EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Safety of the food chain
Chemicals, contaminants, pesticides

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GUIDANCE DOCUMENT ON DATA REQUIREMENTS ON EFFICACY FOR THE DOSSIER TO BE SUBMITTED FOR THE APPROVAL OF NEW ACTIVE SUBSTANCES[1] CONTAINED IN PLANT PROTECTION PRODUCTS

SANCO E3 WORKING DOCUMENT DOES NOT NECESSARILY REPRESENT THE COMMISSION'S VIEWS

[1] As defined under Regulation (EC) No 1107/2009.

Contents

Introduction

Regulation (EC) No 1107/2009 is divided into Chapter II on the approval of active substances, and Chapter III on the authorisation of plant protection products containing approved active substances.

Regulation (EC) No 1107/2009 states in Chapter II, Article 4(3), that 'a plant protection product, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use, shall meet the following requirements: a) it shall be sufficiently effective and c) it shall not have any unacceptable effects on plants or plant products. Regulation (EC) No 1107/2009 Annex II point 3.2 also states that 'an active substance alone or associated with a safener or synergist shall only be approved where it has been established for one or more representative uses that the plant protection product, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use is sufficiently effective. This requirement shall be evaluated in accordance with the uniform principles for evaluation and authorisation of plant protection products referred to in Article 29(6).'

The Regulation also states in Article 8 that a summary dossier shall include information with respect to one or more representative uses on a widely grown crop in each EU Regulation 1107/2009 zone of at least one plant protection product containing the active substance, demonstrating that the approval criteria provided for in Article 4 are met i.e. sufficiently effective and with no unacceptable effects on plants or plant products. It also states that 'where the information submitted does not cover all zones or concern a crop which is not widely grown, justification for this approach'.

Chapter III, Article 29 (e) which deals with the authorisation of plant protection products containing approved active substances repeats the requirements of Article 4(3) on effectiveness and the absence of unacceptable effects on plants or plant products.

It is very important to make a distinction between efficacy of an active substance at the approval stage and efficacy of plant protection products containing that active substance at the authorisation stage.

The efficacy of an active substance determines the GAP and therefore the 'risk envelope.'[2] The GAP and 'risk envelope' for the most part form the basis for all other aspects of the risk assessment (e.g. consumer risk, operator exposure, environmental risk). The risk envelope approach for some special categories of plant protection products e.g. low risk products or products that contain microorganisms might not be applicable to certain parts of dossiers or to the entire dossier and in this case risk envelope needs to be adapted accordingly or not to be followed at all. Where the 'risk envelope approach' is applicable it is very important that the GAP for active substances are based on realistic assumptions that particularly encompass the 'worst case' GAP. In effect data are required only to establish that the proposed dose(s) is/are sufficiently effective and selective, and that broadly speaking appropriate.

For authorisation of a plant protection product containing an approved active substance there needs to be a consideration not only of effectiveness and crop safety for **all** proposed uses but also of resistance, risks to adjacent and succeeding crops etc. These together determine the

[2] SANCO Guidance document SANCO/11244/2011 rev+. 5 'Guidance document on the preparation and submission of dossiers for plant protection products according to the "risk envelope approach'.

practical agronomic use of plant protection products that goes beyond the 'risk envelope'. The existence of a full efficacy evaluation that completely satisfies the demands of Regulation (EC) 1107/2009 is important and will be made as part of product authorisations for all uses. Efficacy data requirements for plant protection products are outlined in Commission Regulation (EU) 545/2011.

Taken literally the efficacy requirements for the approval of active substances and the authorisation of plant protection products containing approved active substances could be interpreted within the Regulation as being identical. However, as highlighted previously, the purpose of the efficacy consideration at active substance level compared to plant protection product is entirely different. This document aims to provide guidance on efficacy requirements for new active substances, and in particular explains the principal objective of an efficacy assessment at the active substance approval stage. The aim should be to avoid a duplication of evaluation work for at least some of the individual GAP, which may otherwise result if efficacy is comprehensively considered for all uses both at approval of the active substance **and** at product authorisation. **The principal objective of the efficacy evaluation of an active substance is to confirm that the doses are realistic for the GAP submitted for risk evaluation and approval and representative for all subsequent authorisations. A summary dossier (as proposed in the appendix of this document) should be submitted.**

(It should be noted that the efficacy requirements for existing active substances when considered in the renewal procedure are different and are presented in Guidance Document SANCO/10387/2010, point 4.7.2).

General requirements

There must be at least one representative formulation available. Under Article 8 there is also an assumption that there is at least one representative use on a widely grown crop in each EU Regulation 1107/2009 zone, or a justification for presenting a use in only one zone.

The GAP with the maximum field rate for each principal crop type/application method (e.g. arable, top fruit, vine, seed treatment) should be identified in the format of the agreed Vol. 1 GAP table, and a summary of effectiveness and crop safety for a representative pest/crop/situation of each should be presented (see Table 1 example). Applicants should consider carefully when providing such evidence which uses will be representative of the 'worst case' GAP in different EU Regulation 1107/2009 zones.

Under Chapter II, Article 4(3) the text relevant to efficacy states that for approval of an active substance 'a plant protection product, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use, shall meet the following requirements: a) it shall be sufficiently effective' and 'c) it shall not have any unacceptable effects on plants or plant products'.

There is no definition in Regulation (EC) No 1107/2009 of 'sufficiently effective' or indeed 'unacceptable effects'. However, guidance is available within Commission Regulation (EU) 546/2011 which outlines the uniform principles for evaluation and authorisation of plant protection products and also EPPO guideline PP1/214 'Principles of acceptable efficacy'. The latter for example states that the product should show results that are significantly superior to those recorded in the untreated control, i.e. that the use of the product is better than no use. The

product should show a consistent, well-defined benefit to the user. The level of effectiveness (however defined) required to deliver such benefits will vary between different crop/target uses, and depend on the biology of the target and nature of the economic damage caused. In addition PP1/214 states that the performance of the test product should be at least of the same order as that of a reference product. However, the guideline notes that if the test product has distinctly lower direct efficacy (i.e. effectiveness) against the target pest or in modifying plant growth than that of the reference product, it may still be possible to regard this as acceptable (provided a benefit is demonstrated) if other characteristics of the test product have advantages over the reference product'. This may be particularly relevant in the consideration of biopesticides (e.g. microbials, semiochemicals, plant extracts) which by their nature or mode of action may have lower, delayed and/or more variable effects than many conventional chemical pesticides but may have other favourable properties i.e. as part of Integrated Pest Management strategies.

The active substance must also have no unacceptable effects on plants or plant products. The term 'unacceptable effects' is not defined and the concept of acceptability is difficult to define in crop protection terms, because it is a balance between any adverse effects and the benefits from effectiveness against the intended targets. This is explained in greater detail in EPPO PP1/214 'Principles of acceptable efficacy'. However, if this is interpreted as unacceptable levels of phytotoxicity then EPPO PP1/135 'Phytotoxicity assessment' provides relevant guidance on how this should be assessed.

The environmental fate assessment for the active substance may identify representative scenarios that predict contamination of groundwater by the active substance or individual metabolite(s) at > 0.1 µg/l. Any metabolite, which might be expected to be at >0.1 µg/l in groundwater, is further assessed. This is essentially a 3-stage assessment involving (i) biological activity screening, (ii) genotoxicity hazard screening, and (iii) toxicity hazard screening. Specific guidance is provided under SANCO/221/2000-rev.10-final 25 February 2003 guidance, section 4. Step 3a. The efficacy assessment of a new active substance may therefore also need to consider the 'biological relevance' of any metabolites that are predicted to contaminate groundwater at levels > 0.1 µg/l.

Efficacy data requirements for the approval of new active substances

Regulation 1107/2009 states that for an application for authorisation of a plant protection product containing an active substance not yet approved, the Member State examining the application shall start the evaluation as soon as it has received the draft assessment report.

In order to address the efficacy data requirements for the active substance evidence must be submitted to demonstrate that the dose(s) proposed is/are sufficiently effective and selective, and broadly speaking appropriate.

Therefore results of testing should be submitted to demonstrate the effectiveness of the active substance against at least one of the target species for which authorisation will be sought, and if appropriate, a range of crop species. Data on non-target plant testing and models of GR50 values should suffice at this stage for consideration of the risks to adjacent and succeeding crops. Data should be supplemented by the results of realistic field trials from at least one year in at least one crop, and on at least one of the target species using the representative formulation. Field trials *preferably* in line with EPPO Standard PP 1/181 *Conduct and reporting of efficacy evaluation trials, including good experimental practice* should be from a relevant region and should seek to confirm that the GAP is based on realistic practical conditions. However, the results from other field trials may be submitted where relevant. Where trials are conducted outside of the EU these

must be conducted to equivalent standards and a case must be provided justifying their relevance to the conditions encountered in the EU. Testing should be conducted at the proposed dose although information on a range of doses may be useful in order to confirm that the dose proposed is sufficiently effective and appropriate. Testing at the proposed dose is also required to confirm that there are no unacceptable effects on plants or plant products.

There is no requirement to submit a Biological Assessment Dossier (BAD) or individual trials reports as part of the approval for the active substance. This is because a full supporting efficacy dossier to demonstrate effectiveness and the absence of unacceptable effects on plants and plant products, for all of the proposed uses is required for plant protection product authorisation. This will be evaluated according to the Uniform Principles. However, where a BAD is available applicants should summarise the efficacy data supporting the product. A concise summary of the effectiveness against named targets representative of proposed uses at the proposed dose(s) and crop safety at the proposed dose(s) should be provided. It may also be useful to include a summary of results at lower doses. This should encompass uses which establish the 'risk envelope'. The summary should also include a brief synopsis of any preliminary screening data which establishes the range of activity of the active substance.

Where a BAD is not available the applicant should provide a summary of the results of any laboratory or field testing conducted the extent of which should be limited to establishing that the proposed GAP is realistic and fulfils the need of a risk envelope approach (see General Requirements). Trials reports may also be submitted.

It is beneficial if the Rapporteur Member State (RMS) evaluating the active substance and preparing the DAR is the same as one of those considering a zonal product authorisation. This should facilitate the active substance approval and any subsequent zonal product authorisation.

Appendix 1 presents an example of how these data could be presented but is illustrative only.

Where only laboratory formulations used in discovery and development are available evaluation of efficacy may not be possible. Efficacy can be highly dependant on formulation and the performance of developmental formulations may be very different to that from products that may ultimately be authorised. Even where formulation is less important e.g. pre-emergence herbicides performance in the glasshouse may be very different to that in the field so some realistic field testing is very important. In the absence of such testing it is likely to be very difficult to provide a convincing case that the proposed GAP is realistic and in such situations, approval of the active substance is highly unlikely.

There are occasions where the active substance being submitted for approval is intended for use in combination with one or many other active substances. Certain active substances may ultimately be formulated with a range of other active substances. There is, however, still a requirement for efficacy to be considered so that these active substances comply with Article 4.

In some cases the new active substance may be intended for use in a solo formulation *and* in co-formulation with another active substance at a dose below that for the solo product. In this situation, if the conditions of use are the same, the worst case GAP is likely to be when the new active substance is applied alone. Therefore, the co-formulated product need not be considered at the new active substance stage but instead should be considered at product authorisation stage. Where the new active substance is intended *solely* for use in co-formulation then the efficacy data supporting it must still demonstrate that when applied alone the active substance is selective and provides an acceptable level of effectiveness (as defined in EPPO PP1/214 'Principles of

acceptable efficacy'). This is essential since substances should only be included in plant protection products where it has been demonstrated that they present a *clear benefit for plant production.* In this case preliminary testing data should be submitted for the new active substance itself. Field data should also be submitted for the new active substance applied alone but also in comparison to the co-formulated product to demonstrate that the combination product provides a benefit in terms of pest control, resistance management etc over the individual active substance(s) when applied alone.

Where a product has a broad use pattern over a number of different use categories (e.g. fungicide AND plant growth regulator) each of the representative uses should be addressed in the summary.

As mentioned previously this should be provided as a concise summary of a BAD or alternatively as a separate document where a BAD is not available.

Appendix 1[3]

B.3 *Data on application and efficacy*

The GAP table will cover elements of B.3.3 to B3.7 and, under some headings, it may be appropriate to:

- *Simply cross-refer to consideration of information in Volume 3 active substance and Volume 1 as appropriate (for example in relation to information on occurrence or possible occurrence of resistance or the biological activity of metabolites)*
- *State that more detailed consideration of a particular aspect will be fully assessed in the context of subsequent applications for product authorisations.*

Product 'XXXX' containing <active substance> has been tested in preliminary tests and field development trials which demonstrated efficacious activity and appropriate crop safety. Product 'XXXX' is formulated with the synergist <substance>.

Authorisation of product 'XXXX', a [*formulation type*] containing <active substance> will be/is being applied for in the Northern, Central and/or Southern EU Regulation 1107/2009 zones.

(For product authorisation in parallel this dossier will be accompanied by a full efficacy dossier to allow a detailed zonal assessment of the efficacy package supporting all uses in compliance with plant protection product data requirements of Commission Regulation (EU) 545/2011 and according to the Uniform Principles (Commission Regulation (EU) 546/2011).

B.3.1 Field of use envisaged

e.g. <*Active substance(s)*> acts as a (name product function e.g. selective post-emergent broad-leaved weed herbicide in maize; fungicide for the control of Septoria tritici in winter wheat; insecticide for the control of Myzus persicae in potatoes, larvae/adults of Diabrotica v. v. in maize).

e.g. <*active substance(s)*> containing products are for use in agriculture/horticulture as e.g. post-emergent foliar sprays in wheat, triticale and rye for dicotyledonous weed control. The active substance is always used together with the safener <substance>, which provides crop tolerance and/ or together with an adjuvant.

e.g. <*active substance(s)*> containing products are for use in agriculture as foliar sprays in potato for the control of potato blight.

e.g. <*active substance(s)*> containing products are for use in agriculture as foliar sprays in maize for the control of Western corn rootworm beetle/as granule ground application in maize for the control of Western corn rootworm larvae.

B.3.2 Effects on harmful organisms

<*active substance*> is a <*pesticide description*> proposed for use in agriculture/horticulture for control of (pest type, y, z) in a range of crops. <active substance> is a <contact /residual, systemic> <pesticide type>belonging to the group of the < *pesticide group*>)

<*active substance(s)*> containing products are proposed at rates as shown in Table 1 and control the most important (*dicot weed species like xxxxxx yyyyyyy*, *zzzzzzzzzz jjjjjjjjjjjj*, *aaaaaa spp.*, and bbbbbbbb *spp.*,)

[3] According to template B3 (Volume 3 – Annex B (PPP) SANCO/12592/2012 –rev. 0 "Template to be used for Assessment Reports

B.3.3 Details of intended use

The GAP table for the intended uses may be inserted here.

Table 1 identifies intended representative uses which support the approval of <active substance. These uses are representative because [*justify why they are representative, including foliage and soil applications, dose rates, frequency of application and time of application for representative products , such that a relevant risk envelope may be defined*].

(The maximum rate GAP for each principal crop type/application method (e.g. arable, top fruit, vine, seed treatment) should be identified and a summary of effectiveness and crop safety for a representative pest/crop/situation of each should be presented (see Table 1 example).)

Table 1: Details of all national GAPs within each zone (to be sorted by crop)

1	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*10*	*11*	*12*	*13*	*14*
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**			**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
1												
2												
3												
4												

General remarks/explanations:

The GAP-Sheet should indicate if the displayed information was provided by the applicant OR was revised by the zRMS (due to the product label and Annex III data) – not relevant for the notification form.
The zRMS has to verify the presented information and to ask (the applicant) for clarification of missing details (e.g. BBCH stages, EC-codes of crops).

All abbreviations in the GAP-Sheet used must be explained. Use separate worksheet for each product.
Make use of existing standards like EPPO and BBCH.

Product:

Please indicate the specific variant of the active substance if relevant.

If additional components have to be added to the applied product (tankmixtures), all relevant information must be provided in the column remarks.

As the product usually will be determined either for professional or non professional use, this information should be given here. Otherwise to be indicated in column 4 of the GAP-sheet (conditions / location of use).

Formulation:

Type:

e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

Refer to:

- GCPF Codes - GIFAP Technical Monograph No 2, (1989), 6th Edition – Revised May 2008 – Catalogue of pesticide formulation types and international coding system.
- Technical Monograph n°2, 6th Edition - Revised May 2008 - Catalogue of pesticide formulation types and international coding system (CropLife International) [1)].

Conc. of as:

g/kg or g/L

In case the plant protection product contains more than one active substance the amount applied for each active substance occurs in the same order as the substances are mentioned in the heading.

Safener/Synergist:

Since safeners and synergists are in scope of REG 1107/2009, information about safeners/synergists should be included in the GAP table as well.

Zone(s):

All relevant zone(s) should be indicated. For interzonal uses (e.g. greenhouse, seed treatment, etc.) "EU" should be chosen.

Explanations to the particular columns:

No.:

Numeration would be important when references are necessary e. g. to the dossier or to the authorisation certificate.

Member state(s):

For a better general view of the valid uses for the particular zones/MS it would be helpful to mention both (the zone as well as the MS) in the column. However, to keep the table clearly arranged it seems dispensable to cite the zone; each MS is distinctly allocated to one zone; moreover the zone(s) are cited in the head of the table.
Desirably MS are put in order accordant to the zone they belong.

Crop and/or situation:

The common name(s) of the crop and the EC (EPPO)-Codes or at least the scientific name(s) [EU and Codex classifications (both)] should be used; where relevant, the situation should be described (e.g. fumigation of a structure). In case of crop groups all single crops belonging to that group should be mentioned, (either in the respective table element or – in case of a very extensive crop group - at least in a footnote).
If it is not possible to mention all single crops belonging to a crop group (e.g. for horticulture), it should be referred to appropriate crop lists (e.g. EPPO, residue (codex). It would be desirable to have a "joint list" of crop groups for the zones.

[1)] http://www.croplife.org/files/documentspublished/1/en-us/PUB-TM/4147_PUB-TM_2008_05_01_Technical_Monograph_2_-_Revised_May_2008.pdf

Exceptions of specific crops/products/objects or groups of these and
restrictions to certain uses (e.g. only for seed production, fodder) must be indicated.

This column should also include when indicated information concerning "crop destination or purpose of crop" and which part of plants will be used / processed (e. g. for medicinal crops roots or leaves or seeds).

Conditions / location of use:

Outdoor or field use (F), glasshouse application (G) or indoor application (I)
"Glasshouse" indicates that the respective trials are acceptable for all zones.

As results achieved in compartments without controlled conditions (temperature, light exposure), e.g. simple plastic tunnels [for those GAPs field trials have to be conducted in the respective zone the use is applied for], are not considered to be applicable for use in other zones the kind of glasshouse should be clearly indicated.

[Remark: Greenhouse definitions are at the moment under evaluation].

Conditions include also information concerning the substrate (natural soil, artificial substrate).

Pests or Group of pests controlled:

Scientific names and EPPO-Codes of target pests/diseases/ weeds or when relevant the common names of the pest groups (e.g. biting and suckling insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
If necessary – in case of pest groups - exceptions (e.g. sucking insects excluding scale insects) should be indicated.
In some cases, the set of pests concerned for a given crop may vary in different parts of the EU region (where appropriate the pests should be specified individually).

If the product is used as growth regulator the target organism is the specific crop, whose development should be influenced; the aim could also be e.g. an empty room for treatment.

Application details:

Method / Kind:

Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench, drilling, high precision drilling (with or without pneumatic systems).
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant - type of equipment used (e.g. ultra low volume equipment (ULVA) or low volume equipment (LVA)) should be indicated if relevant.

Timing of Application / Growth stage of crop & season:

Time(s), period, first and last treatment, e.g. autumn or spring pre- or post-emergence, at sufficient pest density or begin of infection, including restrictions (e.g. not during flowering).

Growth stage of crop (BBCH-code, …) – period, first and last treatment.
Since the BBCH-codes are accomplished in the individual member states at different time periods the month(s) of application should be indicated in addition.

BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

It seems sensible to constrain specifications in this column only to the crop, - information concerning the pest should be dealt in column “pest or group of Pests controlled”.

In certain circumstances it might be helpful to give information about the expected rate of interception related to the BBCH codes. In many minor crops no BBCH/interception rate scenarios have been specified so far. This could also simplify grouping for the envelope approach.

Number of applications and interval between applications

a) Maximum number of applications per growing season used for the named crop/pest combination possible under practical conditions of use.
b) The proposed maximum number in the crop including applications on all pests/targets on the same crop in a growing season should be given.

It should be clearly indicated whether the displayed number of applications is per season, per crop cycle or per pest generation.

Minimum interval (in days) between applications of the same product. The figure for the interval between the applications is to be set in brackets.

Application rate:

Application rate of the product per ha:

a) (Maximum) product rate per treatment (usually kg or L product / ha). For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms or pallox (= big box used for storage potatoes, fruits, roots).
b) Maximum product rate per growing season (especially if limited) or per crop cycle should be cited.

Especially in three dimensional crops other dose expressions (kg/L per 10.000 m² leaf wall area or kg/l per ha per meter crown (canopy) height) should be given additionally.

For seed treatment also the load of product (L/g, kg) per kg, 100 kg or unit treated seed should be stated beside the application rate per hectare. The number of seeds per (seed) unit is to be given.
The maximum seed drilling rate (=number of seed sown/maximum seed volume) per row and ha should be indicated.
Information concerning the sowing method (precision drilling, …) would be advantageous.

See also EPPO-Guideline PP 1/239 Dose expression for plant protection products (please note, additional EPPO-guidelines may be developed).

Application rate of the active substance per ha:

a) (Maximum) as rate per treatment (usually kg or L product / ha). For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms or pallox (= big box used for storage potatoes, fruits, roots).
b) Maximum as rate per growing season (especially if limited) or per crop cycle should be cited.

The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).

In case the plant protection product contains more than one active substance the amount applied for each active substance occurs in the same order as the substances are mentioned in the heading.

Water L/ha:

It should be clearly indicated if a stated water volume range depends upon the developmental stage of the crop (low volume – early crops stage, high volume – late crop stage) which causes a consistent concentration of the spray solution, or if a water volume range indicates different spray solution concentrations.
In the last mentioned case extremely low water volumes (indicating high concentrated spray solutions) need to be covered within selectivity trials.
If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.

PHI (days) – minimum pre harvest interval

PHI - minimum pre-harvest interval

For some crop situations a specific PHI may not be relevant. If so an explanation (e. g. the PHI is covered by the time remaining between application and harvest.) should be given in the remarks column (e.g. crop harvest at maturity or specific growth stages).

Remarks:

Remarks may include: amount of safener/synergist per ha or
extent of use/economic importance/restrictions, e.g. limiting the number of uses per crop and season, if several target pests/diseases are controlled with the same product.

Additional recommendations:

For the description of uses of a PPP the following EPPO Standards should be considered:

- EPPO Standard PP 1/240 “Harmonized basic information for databases on plant protection products”
- EPPO Standard PP1/ 248 “Harmonized classification and coding of the uses of plant protection products“

Whereas EPPO Standard PP1/ 248 gives more general information on possible description of uses, EPPO Standard PP 1/240 especially gives an overview of all points necessary to fully understand a use.

For EPPO-Guidelines, see: http://archives.eppo.org/EPPOStandards/efficacy.htm

Use EPPO extrapolation tables, see http://www.eppo.org/PPPRODUCTS/extrapolation/tables.htm

For EPPO Plant Protection Thesaurus, see: http://eppt.eppo.org/

B.3.4 Application rate and concentration of the active substance

B.3.5 Method of application

B.3.6 Number and timing of applications and duration of protection

B.3.7 Necessary waiting periods or other precautions to avoid phytotoxic effects on succeeding crops

[Note: the GAP table will cover elements of B.3.3 to B3.7 and therefore it may be appropriate simply to refer to the GAP table]

B.3.8 Proposed instructions for use

B.3.9 Effectiveness

A BAD has been submitted to support the authorization <product name> containing <active substance> in <MS>. The most challenging target is considered to be <*target pest 1*> requiring the highest dose of active substance (see Table 1).

Preliminary glasshouse screening with <active substance> in the representative formulation <name> was conducted. This can be summarized as follows: <insert brief summary of screening against targets and crops>

The field trials data supporting effectiveness against this target comprise <no of trials> conducted over x years. The trials were undertaken by Official and/or Officially Recognised Organisations., all of which follow EPPO guidelines. Trials were conducted in the following Member States: xxxx in <year trials conducted>. These are representative of the following EPPO climatic zones according to EPPO Standard PP1/241 (1); x,y,z

<*Product name*> was tested at a range of rates from x to x g a.s./ha/hL (x to xx mL product per hectare/hectolitre) in order to determine the most appropriate dose for the control of <*target pest 1*>. Standard reference material(s) was/were included and product choice was based on the commercial standard used to control the pest within the crop at the time of testing.

Table 2 Summary data showing performance of [a.s.] against named targets representative of proposed uses at the proposed dose (and including data from reduced doses) (Please specify whether results are derived from laboratory or field trials).

Crop	Crop growth stage and season	Pests or group of pests controlled	Situation	Formulation type/application method	A.S. dose applied	Interval between applications (days)	Number of applications	Summary of Control achieved [by EU Regulation 1107/2009 zone if appropriate]		
								EU Zone trials conducted	At reduced doses (*please specify)*	At 1 N
Winter wheat		*fungal pathogen1*	Outdoor	*SC 240 g/L foliar spray*	*100 g a.s./ha*	*21*	*3*	*N*	*67%*	*81% (mean 8 trials)*
								C	*69%*	*84% (mean 5 trials*
Potatoes		*fungal pathogen1*	Outdoor	*SC 240 g/L foliar spray*	*150 g a.s./ha*	7	*5*	*C*	75%	*85% (mean 5 trials)*
Vines		*fungal pathogen1*	Outdoor	*SC 240 g/L foliar spray*	*200 g a.s./ha*	7	*5*	S		
Apple		*fungal pathogen1*	Outdoor	*SC 240 g/L foliar spray*	*200 g a.s./ha*	14	3	C		
Tomato		*fungal pathogen1*	Protected	*SC 240 g/L foliar spray*	*250 g a.s./ha*	-	1	S		

B.3.10 Information on the development of resistance

Only the inherent risk should be described/ evaluated here (according to the EPPO Standard Resistance Risk Assessment). A full assessment of the risk for the development of resistance should be conducted in the framework of the evaluation of the plant protection product.

Biochemical & Biological mode of action
Insert description on mode of action.

Preventative / curative / residual activity
Insert description / information on relevant activity attributes

Systemic movement
Insert description on systemic properties of product.

Redistribution
Provide information and evidence of redistribution properties.

<active substance> is classified by (HRAC/IRAC/FRAC) in <RAC GROUP>

Summary information on <active substance>

<A.I. >	
IUPAC name (if applicable):	
Chemical group or equivalent:	
Mode of action:	
Plant translocation:	Systemic/translaminar/contact etc, where applicable.
Biological action: Harmful organism, plant growth regulator, growth/developmental stage of pest (e.g. IGRs), etc.	
Root-uptake, foliar-uptake, systemic etc.	

Insert a brief summary of resistance status of the targets and the mode of action.

B.3.11 Adverse effects on treated crops

Crop safety in this crop has been considered in all effectiveness trials and x specific crop safety trials which included N doses (and 2N doses for herbicides). Levels of phytotoxicity were as follows < insert brief summary>. Yielded trials indicate that < insert brief summary>.

Table 3: Summary data showing crop safety of [a.s.] on named crops representative of proposed uses at the proposed dose and twice the proposed dose. (Where appropriate a separate table should be included showing the results of any yielded crop safety trials). (Please specify whether results are derived from laboratory or field trials).

Crop	Crop growth stage and season	Pests or group of pests controlled	Situation	Formulation type/application method	A.S. dose applied	Interval between applications (days)	Number of applications	Summary of Maximum % phytoxicity [by EU Regulation 1107/2009 zone if appropriate]		
								EU Zone trials conducted	At 1N	At 2 N
Winter wheat		*fungal pathogen1*	Outdoor	*SC 240 g/L foliar spray*	*100 g a.s./ha*	*21*	*3*	*N*	*0*	-
								C	*0*	-
Potatoes		*fungal pathogen1*	Outdoor	*SC 240 g/L foliar spray*	*150 g a.s./ha*	7	5	*C*	0	-
Vines		*fungal pathogen1*	Outdoor	*SC 240 g/L foliar spray*	*200 g a.s./ha*	7	5	S		
Apple		*fungal pathogen1*	Outdoor	*SC 240 g/L foliar spray*	*200 g a.s./ha*	14	3	C		
Tomato		*fungal pathogen1*	Protected	*SC 240 gLl foliar spray*	*250 g a.s./ha*	-	1	S		

B.3.12 Observations on other undesirable or unintended side-effects

Insert a brief summary of any testing on impacts on succeeding or adjacent crops or effects on beneficial organisms.

B.3.13 References relied on