 1 | 2 | | 1 | 2.1 |
| 28 | | 1 | 3 | | 2 | 3 | | 2 | 4 | 3 | 3 | 4 | 4 | 3 | 3 | 2 | 3 | 3 | 2 | 3 | 2.8 |
| 29 | x | 1 | 3 | | 4 | 3 | | 4 | 4 | 4 | 3 | 4 | 4 | 3 | 4 | 3 | 3 | 4 | 4 | 3 | 3.4 |
| 30 | x | 3 | 4 | | 3 | | | 3 | 4 | 4 | 3 | 4 | 4 | 3 | 3 | 4 | 3 | 4 | 4 | 3 | 3.5 |
| 31 | x | 4 | 3 | | 4 | | | 4 | 4 | 4 | 3 | 4 | 4 | 3 | 3 | 4 | 3 | 4 | 4 | 3 | 3.6 |
| 32 | | 1 | 2 | | | | | 3 | 3 | 4 | | | | 2 | | | 1 | 4 | | 1 | 2.3 |
| 33 | x | 4 | 3 | | 4 | | | 3 | 4 | 4 | 4 | 3 | 4 | 3 | 3 | 4 | 3 | 4 | 3 | 4 | 3.6 |
| 34 | x | 4 | 4 | | 4 | 4 | 4 | 4 | 4 | 4 | 3 | 4 | 4 | 3 | 3 | 4 | 3 | 4 | 3 | 4 | 3.7 |
| 35 | x | 4 | 4 | | 4 | | | 3 | 4 | 4 | 3 | 4 | 3 | 4 | 4 | 3 | 3 | 4 | 4 | 4 | 3.7 |
| 36 | | 2 | 2 | | | 2 | 2 | 3 | 2 | 1 | | | | 2 | | | 2 | 1 | | 1 | 1.8 |
| 37 | | 1 | 1 | 1 | | 1 | 3 | 2 | 2 | 2 | | | | 3 | | | 2 | 3 | | 1 | 1.8 |
| 38 | | 1 | 1 | | 3 | | | 2 | 2 | 2 | 3 | 2 | 3 | 3 | 2 | 3 | 3 | 4 | 2 | 3 | 2.4 |
| 39 | | 2 | 3 | | 4 | | | 3 | 3 | 3 | 3 | 2 | 2 | 3 | 3 | 2 | 3 | 4 | 3 | 4 | 2.9 |
| 40 | | 2 | 1 | | | | | 3 | 4 | 3 | 3 | 2 | 1 | 3 | 2 | 2 | 2 | 1 | 2 | 1 | 2.1 |

| | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Mean (assessor) | 2.4 | 2.7 | 2 | 3.1 | 2.8 | 3.5 | 3.2 | 3.1 | 3.1 | 3.2 | 3.6 | 3.3 | 2.9 | 2.8 | 3 | 2.6 | 3.4 | 3 | 2.6 | |

**Assessment and Discussion**

The assessment and discussion takes into account the four answer tables presented above, but also the answers to the fifth question which is related to the items that should be improved in the trial report, the comments received from the evaluators that have participated in this exercise, and the previous comments made by the applicants or by applicants and GEP contractors in the framework of dossier evaluations or GEP audits.

***Preliminary remark***

Each report has been taken as an example. The quality of one report cannot be fully related to the general quality of the GEP organization that has produced it.

***General evaluation of the trials***

Several trial reports (10, 14, 20, 21, 22, 24, 29, 30, 31, 33, 34, 35) have been (almost) unanimously evaluated by the evaluators as reports of high quality. They were all performed by GEP contractors or by the local branch of major agrochemical companies. (Reports with the mean of 'general evaluation score' $\geq 3.3$)
The institutions that have prepared these reports generally hold their trial notebooks in a computerized format. As proposed in the EPPO Standard PP 1/181: *"data on the execution of treatments, recording and measurements is often captured in a computer system directly in the field, or immediately on return to the office, for electronic transmission to headquarters where it will be used in drafting the trial report and trial series report. "*

***Study reports containing 1-4 pages***

It can be considered that these reports generally do not contain all the necessary information. They could be discarded as they are not GEP.

***Study reports in languages other than English***

Several experts have mentioned that they did not score the reports that were not presented in English or in their national language. However, they acknowledged that some of them are probably of good quality, that they seem sufficient but that they were not able to understand them.

***GEP certificate***

The GEP certificate should be included in the trial report. The certificate should preferably be written in / translated into English.
The certificate should be valid and cover the period in which the trial has been performed. (Certificates that do not belong to the institution that has performed the trial or 'authorizations for importation of plant protection product' are sometimes included in the report as GEP certificates and this is not acceptable). The scope definition in the different countries is not always as detailed.

A box "yes-no" indicating that the study is GEP is not sufficient to prove the status of the study. (In some cases, this box is disabled by the end-user in order to ease the electronic management of the data).

The large discrepancies between the evaluators that are observed for the studies 2, 6, 13, 19, 34, 38 could be explained by the fact that some evaluators do not consider the presence of the GEP certificate as absolutely fundamental, or by the fact that a box "yes-no" is sufficient.

***The preparation of the reports by the sponsors themselves***

The main companies use a centralized database system to request trials from their GEP contractors, to collect the data that are generated by the GEP contractor, to archive them, and to retrieve them to produce the individual reports and biological assessment dossiers that are submitted to the regulatory authorities.

These reports very often present the following deficiencies:

- There is a lot of confusion in the reports on who has actually performed the trial (the personnel of the GEP organization) and on the person (sometimes a member of the sponsor company) that has introduced the data in the sponsor database;
- Addenda are not always included in the sponsor database and, consequently, are not submitted to the regulatory authorities. This is often the case with weather data, soil data.
- The GEP certificate is not always present in the report
- The conclusions (+ comments) that have been prepared by the GEP organization are generally too limited and cannot be taken into account. The interpretation of the results is lacking or very limited.
- The experimental conditions are not always fully reported (depending on the boxes that have been filled in by the experimenter/ responsible person in the GEP organization or available in the sponsor customized database). Notation scales are not described.
- The layout of the report and of the text is sometimes of poor quality: tables are transformed to long lists of figures and headers, abbreviations are included that cannot be understood.

These deficiencies invalidate the reports since they lose the two qualities referred to above:
1) Comprehensiveness and readability and 2) Traceability.

This situation leads to the refusal of the dossiers with a loss of energy and time by the evaluators and by the applicants.

- **Conclusions of the EPPO Panel on General Standards on Efficacy Evaluation (March 2013)**

- The problem of inadequate trial reports has been recognized.
- The trial report should be comprehensive and readable.
- Traceability is important / needed.
- Not all reports comply with the Standard PP 1/181.
- Poor quality trial reports make the job of BAD writing more difficult.
- Good science and high quality reports are important.
- Trial reports based on high quality data, according to the principles of GEP, and good quality BAD, concise dRR (draft Registration Report) is necessary.
- Not every GEP trial can be audited; therefore some uncertainties have to be accepted.
- The work of evaluators is based on trust, as not all data can be checked.
- GEP certification should be generated by the experimental organization and not the individual experimenter and it is the responsibility of the GEP facility to produce the report.
- There was no consensus that raw data are required to be submitted in the trial report.
- ARM (software for managing and summarizing agriculture research experiments) based reports are acceptable if of sufficient quality.

The outcome from this meeting is the following recommendation to all parties involved:
*The use of EPPO Standards provides the basis for the recognition of efficacy data between countries. It was agreed that EPPO Standard PP 1/181 provides a good framework for the conduct and reporting of Efficacy trials. There was agreement that the GEP institutions, sponsors, applicants and the regulatory authorities should follow more closely the principles for GEP as outlined in the Standard PP 1/181.*

- **Conclusions of the Efficacy Evaluators meeting (October 2013)**

The main conclusions of the Belgian study (questionnaire) should be published on the EPPO website alongside a selection of anonymous examples of trials reports (14, 20, 24, 29, 30, 31, 33, 34, 35) performed according to GEP and that have been particularly valued by the efficacy evaluators.

The EPPO Working Party on Plant Protection Products and the Panel on General Standards on Efficacy Evaluation agreed with the above proposal.