ECPA Technical Guidance Paper

No: 2011/1

Technical guidance for applicants in preparing a concise efficacy summary as part of a draft Registration Report (dRR).

Introduction

This Technical Guidance Paper has been developed to provide guidance for applicants in preparing a concise efficacy summary within the draft Registration Report (dRR) as part of the Core Assessment relevant for the EU regulatory zone.

Under Directive 91/414/EEC efficacy data were presented in a Biological Assessment Dossier (BAD) format, originally in accordance with Commission guidance 7600/VI/95 (rev.6). Subsequent to that the Standing Committee on Plant Health identified that as from 31 December 2004 all Biological Assessment Dossiers should be submitted in OECD format (SANCO/3989/2001).

The BAD has traditionally been submitted at National level as part of country specific dossiers. The **draft Registration Report (dRR)** has been developed as a **concise summary** document prepared by the applicant for all areas of the risk assessment, including efficacy (Section 7), and the dRR will form the basis for product assessments under Regulation EC No 1107/2009. To meet the requirements of Regulation EC No 1107/2009 ECPA recommends that applicants should:-

a. Continue to use the current **BAD** to provide the overall **comprehensive summary** and assessment of data and submit it as a K-document. The BAD is therefore to be regarded only as a reference document in the same manner as an individual trial or trial series report.

b. Part B, **Section 7 of the dRR** should be used to provide **short concise summaries** for each of the Annex points, cross-referencing to the relevant sections within the BAD, and identifying the key issues.

The relationship between the dRR and the BAD(s) is represented graphically in Figure 1 and clearly shows that the BAD is a reference (K) document amongst all the other reference documents submitted.

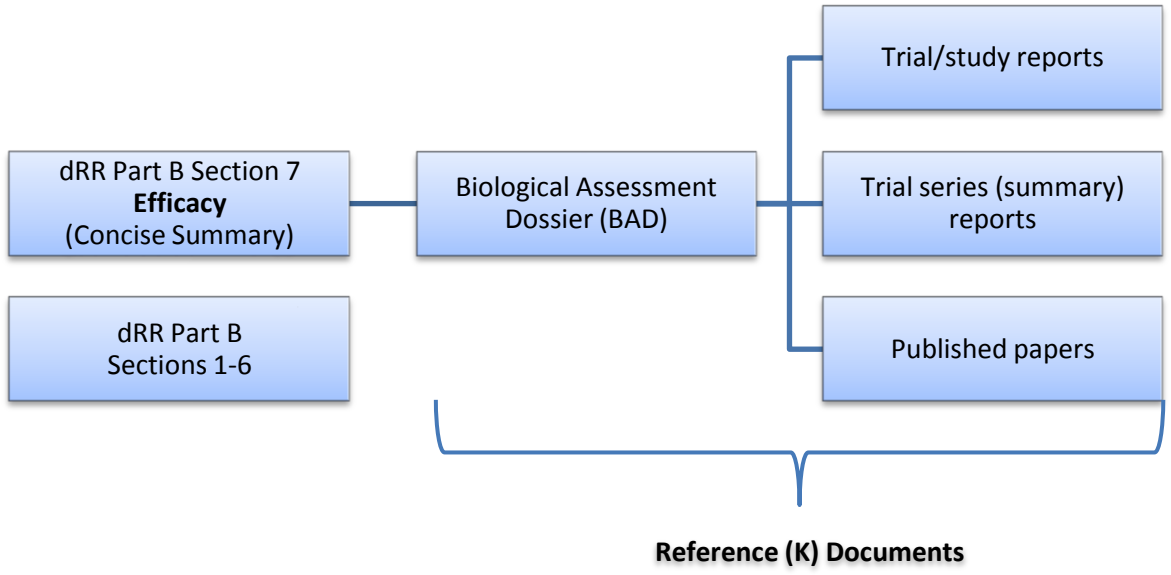

Figure 1 Relationship between the dRR and BAD

As a result, each individual zonal submission will usually consist of a dRR and the associated BAD. A submission made in only one regulatory zone will usually consist of a dRR and associated BAD. When making a submission in multiple regulatory zones there are two options:

a. A dRR for each regulatory zone accompanied by a single, multi-regulatory zone, BAD. This is the preferred option when crops and/or targets and/or the GAP are common across multiple regulatory zones, and avoids unnecessary replication.

   OR

b. A dRR for each regulatory zone accompanied by an individual BAD for each regulatory zone.

Where there are particular National Requirements that may require further information and/or data, these should be addressed in accompanying National Addenda.

Whilst the dRR part B, Section 7 'template' itself gives some guidance on what needs to be included to address each Annex point, applicants and regulatory authorities have agreed that additional guidance would be useful to give some indication of the level of detail such a summary should contain. That is what this Technical Guidance Paper sets out to do. It also provides some guidance on the length of each section. It is clearly impossible to be precise about the length as it depends on so many factors, however, as with any summary, it is envisaged that the average length of a complete dRR Part B, Section 7 would be approximately 10-15% of the full information set that it is summarising. Where examples of tables are provided it is envisaged that these will be integral to the text.

This Technical Guidance brings together suggestions from a number of sources. It is not intended to provide a definitive description of what exactly is required as this will ultimately vary depending on the type of product, crops, targets and a host of other factors.

The authors acknowledge that further refinement of this Technical Guidance Paper may be required over time. Any comments on possible future refinements would be welcome at *ecpa@ecpa.eu.*

Notes

- Text in red **summarises the minimum information** that should be provided in each section.
- Text in blue provides **general information/support.**
- Text in black shows the headers for each section. It also shows **example text.** The text/tables **are not fixed** and provided only as examples and should be adapted to suit the product being evaluated.
- Text in green shows **fields to be completed** in the example text.

REGISTRATION REPORT
Part B

Section 7: Efficacy Data and Information
Concise Summary

<Product Name/Code>

<Active Substance 1>
<Active Substance 2>
<Active Substance n>

<Zonal Rapporteur Member State>

CORE ASSESSMENT

Assessment relevant to zone: <EC Regulatory Zone>

Applicant: <Applicant Company>

Date: <dd/Mon/YYYY>

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IIIA 6 Efficacy Data and Information (including Value Data) on the Plant Protection Product

This introductory section should include the following information:

- Reference to Inclusion Directive
  - include any specific provisions to be addressed as listed in Annex I of Inclusion Directive

Reference should be made to the Biological Assessment Dossier (BAD) as the source for the detailed presentation of all efficacy data and the full evaluation. The BAD is therefore to be regarded only as a reference document in the same manner as an individual trial or trial series report.

Where no data is provided for a section this should be explained/justified in the context of the product type etc.

The content of this section may vary depending on whether the product contains new or existing active substances. It is not necessary in this section to provide a summary of what follows in all other sections. This document is already a summarisation of the BAD and as such does not need summarising further. It is expected to be approx. 1-2 pages

For a new active substance:-

A statement should be made regarding the product, its active components and concentration(s), and the formulation type.

Then proceed as for existing active substances.

For existing active substances:-

Standardised text has been developed as follows:

This document summarises the information related to the efficacy data of the plant protection product <*insert product code*> containing the <*insert active substance*> which was included into Annex I of Council Directive 91/414/EEC (<*insert directive number*>).

The SANCO/EFSA report for <*active substance 1*> (<*insert document ref*>) is considered to provide the relevant review information (*or provide a reference to where such information can be found).*

The Annex I Inclusion Directive for <*active substance(s)*> (*xxxx/xxx*/EC) provides specific provisions under Part B which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation:

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on <*active substance(s)*>, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on <*date*> shall be taken into account. Consideration of active substances for Annex I inclusion

does not include an evaluation of efficacy. Therefore there are no concerns to address arising from the inclusion directive of <*insert active substance(s)*> relating to efficacy.

For existing substances/products a table listing current registrations in Member States in the regulatory zone(s) may be beneficial. Registrations in other Member States outside of the regulatory zone may also be beneficial where data from these Member States forms part of the BAD:-

Table 1 Example of table to show existing registrations

Country	Product	Formulation		Authorisation No.	Registered rate(s)	Uses
		Type	Conc.			

For new and existing active substance then proceed as follows:-

Refer to Appendix 1 of the dRR Part B, Section 7 which contains a list of references included in this document for support of the evaluation. (Appendix 1 may be very short as it may only refer to the BAD).

Reference should be made to the proposed uses (GAP) in Appendix 2.

The detailed assessment of the individual trial and study data is located in the following report: IIIA 6.0/01 Biological Assessment Dossier for <Product>.

Description of the plant protection product

Statement that information on the detailed composition of <*product code*> can be found in the confidential dossier of this submission (Registration Report - Part C).

General information regarding the active substance(s)/product should be included:-

- chemical group (s)
- mode of action
- other biological properties that may be relevant (e.g. systemic activity, mobility, persistence etc.)

<Product> is an <e.g. emulsifiable concentrate (EC)> containing <number> grams per litre (g/l) <active substance(s)> for use on <crop(s)>. Further details are given in Table 2.

Table 2 Details of the active substances

Active substance	**AS1**	**<2>**	**<n>**
g/kg or g/L	200		
Chemical group:	auxin		
Mode of action:	IAA regulator		
Biological action:	e.g. post-emergence herbicide		

For further physico-chemical properties, reference should be made to Registration Report Part B Section 1: Identity, physical and chemical properties, other information.

The data presented in this BAD fully support the label claim for <Product> for the control of <targets 1, 2 etc.> in <crop(s)>.

Proposed uses for this product are supplied in Appendix 2.

The detailed assessment of the individual trial and study data is located in the following report: IIIA 6.0/01 Biological Assessment Dossier for <Product>.

IIIA 6.1 Efficacy data

It may be appropriate at this point to summarise the type of organisations carrying out the trial work and the general location of the trials. It is also important to describe how trial data has been grouped for summarisation. Grouping should be driven by scientific principles not upon some arbitrary measure and should be decided on a case by case basis. Where data is grouped a justification for the applicability of the data should be provided. Data comparability may be addressed for a number of factors including

edaphic, agronomic and biological factors. Data may be grouped based on climatic conditions using the EPPO climatic zones, but as data comparability is already accepted in this case no further justification is required.

Grouping data by EU regulatory zone will rarely be justified biologically unless the geography of the EU regulatory zone coincides with some biological criterion.

Although the first example summarises the data by EPPO climatic zone this is not compulsory – the separation of data is best decided on a case by case basis as previously described

Example

Trials in this BAD were carried out by <applicant company>, contractor companies and Official Research institutes, all of which follow the EPPO standards and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP).

On the basis of the EPPO standard 1/241 '*Guidance on comparable climates*', the trials included in the BAD have been grouped and summarized by EPPO climatic zone. EPPO climatic zones have been defined by taking into account differences between the agro-climatic sub-areas of the EPPO region.

The EC <insert appropriate zone> regulatory zone covers countries in EPPO climatic zones <insert EPPO zones> as described in EPPO standard PP 1/241. This submission includes data from the <xx, xx, xx, EPPO zones> which are representative of the proposed GAP.

Other examples of grouping

Agronomic risk (pest pressure)

Soil type

Application timing (spring vs. autumn

Resistance status.

IIIA 6.1.1 Preliminary range-finding tests

- Details of the evaluation
- Conclusions
- Does the product comply with the Uniform Principles?

A statement should be made regarding the availability or otherwise of results from preliminary tests. If no tests are available it should be stated.
Where test results are available a short description of the number, nature and type of test carried out should be made. Minimum details should include:
Year conducted, location, type of study (e.g. laboratory, glasshouse, field), target organisms, outline methodology (e.g. foliar herbicide, contact insecticide, preventative fungicide).

It should be made clear if the tests were carried out according to GEP (not a requirement for preliminary tests) and the outcome and overall conclusion of the tests. It may be possible to present the information in the form of a simple table where appropriate.

Suggested length, maximum one page.

Laboratory/greenhouse tests

Brief description of experiments (1-3 paragraphs).

- Spectrum
- how was the decision on dose ranges to be tested in 6.1.2 made from the data

Justification of the Co-formulation

If the product is a co-formulation, justify the use of each active substance in the mixture and show the benefit of the combination, e.g. synergy, spectrum, or added persistency.

< Product > at <number> <L/ha or kg/ha> (<active substances>) was compared to the single active substance products <Product 1> (<active substance>) and <Product 2> (<active substance>) at similar rates of the single active substances against different targets. Results are presented in Table 3.

Table 3 Efficacy of active substance components in < Product >

Target	No. trials	% control					
		<Product>		<Product 2>		<Product 3>	
		Mean	Min & Max or S.D.*	Mean	Min & Max or S.D	Mean	Min & Max or S.D
<Target 1>							
<Target 2>							
<Target 3>							

*standard deviation

According to the presented results, <Product> provided better control than the single active substance products against these <number> major <diseases/weeds/pests>, for which activity of <Product> is claimed. As <diseases/weeds/pests> often occur as complexes of several pathogens throughout a season, <number> application(s) of <Product> at <number> <L/ha or kg/ha> should therefore be used to efficiently control all pathogens claimed on the label.

IIIA 6.1.2 Minimum effective dose tests

- Details of the evaluation
- Conclusions
- Does the product comply with the Uniform Principles?

A statement should be made regarding the availability or otherwise of results from tests describing the minimum effective dose. These may be the same tests as also used in Section 6.1.3 to describe the efficacy of the proposed label rate(s).
Where test results are available a short description of the number, nature and type of test carried out should be made. Minimum details should include:
Year conducted, location, type of study (e.g. glasshouse, field), trial design, target organisms, outline methodology (e.g. foliar herbicide, contact insecticide, preventative fungicide). It should be made clear if the tests were carried out according to GEP, by officially recognised testing organisations and the guidelines (e.g. EPPO) followed. The outcome and overall conclusion of the tests should be provided. It may be possible to present the information in the form of one or more simple tables where appropriate.

Reference should be made to EPPO standard PP 1/225 '*Minimum effective dose'* which addresses the minimum requirements necessary to ensure consistency of decision making.

Where differences exist in the minimum effective dose rate across the regulatory zone, all the different rates should be addressed in this section.

Suggested length, approx. one page.

Field trials were established in order to determine the minimum effective dose for the control of the targets claimed in this BAD. <Product> was tested at <number > to

<number> < L/ha or kg/ha > (<number – number> g <active substance>) in <crops> for the control of <targets>. The rates reflect the proposed label rate and X% and Y% of the full recommended rate of <Product>, in accordance with the EPPO standard PP 1/225 '*Minimum effective dose'*. Efficacy is tested under a range of environmental conditions to fully challenge the product

A summary of the dose response results is provided in Table 4.

According to the presented results, the dose of <number> < L/ha or kg/ha > of <Product> provided the optimum overall control and should be considered as effective against these <number> major diseases, for which activity of <Product> is claimed. As diseases often occur as complexes of several pathogens throughout a season, <number> application(s) of <Product> at <number> <L/ha or kg/ha> should therefore be used to efficiently control all pathogens claimed on the label.

As a result, the proposed rate of <number> < L/ha or kg/ha> should be considered the minimum effective dose to deliver broad spectrum control of <targets> under a wide range of environmental conditions.

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Table 4 Minimum effective dose efficacy of < Product > at proposed label rate and X% & Y% dose rate

Target	Grouping	# trials	% control with <Product>					
			<rate1> (X % of full rate)		<rate2> (Y % of full rate)		<rate3> (Full rate)	
			Mean	Min & Max or S.D.	Mean	Min & Max or S.D.	Mean	Min & Max or S.D.
<Target 1>	All							
	A							
	B							
<Target 2>	All							
	A							
	B							
<Target 3>	All							
	A							
	B							

IIIA 6.1.3 Efficacy tests

- Details of the evaluation
- Conclusions
- Does the product comply with the Uniform Principles?

It is important that this section summarises all of the points addressed in the appropriate section of the BAD, however, it is not necessary to provide details of individual trials either in text or tabular form – these are all available in the BAD. Trial results may be summarised by EPPO climatic zone but it may be appropriate to summarise across climatic zones or in other ways, where justification has been provided.

It should begin by summarising the extent of the trials programme carried out, whether or not the trials were carried out to GEP, by officially recognised testing organisations and which guidelines (e.g. EPPO) were followed. It may help to provide a table as shown below. The organisation of the table may vary depending on the type of product, crop/target combination. For example it may be more appropriate to organise herbicide trials in cereals by the target weed, as extrapolation between crops is appropriate, whilst for a foliar fungicide it may be more appropriate to organise the table by crop and then target.

The text should summarise the general methodology, trial design and reference standards used in the trials and the evaluations carried out.

Then, a summary of the results and a conclusion should be provided. It may be easier to summarise the results in a tabular format as this is often done as part of writing the summary in the BAD itself. An example is provided below.

The data in the table may be organized/grouped in different ways e.g. if there are country specific use rates or soil type etc.

Appropriate reference should be made to other label statements pertaining to efficacy such as water volume, soil type etc. where relevant and the tests conducted and results summarised.

This is likely to be the longest section of Section B, Part 7 of the dRR and will depend entirely on the number of crops and spectrum of activity of the product, however, it is to provide a **concise summary**.

A total of 60 trials were carried out to evaluate the efficacy of <*product*> for the control of <*target(s)*> in <*crop(s)*>. Efficacy data for <*target(s)*> are presented from <number> efficacy trials assessed. All trials were conducted to GEP and followed the appropriate EPPO standards by officially recognized testing organisations. All trials were of a randomized complete block design with four replicates and a minimum plot size of 22m^2. The distribution of trials by location and year are described in Table 5 and Table 6 (or a map).

Table 5 Number of efficacy trials included in the BAD.

Year / Country	2000	2001	2002	2003	2004	2009	2010	Total
France	8	-	6	7	13	9	4	**47**
Italy	2	-	-	-	-	-	-	**2**
Portugal	-	5	-	-	-	-	-	**5**
Spain	-	4	-	-	-	-	-	**4**
Total	**10**	**9**	**6**	**7**	**13**	**9**	**6**	**60**

Table 6 Location of the trials in the EPPO climatic zones.

	Maritime zone	Mediterranean zone
France	4	45
Italy	-	2
Portugal	-	5
Spain	-	4

Table 7 shows a summary of the control of all <assessment type> on <crop part> for <*target*>.

Table 7 Efficacy of < Product >

Target	Grouping	# trials	% control			
			< Product > at <rate>		< Standard> at <rate>	
			Mean	Min & Max or S.D.*	Mean	Min & Max or S.D.
<Target 1>	All					
	A					
	B					
<Target 2>	All					
	A					
	B					
<Target 3>	All					
	A					
	B					

*standard deviation

Trials have been conducted between <year> and <year> in <list countries> representing the <list EPPO zones> EPPO climatic zones. Data demonstrated that <Product> at the proposed rate of <number> <L/ha or kg/ha> was <equivalent to/superior to> the efficacy of <list standards and rates> against <*target(s)*>. The data also demonstrated that there was no difference in the performance of <product> when trial data was grouped as presented in Table 7.

IIIA 6.1.4 Effects on yield and quality

IIIA 6.1.4.1 Impact on the quality of plants and plant products

- Details of the evaluation
- Conclusions
- Does the product comply with the Uniform Principles?

Brief description of experiments (1-3 paragraphs).

A statement should be made regarding the availability or otherwise of results from trials that evaluated the impact on quality. These trials may include efficacy trials (as presented in section 6.1.3) or phytotoxicity trials (section 6.2.1). The individual assessments required for aspects of yield (quality) will be dependent on the proposed use in particular the crop. Reference may be made to individual EPPO standards and for consideration of taint reference may be made to EPPO standard PP1/242 '*Taint tests'* to determine if this is relevant for any of the proposed uses and, if so, what data may need to be submitted.

Where test results are available a short description of the number, nature and type of test carried out should be made. Minimum details should include:
Year conducted, location, type of study (e.g. laboratory, glasshouse, field), crop, outline of methodology.

The results should be summarised, in tabular form if appropriate, and a conclusion drawn. As an effect on yield can be considered as part of the assessment of the product's effectiveness (in the presence of the target) or potential adverse effects (in the absence of the target) it is appropriate to present the results separately.

It is not possible to provide example text as it is very dependent on the individual submission.

IIIA 6.1.4.2 Effects on the processing procedure

- Details of the evaluation
- Conclusions
- Does the product comply with the Uniform Principles?

Brief description of experiments (1-3 paragraphs).

The relevance of the product uses to processing procedures (brewing, fermentation, baking) should be described and a statement made regarding the availability or

otherwise of trial results. Reference may be made to EPPO Standard PP 1/268 '*Study of unintentional effects of plant protection products on fermentation processes and characteristics of wine*' and Standard PP 1/243 '*Effects of plant protection products on transformation processes*' which provides an indication of the circumstances under which data on transformation processes are required.

Where test have been carried out the number and type of tests should be described including testing organisations and guidelines followed.

The results should be summarised, in tabular form if appropriate, and a conclusion drawn.

It is not possible to provide example text as it is very dependent on the individual submission.

IIIA 6.1.4.3 Effects on the yield of treated plants and plant products

- Details of the evaluation
- Conclusions
- Does the product comply with the Uniform Principles?

Brief description of experiments (1-3 paragraphs).

A statement should be made regarding the availability or otherwise of results from trials that evaluated the impact on yield. These may be efficacy trials (as presented in section 6.1.3) or phytotoxicity trials (section 6.2.1). The individual assessments required for aspects of yield will be dependent on the proposed use. The results should be summarised , in tabular form if appropriate, and a conclusion drawn.

Pest/weed/disease free Yield Trials

A summary of yield data from specific pest free trial sites are presented in Table 8. A total of <number> trials were carried out between <year> and <year> in <countries>.

Table 8 Yield effect of <Product> in Pest/weed/disease free trials

Crop	Grouping	# trials	% yield relative to the untreated			
			< Product> at <rate>		<Standard> at <rate>	
			Mean	Min & Max or S.D	Mean	Min & Max or S.D
<Crop 1>	All					
	A					
	B					
<Crop 2>	All					
	A					
	B					
<Crop 3>	All					
	A					
	B					

Yield from efficacy trials

A summary of the yield data from efficacy trials are presented in Table 9. A total of <number> trials were carried out between <year> and <year> in <countries>. The objective was to confirm the yield response of <Product> in the presence of <pest/weed/disease>.

Table 9 Yield effect of < Product > in efficacy trials

Crop	Grouping	# trials	% yield relative to the untreated			
			< Product > at <rate>		< Standard> at <rate>	
			Mean	Min & Max or S.D.	Mean	Min & Max or S.D.
<Crop 1>	All					
	A					
	B					
<Crop 2>	All					
	A					
	B					
<Crop 3>	All					
	A					
	B					

Conclusion

<Product> at the proposed label rate of <number> <L/ha or kg/ha> had < no or describe> negative effect on the yield of <crop> in the absence or presence of pest/weed/disease. In fact, in the presence of <disease/weed/pest> there was an <number>% increase in yield over the untreated.

IIIA 6.2 Adverse effects

IIIA 6.2.1 Phytotoxicity to host crop

- Details of the evaluation
- Conclusions
- Does the product comply with the Uniform Principles?

Data may be presented from efficacy trials conducted and presented in Section 6.1.3 and/or specific trials conducted to evaluate potential phytotoxicity.

EPPO standard PP 1/226 '*Number of efficacy trials'* provides useful guidance on the number and type of trials in target crops needed to demonstrate the crop safety of a plant protection product at the normal (N) and at twice the normal (2N) dose rate.

Phytotoxicity was evaluated in a total of <number> efficacy and <number> crop safety trials. Crop phytotoxicity symptoms were seen in <number> trials. <No or describe> impact on yield was observed. A summary of the trials where phytotoxicity was observed is provided in Table 10.

Table 10 Phytotoxicity of < Product >

Test report	Variety	Maximum phyto' at <1N> rate (%) (DAA)	Maximum phyto' at <2N or other> rate (%) (DAA)	Yield at <1N> as % of untreated	Yield at <2N or other> rate as % of untreated

In the remaining <number> <split by crop> efficacy/ pest free trials phytotoxicity was not directly evaluated, but no adverse findings were reported.

The potential impact of variety on the occurrence of phytotoxicity is summarised in Table 11 and demonstrates the wide range of varieties included in the trials across all climatic zones. There was no relationship between the occurrence of phytotoxicity and the variety in any crop tested.

Table 11 Crop varieties included in trials assessed for phytotoxicity.

Crop	Grouping	No. trials	<Varieties (No. trials if >1)>
<Crop 1>	All		
	A		
	B		
<Crop 2>	All		
	A		
	B		
<Crop 3>	All		
	A		
	B		

(No) phytotoxicity symptoms caused by <product> at the proposed use rate of <L/ha or kg/ha>were recorded in <all/the vast majority of/some> trials. Trials were carried out on <crops> in <countries> over <number> seasons from <year-year> on a wide range of commercially grown varieties.

IIIA 6.2.2 Adverse effects on health of host animals

This is not an EC data requirement/ not required by Council Directive 91/414/EEC.

IIIA 6.2.3 Adverse effects on site of application

This is not an EC data requirement/ not required by Council Directive 91/414/EEC.

IIIA 6.2.4 Adverse effects on beneficial organisms (other than bees)

- Details of the evaluation
- Conclusions
- Does the product comply with the Uniform Principles?

Where the target crop(s) has no special considerations relating to beneficial species or where beneficial species are not an important factor in providing control of targets (both those proposed as targets for the plant protection product or not), a cross reference to other sections of the dRR (e.g. ecotoxicology) should be included.

or

Where there are specific label recommendations for use of the product in Integrated Pest Management (IPM) then data supporting the safety when used in conjunction with the listed beneficial species should **not** be included in this section but in Section 6.5.

Detailed studies on the potential adverse effects to beneficial organisms are submitted in Part B Section 6 Annex Point IIIA 10.5 and IIIA 10.6 and summarised in the dRR Part B Section 6.

IIIA 6.2.5 Adverse effects on parts of plant used for propagating purposes

- Details of the evaluation
- Conclusions
- Does the product comply with the Uniform Principles?

Reference may be made to EPPO Standard PP1/135 '*Phytotoxicity assessment*' which provides an indication of the circumstances under which data on plant parts for propagation are required. If data are required it may be possible to define core data that are available from a representative range of conditions across the regulatory zone.

<Number> studies conducted between <year> and <year> in <countries> on <crops> revealed <no> negative impact of <Product> on propagation material <cereal seed, tubers etc.>.

IIIA 6.2.6 Impact on succeeding crops

- Details of the evaluation
- Conclusions
- Does the product comply with the Uniform Principles?

A step-wise approach should be taken following EPPO Standard PP 1/207 '*Effects on succeeding crops'*, starting with the pre-emergence herbicidal activity of the active substance, through glasshouse screening, laboratory bio-assays of treated field soils, field screening, monitoring of effectiveness/crop safety field trials and if necessary, specific following crop 'replanting' trials using risk mitigation measures such as different cultivation techniques. Data from other parts of the submission (e.g. Ecotoxicology – non-target plant pre-emergence data, Residues – soil) can be included in this section or cross referenced to where such data are located.

<Number> studies conducted between <year> and <year> in <countries> on <crops> revealed <no or describe> restrictions on following crops after application of <product>.

IIIA 6.2.7 Impact on other plants including adjacent crops

- Details of the evaluation
- Conclusions
- Does the product comply with the Uniform Principles?

A step-wise approach should be taken following EPPO Standard PP 1/256 '*Effects on adjacent crops'*. It is important to consider all crops which are likely to be present as adjacent crops (either already emerged or yet to emerge) across the regulatory zone. Data from other parts of the submission (e.g. Ecotoxicology – non-target plant pre and post-emergence data) can be included in this section or cross referenced to where such data are located. In addition to drift, the volatility of the active substance (and if known the formulated product) should be considered, as this may affect adjacent crops.

Reference is made to Part B Section 6 IIIA 10.8.1. Emergence and vegetative vigour evaluations were made for a range of monocot and dicot indicator crops. ED/ER 50

values were calculated. The impact of drift was incorporated to calculate the TER values.

The TER value for <Product> is <number> which is <below / above> the trigger value of 5.0.

The data presented within this Annex Point justifies the recommendation of <no or describe> restrictions on adjacent crops after the application of <product>.

IIIA 6.2.8 Possible development of resistance or cross-resistance

- Details of the evaluation
- Conclusions
- Does the product comply with the Uniform Principles?

EPPO Standard PP 1/213 '*Resistance risk analysis'* provides a framework for resistance risk assessment and resistance risk management. Each of the points that formed part of this section in the BAD should be briefly summarised ensuring it is clear what evidence is available and on what basis a particular decision was made. To a great extent the resistance risk assessment considers the inherent risk of resistance development and depends on various factors, some of which are associated with the product and others with the pest. Resistance risk management may be driven by specific national concerns, such as resistance status of the pest, availability of alternative control methods and the requirement for a specific number of applications. Whilst the resistance risk analysis may be able to identify inherent risk factors, the need for, and type of, resistance management strategies may need to be considered at a national level. However, the principles of an adequate resistance management strategy may apply generally and these should be stated.

<Active substance > is a <fungicide group/herbicide group/insecticide group> <fungicide/herbicide/insecticide>, which acts by < mode of action>. It belongs to <FRAC/HRAC/IRAC> <group> which are considered at <risk class> to <fungicide/herbicide/insecticide> resistance development.

Repeat for all active substances.

For <Product> being a mixture of a <fungicide/herbicide/insecticide group1> (<active substance1>) and a <<fungicide/herbicide/insecticide group2> (<active substance2>) the following anti-resistance use recommendations are therefore valid:
Description of the appropriate recommendations for the fungicide/herbicide/insecticide product.

IIIA 6.3 Economics

This is not an EC data requirement/ not required by Council Directive 91/414/EEC.

IIIA 6.4 Benefits

IIIA 6.4.1 Survey of alternative pest control measures

This is not an EC data requirement/ not required by Council Directive 91/414/EEC.

IIIA 6.4.2 Compatibility with current management practices including IPM

This is not an EC data requirement/ not required by Council Directive 91/414/EEC.

IIIA 6.4.3 Contribution to risk reduction

This is not an EC data requirement/ not required by Council Directive 91/414/EEC.

IIIA 6.5 Other/special studies

- Provide any additional information that is considered relevant

Studies that may be included as core data are:

Biological compatibility (if tank-mixes are recommended on the proposed label
Rainfastness
Cleaning application equipment
Justification for recommended water volumes

Where there are specific label recommendations for use of the product in Integrated Pest Management (IPM) then data supporting the safety when used in conjunction with the listed beneficial species should be included in this section.

IIIA 6.6 Summary and assessment of data according to points 6.1 to 6.7

- Provide table of recommended uses for registration, uses conditions and restrictions

Reference may be made to the GAP in Appendix 2 or an additional table provided. It is **not** necessary to summarise sections 6.1 – 6.5 as the dRR is itself already a concise summary.

Proposed uses for this product are supplied in Appendix 2.

OR

The proposed uses are summarised in Table 12.

Table 12 Proposed uses.

Crop	Target	Application rate		Spray volume L/ha	Number of applications (max.), interval (days)	Method and timing of application
		L/hL or kg/hL	L/ha or kg/ha			

No further summary of the data is given.

IIIA 6.7 List of test facilities including the corresponding certificates

The list of test facilities including the corresponding certificates is located in the following report: IIIA 6.0/01 Biological Assessment Dossier for <Product>.

Appendix 1: List of data submitted in support of the evaluation

Annex Point[1]	Author	Report Date	Title	Source[2]	Company Report No.	GLP/GEP Y/N	Published Y/N	Data Protection Claimed Y/N	Owner[3]
IIIA 6.<**>	<Author>	<Date>	Biological Assessment Dossier <Product>	<Applicant>	<DocumentID>				<Applicant>

[1] Include all relevant Annex points
[2] Where different from applicant
[3] Applicant company, public etc.

Appendix 2: GAP table(s)

Crop and/ or situation (a)	Country(s)	Product code	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of a.s. (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		

Remarks:

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions