Bulletin OEPP/EPPO Bulletin (2012) **42** (3), 382–393 ISSN 0250-8052. DOI: 10.1111/epp.2611

European and Mediterranean Plant Protection Organization
Organisation Européenne et Méditerranéenne pour la Protection des Plantes

PP 1/181(4)

Efficacy evaluation of plant protection products
Evaluation biologique des produits phytosanitaires

Conduct and reporting of efficacy evaluation trials, including good experimental practice

Specific scope

This standard, intended for use in association with EPPO Standards PP 1 *Efficacy evaluation of plant protection products,* describes the conduct and reporting of efficacy evaluation trials.

Specific approval and amendment

First approved in 1992-09.
First revision approved in 1996-09.
Second revision approved in 2003-09.
Revision mainly to reflect zonal assessment approved in 2012-09.

Introduction

This standard is designed to be used in conjunction with the specific EPPO Standards from the series PP 1 on efficacy evaluation of plant protection products. It provides guidance on how to organize trials, and how to plan, conduct and assess them, then record and interpret them, so as to obtain comparable and reliable results. It is also based on the principle that trials should be performed according to Good Experimental Practice (GEP), as developed below.

This standard 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. 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.

While individual EPPO standards are concerned with the conduct of single trials, this standard develops the concept of the 'trial series'. Full understanding of the performance of plant protection products can only be obtained from such trial series. Thus, results should be interpreted for the series as a whole and not only for single trials. During the setting up and conduct of trial series, successive documents are created describing the individual trials and the series. A further aim of this standard is to explain the nature, aim and content of these documents.

This standard is mainly designed for:

- The person/s responsible for writing the protocols for trial series or relevant studies (e.g. oenological tests, germination tests, taint tests);
- The person/s responsible for setting up the trials;
- The person/s responsible for assembling and submitting the biological dossier, who are advised on the successive points to be considered;
- The national authorities which are responsible for assessment of registration dossiers and which have to ensure that the data in the dossiers has been obtained following EPPO Standards and in accordance with GEP.

For the purposes of this standard, a region might be considered as a country or countries with some differences in climatic, agronomic and edaphic conditions. Where the region becomes larger and the conditions more diverse, a broader consideration of the number of trials is required. This is particularly so where there is more diversity in the agronomy of the crop as well as the severity of pest pressure and its sensitivity to plant protection products. In such situations reference to PP 1/278 *Principles of zonal data production* and evaluation should be made, where a 'region' is generally termed, an 'authorization zone'.

Conduct of trials

Individual trials

The EPPO Standards for the efficacy evaluation of plant protection products provide essential information for the conduct of individual trials. A trial is an experimental study carried out under suitable conditions to obtain information on certain effects, properties and conditions of use of plant protection products (e.g. efficacy trials, crop safety

trials). Each individual standard deals with a particular object on a particular crop (pest, growth regulator) and may include information on trials conducted for different purposes on that combination. Before writing the experimental protocols, it is essential to consult the present standard, and also the general EPPO Standards PP 1/135 *Phytotoxicity assessment*, PP 1/152 *Design and analysis of efficacy evaluation trials* and PP 1/225 *Minimum effective dose*.

EPPO Standards are generally laid out in the following order:

1. 'Experimental conditions', covering the aspects on which the experimenter can take decisions in setting up the trial.
2. 'Application of treatments', covering the products and the application conditions, which again the experimenter decides.
3. 'Mode of assessment, recording and measurements', covering the data on pest populations, damage and loss which the experimenter records during the trial. Also included are observations on meteorological and soil conditions, which are not normally within the experimenter's control.
4 'Results'.

Trial series

Product performance should be based on the interpretation of the results of a trial series as a whole, and not only on those of single trials. A trial series is a set of trials on the same subject (e.g. efficacy, or crop safety, of a given product) set up following a general experimental protocol as applicable, at different locations and/or in different years or growing seasons. Such series are sometimes called 'multi-site' or 'multi-year' trials. The trial series allows for differences in environment and climate. This is essential since the performance of a plant protection product may not be the same at different sites or in different seasons. In practice, a general experimental protocol describes the core treatments to be tested on all selected environments, allowing the experimenter to add specific practices only used locally. The analysis of a trial series is primarily based on analysing the core protocol.

Individual standards give basic recommendations on trial series. The most frequent is the following: 'The trial should form part of a trial series carried out in different regions with distinct environmental conditions and preferably in different years or growing seasons'. This recommendation is often modified according to the particular crop/pest combination. In general, the number of trials in a trial series depends on consideration of factors such as the following: overall importance of the crop and pest, severity of damage caused, cultivar effects, impact of soil and climatic factors, prior knowledge of the active substance or product in related uses, general consistency of trial results.

Additional recommendations on the conduct of trials

In some cases, the national authority may consider it useful to make additional recommendations, for example official national methods, for setting up a trial, or a trial series, in a particular area. These should respect the general principles of the specific EPPO Standard, should be limited to what is strictly necessary and should be subject to revision if the standard is revised. They may:

- Specify certain aspects of the conduct of the trial, e.g. choice of sites or cultivars, time and frequency of treatments, type, time and frequency of assessments, reference product(s), suitable methods of statistical analysis;
- Assist in the assembly of the biological dossier by indicating certain additional trials which are needed for a particular crop/pest combination (e.g. assessment of effects on the quantity and the quality of the harvested product or of processed products derived from it).

It is recommended to take account of these recommendations when setting up trials in the area concerned.

Special trials

In some cases, efficacy trials point to the existence of unwanted side-effects which may need to be assessed by special trials. EPPO Standards exist for some of these cases: phytotoxicity assessment (PP 1/135), effects on natural enemies (PP 1/142, PP 1/151, PP 1/180), effects on succeeding crops (PP 1/207), resistance risk analysis (PP 1/213). There are also other types of trial which provide data for the registration authority if it so requires: preliminary trials (especially those which cover a range of dose rates and are used to arrive at the recommended dose), minimum effective dose trials, practical use trials.

Experimental protocol

The person responsible for the trial series refers first to the specific EPPO Standard and to any additional national recommendations, and then devises an 'experimental protocol' which exactly specifies the trial series concerned. This protocol sets out the criteria followed in choosing particular sites for the trial series: geographical location, cropping conditions, soil conditions, and conditions favourable to pest development. It also sets out, for all test products and reference products, the dose rates and application times, and the type of application. If there is a risk of interference with other products, the protocol may set out the other products to be used, to ensure that they are applied uniformly throughout the trial series. The experimental protocol should cite the specific EPPO Standards followed, and also any additional recommendations which are made.

Good experimental practice

The primary aim of Good Experimental Practice (GEP) is to ensure that high-quality trials are conducted. This ensures that results can be used by different registration authorities. GEP is concerned with the management of efficacy evaluation trials and with the conditions under which trials should be planned, conducted, assessed, recorded and interpreted so that their results should be comparable and reliable. GEP relates to various aspects: staff qualifications, use of suitable equipment and facilities, protocols, modes of operation, recording of results. In practice, GEP requires consideration of the following:

- The criteria to be respected by the organizations responsible for the trials;
- The modes of operation of these organizations;
- The internal procedures for verification of the use of GEP.

A quality control unit is not required.

Criteria for organizations responsible for the trials

Identity of the organization

The organization should be official or officially recognized. The field of activity, location and structure of the organization should be known over the whole area in which a trial series is conducted. The organization should be able to ensure that GEP is applied over the whole period and geographical extent of its trials.

Identity of the trial sites

The organization should establish the identity of the trial sites and of the data coming from each, so that this identity can be maintained throughout all successive documents from the first set-up of the trial to the final report.

Management of trials

The organization should ensure structured management of its trials. It should have sufficient staff and resources to set up and manage trial series to the same standard.

Staff

The organization should employ scientific and technical staff with the appropriate training, knowledge and experience to perform the tasks assigned to them. These qualifications may derive from formal education in agriculture or a related subject, from professional experience or from continued training. Temporary staff should be adequately directed by permanent staff to ensure high-quality work.

Assignment of responsibilities

The organization should clearly assign the tasks of the staff responsible for drawing up protocols, planning trials within a series, performing trials, writing reports. The organization should ascertain that staff have the resources required for the tasks assigned and that their responsibilities are clearly defined.

Equipment

The organization should have available equipment of suitable design, in suitable quantities. The different types of equipment should be inventoried; modes of operation for their use, maintenance, adjustment and calibration should be established.

Facilities

The facilities used by the organization (buildings for storing and preparing products, buildings for storing and maintaining equipment, field plots, glasshouses and shelters, data-processing facilities, as appropriate) should be located and designed so that they can be used for high-quality trials.

Modes of operation

The organization should ensure that trials are conducted following the relevant EPPO Standards and, as appropriate, any additional recommendations for the area concerned. The organization should also define modes of operation for certain tasks not specifically covered by standards or protocols. The modes of operation which should be defined within each organization include the following: distribution, receipt and handling of products, lay-out of trial, adjustment and use of weighing apparatus, use of volumetric equipment, checking, adjustment, use and maintenance of application equipment, application of products, recording of results, sowing and planting equipment, harvesting equipment.

Verification of the use of GEP

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.

Verification at the planning stage

The experimental protocols should be validated, to ensure that EPPO Standards are followed and that additional national recommendations for the area concerned are taken into account. Any deviations from the standards or recommendations should be justified.

Verification during conduct of the trials

Results are recorded throughout trials following the mode of operation for 'Recording of results'. The organization should ensure that results are recorded in full during trials so as to be available for the preparation of the trial report or trial series report. The information to be recorded is set out in the following sections of this standard.

The different operations can be validated by the experimenters themselves, who should ensure that their procedures conform to GEP. Any deviation from the modes of operation or from the experimental protocol should be noted and reported so that the persons responsible for trials and for reporting trials are fully informed.

Information to be collected during trials: constitution of the trial notebook

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 organization may choose whether to prepare an individual trial report based on each trial notebook, or to combine the trial reports directly into a trial series report (in which case the data on each trial is generally presented in a series of appendices). In both cases, a critical analysis should be made of the conduct of every trial and, if the trial is validated, of its results.

The elements which should appear in the trial report are set out in the Appendix I, in relation to the main sections of the EPPO Standards. Under each of these main headings the essential requirements of the report are indicated, together with remarks on other elements which can also usefully be given.

Each trial report indicates the identity of the trial and contains all relevant information from the trial notebook. In general, wherever a specific EPPO Standard or the additional national recommendations state that a particular action should be carried out, the report on the trial should include adequate information to show that it was done. Where it is stated that an action may be taken, and the experimenter wishes to choose this option, adequate details should again be reported. If any part of the standard has not been followed, the report should explain the reasons for this.

Trial report and trial series report

Trial report

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 (see below).

Trial series report

Evaluation of a plant protection product for efficacy in relation to a particular crop/pest combination is almost always based on the results of a series of trials, over one or several years. A trial series report may be prepared, which then facilitates the preparation of the biological dossier. The trial series report should include, before any results are combined, a detailed critical evaluation of the trials as indicated above for the trial report. The trials covered by the trial series report are then combined, in a manner which will depend on the nature of the investigation (efficacy, crop safety, practical use).

In this analysis, results can be grouped according to comparable criteria, for example by climate, soil, species or stage of development of pest at time of treatment, infestation level, date of application, region and performance. The trial series report should include:

- The aim of the trial series;
- The experimental protocol for the series, and assessment methods;
- The list of test and reference products, with doses and application times of frequencies.

Information from the trial notebooks should be summarized, if possible by year, for example in tabular form:

- Design and lay-out of trials;
- Details of the treatment applied;
- Mode of application;
- Mode of assessment, recording and measurements;
- Results of assessment, recording and measurements;
- Results of statistical analysis.

The results of the trial series can also be subjected to suitable statistical analysis.

Biological dossier

The biological dossier contains all relevant information from the efficacy evaluation programme for a given product use, submitted to the registration authority to support the product label (Fig. 1) and to address specific data requirements in the relevant legislation (e.g. resistance risk). It forms part of the complete dossier (covering also toxicological studies, environmental studies, etc.). The biological dossier will include the reports of several trial series (see above and, if appropriate, of any special trials. It should allow a comprehensive understanding of the application for registration, and facilitate evaluation and decision-making. The biological dossier should include a proposal for the decision to be taken by the registration authority on the efficacy and conditions of use of the plant protection product for the uses proposed.

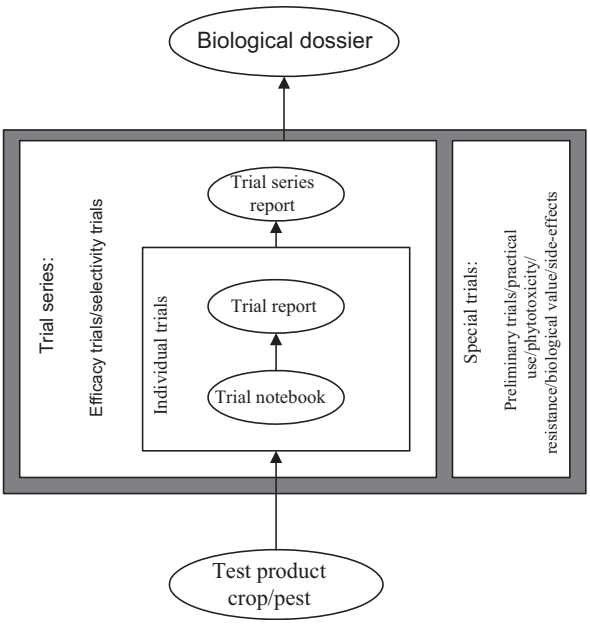

Fig. 1 Origins of biological dossier.

The biological dossier should present summaries and assessments which accurately reflect the data and information submitted in the trial reports. The main objective of the dossier is to draw conclusions from these summaries and assessments. These conclusions should cover:

- The duration of the effects of the treatment and, if relevant, the number of applications required and the suitable intervals between applications;
- Evidence that the proposed dose, timing and mode of application provide adequate results for control or protection and that they produce the required effect for all the proposed uses;
- If relevant, influence of environmental factors such as temperature or rainfall on the action of the plant protection product;
- Evidence that the plant protection product does not have unacceptable effects (such as phytotoxicity, yield reduction, quality decrease of treated crop, impact on succeeding or adjacent crops, appearance of resistance);
- If the proposed use includes recommendations on the use of the plant protection product in a mixture with other plant protection products and/or adjuvants, information on the expected results of the mixture;
- If the proposed use is to cover a broader area such as demonstrating performance and seeking authorization across a substantive area or 'authorization zone', information on the different conditions encountered across that region and performance under those conditions. Further information on such zonal submissions and evaluations is available in PP 1/278 *Principles of zonal data production and evaluation*.

Where feasible, the discussion and interpretation of the data for each of the above points should be supported by a tabular presentation of the data.

Appendix 1

Information to be collected in individual trials, presented in the sequence of the EPPO Standards

1. Experimental conditions

1.1 Objective of the trial and basic information on the trial site

The objective of the trial should be specified, including in particular:

- The pest or pests against which the crop is to be protected (give scientific names and/or EPPO Codes);
- The environment of the trial (field, glasshouse);
- The type of protection intended, as appropriate, protectant/curative, activity against certain stages (eggs, larvae, adults), activity at certain periods in the season (pre-sowing, post-harvest, etc.);
- The inclusion of other variables in the trial (dose rates, application conditions).[1]
- Whether the trial is for evaluation of efficacy, selectivity (crop safety) or another purpose (germination test, quality of the harvested product, effects on succeeding crops, etc.);

The following basic information should be provided on the trial site:

- Full address and if possible also geographical coordinates;
- Crop and cultivar;
- Any useful details on the site (e.g. exposure, slope).

1.2 Trial conditions

The relevant conditions of the plot and crop should be adequately described, e.g.:

- For an annual crop, sowing or planting date and density, row spacing;
- For a perennial crop, arrangement and spacing in rows or as single plants, pruning or training system, rootstock, canopy height, plant width, age, whether in production;
- For a glasshouse crop, arrangement within compartments, on benches, in soil-less culture, etc.

In certain cases (when the EPPO Standard requires it), the preceding crop should be specified.

The cultural conditions of the crop should be adequately described, in particular tillage, fertilizer and irrigation regimes. Information should be given on whether the crop was growing normally or was under stress at the time(s) of treatment (e.g. drought, frost, wind on effects of other overall chemical treatments, and on effects of other pests (including diseases and weeds).

1.3 Design and lay-out

The design and lay-out of the plots should be described, preferably with a plan: in particular, the number, size and

[1]If different formulations of an active substance are included in a trial, they are considered as different test products;

shape of plots, whether defined by plot dimensions on the ground or a certain lay-out of plants; the arrangement of gross and net plots, i.e. details on the protection zones between plots, including how they are planted; the assignment of the plots to treatments and to blocks (as appropriate). The type of experimental design should be indicated (for further details, see EPPO Standard PP 1/152 *Design and analysis of efficacy evaluation trials*). The arrangements made for the untreated control (included, imbricated, excluded) should be precisely indicated, together with details on any other control treatments (e.g. with/without artificial inoculation).

Particularly for herbicide trials, efficacy and selectivity trials may have different requirements, and appropriately different designs may be used in the two cases. In particular, herbicide selectivity trials will normally include the double dose as a treatment.

2. Application of treatments

Precise information should be provided on the formulation, application method, concentration and amounts of the test product. Normally, these should be the same as in the application for registration.

2.1 Test and reference products

The products included in the trial (test and reference) should be specified, giving the common name of the active substance(s) by ISO or other specified standard (if available), and also the exact name or other designation of each formulated product. For reference products, where possible, the approval number, maximum dose and any relevant usage recommendations such as application interval should be detailed. Where possible a copy of the product label should be included.

2.2 Mode of application

The information provided should be sufficient to establish that good standard practice is being followed:

- The application method and equipment used;
- Any significant deviations from the intended dosage;
- The operating conditions, insofar as they may affect efficacy or selectivity (e.g. for sprays, pressure, nozzle type, spray quality and speed of travel of sprayer);
- The number of applications made;
- The date of each application (including year, preferably by dd-mm-yyyy);
- The growth stage of the crop (and for herbicides, the weeds) at the time of each application (see BBCH Growth Stage Keys);
- Where appropriate, the development stage of the pest or infestation level at the time of each application;
- Specification of the system for timing applications (calendar, phenological stage of crop, threshold levels or development stage of pest, external warning system);
- The doses (kg or L formulated product per ha) used, and the spray volumes.[2]

If other plant protection products (or any biological control agents) have been applied to the whole trial, the same details should be provided on each. In some cases (herbicides, growth regulators), EPPO Standards may require such information on products applied in the preceding seasons.

3. Mode of assessment, recording and measurements

3.1 Meteorological and edaphic data

3.1.1 Meteorological data. The meteorological data requirements for field trials are fixed for the EPPO Standards, but with slightly different requirements for insecticides/fungicides on the one hand, and herbicides/growth regulators on the other (see individual standards). The data requirements fall into three categories:

- Observations by the experimenter around the date of application on data which may affect the course of trial. These depend on the judgement of the experimenter and need not be given in such specific detail as for the date of application. However, at least a general description of the weather during this period should be given, backed by specific data as appropriate;
- Observations made by the experimenter on the date of application, including certain standard data which should always be provided for that day;
- Observations by the experimenter throughout the trial. These relate only to extreme conditions, which should be recorded. Relevant data concerning irrigation should also be recorded.

For trials in glasshouses, appropriate requirements are specific in the standards. It may be noted that the experimenter can in this case decide to a certain extent on the glasshouse conditions. However, data provided in the report should relate to observed conditions.

3.1.2 Edaphic data. For convenience, the EPPO Standards bring together the requirements for edaphic data under a single heading. In fact, certain edaphic elements will pre-exist at the trial site, which the experimenter may have chosen partly for that reason. In other cases, the edaphic conditions of the trial site will not have been determined in advance, and the experimenter will simply have to record them, as he would for meteorological conditions.

For products likely to be influenced by soil characteristics, the basic pre-existing conditions specified are pH, organic matter content and soil type. While the results of a soil analysis may usefully be provided, it is usually sufficient for the experimenter to report simple qualitative

[2]The dose may also be specified in g active substance per ha. For certain types of application (directed along rows, drenches, seed treatments), the dose may be specified in other ways, indicated in the individual standards. See further guidance in PP 1/239 *Dose expression of plant protection products*.

information based on his observations and local knowledge. Other soil conditions arise around the time of application and have to be observed by the experimenter, e.g. moisture (whether the soil is dry, wet or waterlogged), seed-bed quality (good, moderate, poor). Again, observations need only be qualitative. Finally, while the fertilizer regime may be decided as part of the trial conditions, it may also be imposed by the owner's practice, in which case it can be regarded as edaphic data to be recorded.

If test plants are grown in composts or other artificial media, these should be described adequately and relevant details should be given of the watering and nutrient regimes used and of the containers in which the artificial media are held.

3.2 Type, time and frequency of assessment

The type and date of each assessment should be given, and should be related to the specifications of the EPPO Standard. The methods used should be described, and appropriately related to the methods specified in the EPPO Standards. In particular, any assessment scales used should be specified.

3.2.1 Direct effects on the crop. The presence or absence of phytotoxic effects should be noted for each plot, with an accurate description of any symptoms (see EPPO Standard PP 1/135 *Phytotoxicity assessment*, as appropriate). Any scale used should be specified. In any case, any problems arising with the crop should be recorded.

3.2.2 Effects on non-target organisms. Any observed effects (quantitatively and/or qualitatively assessed) on the incidence of other pests or on non-target organisms should be recorded, describing any methods used. In any case, significant occurrence of non-target pests should be recorded.

3.2.3 Yield. Yield and quality should, when specified, be recorded, taking careful note of the specific parameters required in each standard. In general, national or international standards should be followed and specified. If any special equipment is used for harvesting, this should be described.

4. Results

All data supporting the label justification should be presented simply and systematically, preferably in a harmonized and tabular form. This body of results from individual trials, used to justify the product label, is assembled into the appendix of the Biological Dossier.

Suggested tables, from each individual trial, for inclusion in the appendix include the 'Product test materials summary', the 'Site details summary', and the 'Single-trial summary'. Data from these is also assembled into a 'Multi-trial summary'. Details are given in Appendix II on the suggested content of these tables (Tables 1–4). Unusual results should be reported and explained. The raw data, i.e. the results of the assessments for individual plots or samples within plots, should be available in an electronic medium on request. If the appendix is prepared for submission in electronic format, the tables can usefully be arranged so they are searchable and sortable by specific parameters (e.g. cultivar, soil type, etc.) as far as is practically possible.

Table 1 Product test material parameters

Item no.	Description
1	Treatment name, commercial or experimental
2	Formulation number, company-specific denomination
3	Formulation type, GIFAP code
4	Active substance(s); common names
5	Concentration of each active substance
6	Concentration unit (g active substance per L or per kg
7	Approval no. (country)
8	Approved/recommended dose
9	Additional information
10	Other

Table 2 Site detail – typical parameters

Item no.	Description
1	Trial number/ID; company designator
2	GEP (yes/no)
3	Testing facility
4	EPPO or other standards
5	Crop; EPPO Code or common name
6	Cultivar
7	Location
8	Sowing/planting date
9	Crop density (e.g. distance between rows and between plants in the row; height of the plants and mid-width of the crown)
10	Seed rate
11	Soil type (= texture)
12	Soil pH
13	Soil organic matter
14	Soil sand
15	Soil silt
16	Soil clay
17	Soil cation exchange capacity (CEC)
18	Previous crop
19	Tillage regime
20	Plot size (net and gross); area or number
21	No. of replicates
22	Trial design
23	Application date(s)
24	Spray volume(s)
25	Meteorological data*
26	Soil moisture
27	Infection type
28	Artificial infection date(s)
29	Other*

*Meteorological data, targets present, other plant protection products used overall, fertilizer regimes and other parameters if relevant, should normally be presented in separate tables or graphics due to the nature of this data.

Table 3 Single-trial parameters

Item no.	Description
1	Trial number/ID; company designator
2	Treatment name, commercial or experimental
3	Formulation number, company designator
4	Crop and cultivar
5	Concentration/concentration unit
6	Application date/growth state of crop
8	Target (and stage at application if relevant)
9	Application rate/unit
10	Evaluation date/growth state of crop
11	Evaluation type (count, visual estimate)
12	Evaluation units (%, number, etc.)
13	Part evaluated (plot, leaves, stem)
14	Treatment evaluation interval
15	Transformation
16	Evaluation data (treatment means)
17	Statistical analysis
18	Other

Table 4 Multi-trial parameters

Item no.	Description
1	Trial number/ID; company designator
2	Treatment name, commercial or experimental
3	Formulation number, company designator
4	Crop; EPPO Code or common name
5	Cultivar
6	Application date
7	Crop growth stage (BBCH code)
8	Target; EPPO Code
9	Target stage at application; if relevant
10	Spray volume
11	Application rate/unit
12	Evaluation type (count, visual estimate)
13	Evaluation unit (%, number, weight)
14	Part evaluated (plot, leaf, stem, root)
15	Treatment evaluation interval
16	Transformation
17	Evaluation data (treatment means)
18	Statistical analysis
19	Other

The data in the appendix (Tables 1–4) should be used to prepare special Summary Tables included in the textual part of the dossier, to explain and support the different points addressed in the Biological Dossier. The format of these Summary Tables will depend on the individual case, and no special guidance is provided in this Standard.

In general, wherever statistical analysis has been used in relation to the data in the Biological Dossier, the methods should be clearly indicated, including any transformations used and the reasons for using them.

Treatment Name	Type	Active Substances (a.s.)	Conc./Unit	Approval No.	Recommended dose	Others
Dursban4	EC	chlorpyrifos-ethyl	480 g a.s./L	Uk4711	1.5 L/ha	
Tracer	SC	spinosad	480 g a.s/L	BBA123	3.5 L/ha	
Reldan22	EC	chlorpyrifos-methyl	223 g a.s./L			
Karate 5EC	EC	lambda-cyhalothrin	50 g a.s./L			
Dimilin	WP	diflubenzuron	250 ga.s./kg			
Vertimec	EC	abamectin	18 g a.s./L			
Novodor	SC	*Bacillus thuringiensis* var. *tenebrionsis*	10 000 IU/mg			
Agri-dex	SO	crop oil concentrate	1000 g/L			

Fig. 2 Example of a product test materials summary.

Appendix 2

Presentation of the results of individual trials in the biological dossier

This Appendix gives the suggested content of the 'Product test materials summary', the 'Site details summary', the 'Single-trial summary' and the 'Multi-trial summary' Table in the Biological Dossier (Tables 1–4). For illustrative purposes only, examples are shown of harmonized tabular formats (Figs 2–7) for presenting the data.

Product test materials summary

The table should contain as appropriate the parameters described in Table 1. An example is given in Fig. 2.

Site details summary

The site details for each individual trial are summarized in Table 2. The presentation of the details is designed with some flexibility to include typical parameters in a concise format that could be used to interpret the data. Not all parameters will be relevant in every case, and in some cases additional parameters may be needed. Examples are given in Fig. 3 (single application) and Fig. 4 (multiple application).

Single-trial summary

This summary is designed to present the summarized results (Table 3) of an individual trial for at least the major pests or targets, for which a registration is claimed. The statistical analysis for each target, if relevant and adequate, is also included. An example is given in Fig. 5.

Multi-trial summary

This summary is designed to present in a two-way table format the summarized results, including relevant statistical parameters, of all the trials done in support of the claims of the label. As indicated in the official international guidance documents, each table should contain the results for one specified target or parameter. The included parameters are described in Table 4. Examples are given in Fig. 6 (single application) and Fig. 7 (multiple application).

Trial series Trial no. Country, Region	Testing Facility GEP Y/N EPPO GL	Test crop Variety Sowing or planting date Artificial inoculation Previous crop	Soil type Soil pH/ OM% Sand/Silt/Clay (%) Soil CEC	Application details: Type of equip./Type of nozzles/ Temp/Pressure/Volume Application Date	Experim. design No. of replicates Plot Size Test method
1 DEV-F-1999-ZX-012-A-01,0 DE-D01-018 GERMANY BADEN-WUERTTEMBERG ---	BASF yes 26, 135, 152, 181	WHEAT, WINTER KANZLER 30/09/1998 no	LOAM 6.6 / 1.8 13 / 65 / 21 ---	SPT / XR8003 / 22 C / 2.8 BAR / 400 L/HA / 22Mar99	RCB 4 10 M2 ---
2 DEV-F-1999-ZX-012-A-01,0 DE-D02-012 GERMANY SAXONY-ANHALT ---	BASF yes 26, 135, 152, 181	WHEAT, WINTER KANZLER --- no	--- --- --- ---	SPT / XR8002VS / 25 C / 2 BAR / 400 L/HA 01Apr99	RCB 4 10 M2 ---
3 DEV-F-1999-ZX-012-A-01,0 DE-D03-012 GERMANY SCHLESWIG-HOLSTEIN ---	BASF yes 26, 135, 152, 181	WHEAT, WINTER RITMO 19/10/1998 no	LOAM 6.8 / 1.0 --- ---	SPT / XR 8002VS / 29 C / 2 BAR / 300 L/HA / 29Mar99	RCB 4 10 M2 ---
4 DEV-F-1999-ZX-012-A-01,0 DE-D04-027 AUSTRIA STYRIA ---	BASF yes 26, 135, 152, 181	WHEAT, WINTER RITMO 16/10/1998 no	LOAM 6.9 / 4.4 10 / 76 / 14 ---	SPT / XR 8004VS / 20 C / 1.8 BAR / 300 L/HA / 18Apr99	RCB 4 12.5 M2 ---
5 DEV-F-1999-ZX-012-A-01,0 DE-D05-319 GERMANY SAXONY-ANHALT ---	BASF yes 26, 135, 152, 181	WHEAT, WINTER RITMO 24/09/1998 no	SANDY LOAM 6.9 /2.0 --- ---	FPT / XR8002 / 16 C / 2.6 BAR / 300 L/HA / 15Apr99	RCB 4 14.75 M2 ---
6 DEV-F-1999-ZX-012-A-01,0 DE-D07-022 GERMANY SAXONY-ANHALT ---	BASF yes 26, 135, 152, 181	WHEAT, WINTER ATLANTIS 13/10/1998 no	SANDY LOAM 7.1 / 2.6 33 /64 / 3 ---	SPT / SS8002 / 21 C / 2.5 / 400 L/HA / 15Apr99	RCB 4 12.5 M2
7 DEV-F-1999-ZX-012-A-01,0 DE-D08-112 AUSTRIA VORARLBERG ---	BASF yes 26, 135, 152, 181	WHEAT, WINTER RITMO 08/11/1998 no	SILTY LOAM 6.9 / 1.7 --- ---	SPT / XR8002VS / 15 C / 2 / 400 L/HA / 12Apr99	RCB 4 15 M2 ---
8 DEV-F-1999-ZX-012-A-01,0 DE-D09-920 GERMANY BAVARIA ---	BASF yes 26, 135, 152, 181	WHEAT, WINTER KANZLER 26/09/1998 no	VERY LOAMY SAND(LOESS) --- --- ---	SPT / XR8002 / 13 C / 2 BAR / 400 L/HA / 30Mar99	RCB 4 13.75 M2 ---
9 DEV-F-1999-ZX-012-A-01,0 DE-D11-016 AUSTRIA VORARLBERG ---	BASF yes 26, 135, 152, 181	WHEAT, WINTER TORONTO 23/09/1998 no	LOAMY SAND 6.3 / 1.9 82 / 13 / 5 ---	FPT / XR8002 / 20 C / 3 BAR / 300 L/HA / 01Apr99	RCB 4 15 M2 ---
10 DEV-F-1999-ZX-012-A-01,0 DE-D12-120 GERMANY BAVARIA ---	BASF yes 26, 135, 152, 181	WHEAT, WINTER MONOPOL 10/10/1998 no	LOAMY CLAY 6.8 / 3.0 2 / 75 / 22 ---	SPT / XR8003 / 19 C / 1.5 / 300 L/HA / 16Apr99	RCB 4 12.5 M2 ---
11 DEV-F-1999-ZX-012-A-01,0 DE-D13-912 GERMANY LOWER SAXONY ---	BASF yes 26, 135, 152, 181	WHEAT, WINTER RITMO 12/10/1998 no	SANDY LOAM 7.6 / 3.0 --- ---	SPT / XR8003 / 20 C / 2.5 BAR / 300 L/HA / 12Apr99	RCB 4 12.5 M2 ---
12 DEV-F-1999-ZX-012-A-01,0 DE-D14-016 GERMANY BADEN-WUERTTEMBERG ---	BASF yes 26, 135, 152, 181	WHEAT, WINTER MONOPOL 21/11/1998 no	LOAM --- --- ---	SPT / XR 8002 / 19 C / 2 BAR / 400 L/HA / 15Apr99	RCB 4 15 M2 ---
13 DEV-F-1999-ZX-012-A-01,0 DE-D15-016 GERMANY BADEN-WUERTTEMBERG ---	BASF yes 26, 135, 152, 181	WHEAT, WINTER BATIS 16/10/1998 no	--- --- --- ---	SPT / XR8002 / 25 C / 2.5 BAR / 300 L/HA / 30Apr99	RCB 4 15 M2 ---

Fig. 3 Example of a site details summary for a single application.

Testing Facility GEP Y/N EPPO GL	Test crop Variety Sowing or planting date Artificial inoculation Previous Crop	Soil type Soil pH/ OM% Sand/Silt/Clay (%) Soil CEC	Application details: Type of equip./Type of nozzles/ Temp/Pressure/Volume Application Date	Experim. design No. of replicates Plot Size Test method
BASF yes 31, 152,181	GRAPE, EUROPEAN MULLER-THURGEAU 1992 no ---	SANDY LOAM 6.7 / 1.8 23 / 55 / 21 ---	TSP / 110015 / 17C / 10BAR / 600 L/HA / 01Apr99 TSP / 110015 / 26C / 10BAR / 600 L/HA / 15Apr99 TSP / 110015 / 20C / 10BAR / 800 L/HA / 02May99 TSP / 110015 / 14C / 10BAR / 1000 L/HA / 18May99 TSP / 110015 / -- / 10BAR / 1200 L/HA / 29May99 SPT / XR8002VS / 25 C / 2 BAR / 1200 L/HA / 16Jun99	RCB 4 30 M2 ---
BASF yes 31, 152,181	GRAPE, EUROPEAN --- --- no ---	LOAM 6.6 / 1.8 13 / 65 / 21 ---	TSP / ALBUSGELB / 18C / 8BAR / 600 L/HA / 18Apr99 TSP / ALBUSGELB / 22C / 8BAR / 600 L/HA / 02May99 TSP / ALBUSGELB / 18C / 8BAR / 800 L/HA / 18May99 TSP / ALBUSGELB / 19C / 8BAR / 1000 L/HA / 30May99 TSP / ALBUSGELB / 21C / 8BAR / 1200 L/HA / 19Jun99 TSP / ALBUSGELB / 22C / 8BAR / 1400 L/HA / 30Jun99	RCB 4 24 M2 ---
BASF yes 31, 152,181	GRAPE, EUROPEAN --- --- no ---	LOAMY SAND	SDG / XR8002VS / 19C / 3BAR / 800 L/HA / 02May99 SDG / XR8002VS / 21C / 3BAR / 800 L/HA / 22May99 SDG / XR8002VS / 20C / 3BAR / 1200 L/HA / 04Jun99 SDG / XR8002VS / 23C / 3BAR / 1200 L/HA / 14Jun99 SDG / XR8002VS / 26C / 3BAR / 1400 L/HA / 01Jul99	RCB 4 20 M2 ---
BASF yes 31, 152,181	GRAPE, EUROPEAN --- 1986 no ---	SAND	SDG / XR8002VS / 24C / 3BAR / 800 L/HA / 03May99 SDG / XR8002VS / 19C / 3BAR / 1000 L/HA / 13May99 SDG / XR8002VS / 24C / 3BAR / 1000 L/HA / 30May99 SDG / XR8002VS / 21C / 3BAR / 1200 L/HA / 15Jun99 SDG / XR8002VS / 26C / 3BAR / 1400 L/HA / 01Jul99 SDG / XR8002VS / 22C / 3BAR / 1400 L/HA / 18Jul99 SDG / XR8002VS / 27C / 3BAR / 1800 L/HA / 04Aug99	RCB 4 20 M2 ---
BASF yes 31, 152,181	GRAPE, EUROPEAN MULLER-THURGEAU --- no ---	LOAMY SAND 6.6 / 1.8 13 / 65 / 21 ---	SDG / XR8002VS / 24C / 3BAR / 800 L/HA / 04May99 SDG / XR8002VS / 19C / 3BAR / 1000 L/HA / 16May99 SDG / XR8002VS / 24C / 3BAR / 1200 L/HA / 01Jun99 SDG / XR8002VS / 21C / 3BAR / 1400 L/HA / 15Jun99 SDG / XR8002VS / 26C / 3BAR / 1600 L/HA / 01Jul99 SDG / XR8002VS / 22C / 3BAR / 1800 L/HA / 18Jul99 SDG / XR8002VS / 27C / 3BAR / 2000 L/HA / 04Aug99	RCB 4 20 M2 ---
BASF yes 31, 152,181	GRAPE, EUROPEAN --- --- no ---	SAND	SDG / XR8002VS / 15C / 3BAR / 800 L/HA / 03May99 SDG / XR8002VS / 18C / 3BAR / 1000 L/HA / 20May99 SDG / XR8002VS / 21C / 3BAR / 1200 L/HA / 10Jun99 SDG / XR8002VS / 22C / 3BAR / 1400 L/HA / 28Jun99 SDG / XR8002VS / 23C / 3BAR / 1600 L/HA / 14Jul99 SDG / XR8002VS / -- / 3BAR / 1800 L/HA / 01Aug99	RCB 4 16 M2 ---

Fig. 4 Example of a site details summary for a multiple application.

		Evaluation date		24May02	03June02		16July02	
		Trt-Eval interval		0DAA1	10DAA1		13DAA3	
		Target		PIERBR	PIERBR		PIERBR	
		Crop growth stage		37-39	39		45	
		Target stage		L 1-2	L2		L4 P	
		Evaluation type		Control	Control		Control	
		Part evaluated		Plant	Plant		Plant	
Treatment Name	**Conc.**	**Application rate**	**Application Date**	**GS crop Application**	**Count**	**Count**	**% control (log transformation)**	**Count**	**% control (log transformation)**
Product A	100 g a.s./L	0.1 L/ha	24May02	37-39	1	4.3	28.3 b	8.6	49.4 c
Product A	100 g a.s./L	0.15 L/ha	24May02	37-39	1	3.5	41.7 b	5.2	69.4 ab
Product A	100 g a.s./L	0.2 L/ha	24May02	37-39	1	1.2	80 a	0.3	98.2 a
Standard B	500 g a.s./kg	0.5 kg/ha	24May02	37-39	1	1.6	73.3 a	0.34	98 a
Standard C	150 g a.s./L	1.0 L/ha	24May02	37-39	1	4.2	30 b	8.9	47.6 c
Untreated	-	-	24May02	37-39	1	6	0 c	17	0 d
			CV%				12.6		18.9
			SE_mean				0.24		0.34
			Replicate Prob (F)				0.56		0.98
			Treatment Prob (F)				0.001		0.001
			MRT				SNK (0.05)		Tukeys (0.05)

Fig. 5 Example of a single-trial summary.

Trial series Trial no. GEP Y/N	Country Region Crop Cultivar	Date of treatment/ Growth stage crop (BBCH)/ Growth stage target (BBCH)/ Water volume	Timing of Assessment DAFT	Assessed Variable (calculated)	Untreated	BAS 48107F 1.5 L/ha	BAS 49303F 1.0 L/ha	Standard 1	 2	 Code
1 DEV-F-1999-ZX-012-A-01,0 DE-D01-018 no	GERMANY --- WHEAT, WINTER KANZLER	26.05.1999 / - 39 - / --- / 400 L/HA	115	Yield (dt/ha) SNK	57,91 a	68,83 b	69,44 b	68,26 b	70,03 b	1=A 2=B
2 DEV-F-1999-ZX-012-A-01,0 DE-D02-012 no	GERMANY --- WHEAT, WINTER KANZLER	31.05.1999 / 47 - 49 - / --- / 400 L/HA	104	Yield (dt/ha) SNK	74,96 a	84,84 b	86,78 b	82,16 b		1=A
3 DEV-F-1999-ZX-012-A-01,0 DE-D03-012 no	GERMANY --- WHEAT, WINTER RITMO	29.05.1999 / - 49 - / --- / 300 L/HA	96	Yield (dt/ha) SNK	80,53 a	97,83 b	100,62 b	95,6 b		1=B
4 DEV-F-1999-ZX-012-A-01,0 DE-D04-027 no	GERMANY --- WHEAT, WINTER RITMO	31.05.1999 / 39 - 49 - / --- / 300 L/HA	112	Yield (dt/ha) SNK	100,65 a	111,65 b	114,14 c	113,21 b		1=B
5 DEV-F-1999-ZX-012-A-01,0 DE-D05-319 no	GERMANY --- WHEAT, WINTER RITMO	02.06.1999 / 39 - 41 - / --- / 300 L/HA	111	Yield (dt/ha) SNK	98,36 a	118,09 b	120,85 b	116,39 b	102,36 a	1=A 2=C
6 DEV-F-1999-ZX-012-A-01,0 DE-D07-022 no	GERMANY --- WHEAT, WINTER ATLANTIS	28.05.1999 / 39 - - / --- / 400 L/HA	107	Yield (dt/ha) SNK	84,69 a	102,48 b	105,94 b	---	---	---
7 DEV-F-1999-ZX-012-A-01,0 DE-D08-112 no	GERMANY --- WHEAT, WINTER RITMO	29.05.1999 / 39 - 49 - / --- / 400 L/HA	108	Yield (dt/ha) SNK	70,94 a	102,89 b	107,62 b	104,2 b		1=B
8 DEV-F-1999-ZX-012-A-01,0 DE-D09-920 no	GERMANY --- WHEAT, WINTER KANZLER	17.05.1999 / 39 - 43 - / --- / 400 L/HA	112	Yield (dt/ha) SNK	64,72 a	89,22 b	93,81 c	88,36 b		1=C
9 DEV-F-1999-ZX-012-A-01,0 DE-D11-016 no	GERMANY --- WHEAT, WINTER TORONTO	27.05.1999 / 37 - 45 - / --- / 300 L/HA	105	Yield (dt/ha) SNK	74,63 a	92,62 b	95,06 b	75,61 a		1=C
10 DEV-F-1999-ZX-012-A-01,0 DE-D12-120 no	GERMANY --- WHEAT, WINTER MONOPOL	19.05.1999 / - - 45 - / --- / 300 L/HA	114	Yield (dt/ha) SNK	67,13 a	75,53 b	77,21 b	78,1 b		1=A
11 DEV-F-1999-ZX-012-A-01,0 DE-D13-912 no	GERMANY --- WHEAT, WINTER RITMO	28.05.1999 / 49 - 49 - / --- / 300 L/HA	97	Yield (dt/ha) SNK	74,01 a	87,06 b	91,48 c	87		1=A
12 DEV-F-1999-ZX-012-A-01,0 DE-D14-016 no	GERMANY --- WHEAT, WINTER MONOPOL	31.05.1999 / 39 - 45 - / --- / 400 L/HA	103	Yield (dt/ha) SNK	72,18 a	82,74 b	85,48 b	---		---
13 DEV-F-1999-ZX-012-A-01,0 DE-D15-016 no	GERMANY --- WHEAT, WINTER BATIS	30.05.1999 / 39 - 49 - / --- / 300 L/HA	99	Yield (dt/ha) SNK	62,7 a	74,34 b	74,96 b	74,11		1=A
				Yield (dt/ha) SNK	75,65	91,39	94,11			

Standard A Product X 1. L pr/ha
Standard B Product X 2.0 L pr/ha
Standard C Product Y 2.5 L pr/ha

Fig. 6 Example of a multi-trial summary for a single application.

Trial series Trial no. GEP Y/N	Country Region Crop Cultivar	Date of treatment/ Growth stage crop (BBCH)/ Growth stage target (BBCH)/ Water volume	Plant part	Timing of assessment DAFT	Assessed Variable (calculated)	Eval. Unit	Untreated	ABCD 0,16 % W/V	ABCD 0,20 % W/V	Standard 1,00	Standard 2,00	Standard Code
1	GERMANY, FED.REP.	14.05.1999 / 13 - 14 - / --- / 600 L/HA	RACEME	82	Frequency	%	16,75	0,00	0,00	0,00	0,00	1=A
DEV-F-1999-ZX-311-A-01,0	---	26.05.1999 / 53 - 54 - / --- / 600 L/HA	RACEME	82	Intensity	%	2,69	0,00	0,00	0,00	0,00	2=B
DE-D06-006	GRAPE, EUROPEAN	08.06.1999 / 61 - 62 - / --- / 800 L/HA	RACEME	95	Frequency	%	19,54	0,00	0,00	0,00	0,00	
no	ORTEGA	22.06.1999 / 68 - 69 - / --- / 1000 L/HA	RACEME	95	Intensity	%	2,10	0,00	0,00	0,00	0,00	
		08.07.1999 / 72 - 73 - / --- / 1200 L/HA										
		26.07.1999 / 78 - 79 - / --- / 1400 L/HA										
		09.08.1999 / 81 - 82 - / --- / 1600 L/HA										
2	GERMANY, FED.REP.	18.05.1999 / 11 - 13 - / --- / 600 L/HA	RACEME	76	Frequency	%	42,75	2,00	0,50	0,75	0,75	1=A
DEV-F-1999-ZX-311-A-01,0	---	31.05.1999 / 30 - - / --- / 600 L/HA	RACEME	76	Intensity	%	13,42	1,25	0,00	0,00	0,00	2=C
DE-D09-951	GRAPE, EUROPEAN	14.06.1999 / 57 - - / --- / 800 L/HA										
no	KERNER	28.06.1999 / 68 - - / --- / 1000 L/HA										
		12.07.1999 / 71 - - / --- / 1200 L/HA										
		27.07.1999 / 75 - - / --- / 1400 L/HA										
		10.08.1999 / 81 - - / --- / 1600 L/HA										
3	GERMANY, FED.REP.	19.05.1999 / 53 - 53 - / --- / 800 L/HA	RACEME	86	Frequency	%	32,00	0,00	0,00	0,00	0,00	1=D
DEV-F-1999-ZX-501-A-01,0	---	01.06.1999 / 55 - 55 - / --- / 800 L/HA	RACEME	86	Intensity	%	1,87	0,00	0,00	0,00	0,00	2=B
DE-VTV-001	GRAPE, EUROPEAN	15.06.1999 / 57 - 61 - / --- / 800 L/HA										
no	KERNER	29.06.1999 / 69 - 71 - / --- / 1200 L/HA										
		13.07.1999 / 75 - 77 - / --- / 1200 L/HA										
		27.07.1999 / 78 - 79 - / --- / 1600 L/HA										
		09.08.1999 / 81 - 81 - / --- / 1600 L/HA										
4	GERMANY, FED.REP.	02.06.1999 / 55 - 55 - / --- / 800 L/HA	RACEME	67	Frequency	%	98,00	2,67	4,67	11,33		1=A
DEV-F-1999-ZX-503-A-01,0	---	16.06.1999 / 57 - 61 - / --- / 800 L/HA	RACEME	67	Intensity	%	40,98	0,13	0,23	0,67		
DE-VTV-005	GRAPE, EUROPEAN	30.06.1999 / 69 - 71 - / --- / 1200 L/HA	RACEME	76	Frequency	%	100,00	6,67	7,33	30,00		
no	MUELLER THURGAU	16.07.1999 / 75 - 77 - / --- / 1200 L/HA	RACEME	76	Intensity	%	47,84	0,33	0,37	1,83		
		28.07.1999 / 78 - 79 - / --- / 1600 L/HA	RACEME	89	Frequency	%	100,00	5,33	8,00	38,67		
		11.08.1999 / 81 - 81 - / --- / 1600 L/HA	RACEME	89	Intensity	%	67,07	0,27	0,40	3,23		
Meanvalues				67	Frequency	%	98,00	2,67	4,67	11,33		
				67	Intensity	%	40,98	0,13	0,23	0,67		
Standard A	Product X 1.0 L pr/hL			n			1	1	1	1		
Standard B	Product X 1.2 L pr/hL			76	Frequency	%	71,37	4,33	3,91	15,38		
Standard C	Product Y 0.35 L pr/hL			76	Intensity	%	30,63	0,79	0,18	0,91		
Standard D	Product Z 0.75 kg pr/hL			n			2	2	2	2		
				82 - 86	Frequency	%	24,37	0,00	0,00	0,00		
				82 - 86	Intensity	%	2,28	0,00	0,00	0,00		
				n			2	2	2	2		
				89 - 95	Frequency	%	59,77	2,67	4,00	19,34		
				89 - 95	Intensity	%	34,58	0,13	0,20	1,61		
				n			2	2	2	2		

Fig. 7 Example of a multi-trial summary for multiple applications.