ECPA Technical Guidance Paper

No: 2012/1

Technical guidance for applicants in preparing a concise efficacy summary as part of a new active substance Annex I submission.

Introduction

This Technical Guidance Paper has been developed to provide guidance for applicants in preparing a concise efficacy summary for the submission of a new active substance for inclusion in Annex I. A separate TGP has been prepared to address the submission of efficacy information for Annex III re-registration submissions post Annex I renewal.

The evaluation for inclusion in Annex I relates to the active substance rather than products containing the active substance. Although information is presented in the Annex I submission relating to a representative formulation and representative uses, this information does not cover all product formulations or uses. Unlike submissions at Annex III level it is not necessary to provide a Biological Assessment Dossier (BAD) for submission at Annex I level.

The information regarding efficacy included in the Annex I submission is a concise summary of efficacy information concerning representative use. This enables the evaluator to set the other information provided as part of the submission in the context of how the active substance will be used in practice. It is **not** the intention that the information provided should enable an evaluation of the effectiveness of products containing the active substance which takes place at the Annex III level.

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 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 active substance being evaluated.
- Text in green shows **fields to be completed** in the example text.

Efficacy Information
Concise Summary

<Active Substance>

<Product Name/Code>
<nn g/L or g/kg>

Applicant: <Applicant Company>
Date: <dd/Mon/YYYY>

Statement

<Active substance> contained in <Product Name/Code> has been tested in preliminary tests and field development trials from <year> to <year> which demonstrated efficacious activity and appropriate crop safety.

1. INTRODUCTION

This document summarises the information related to the efficacy of <active substance>.

2. FUNCTION

A description of the function of the active substance should be provided. This should include whether or not it is selective, the timing of application and its activity.

<Active substance> acts as a <selective, non-selective>, <pre-emergence, post-emergence, foliar etc.>, <herbicide, insecticide, fungicide>.

3. FIELD OF USE

A description of the field of use of the products containing the active substance should be provided. This should include the representative crops and also indicate if any particular crops might be excluded. It should also indicate if the selectivity is dependent on the use of a safener or other factor such as timing of application e.g. pre-emergence.

Products containing <active substance> are used to be used as <post-emergent foliar sprays> in <crop(s)> for <purpose>. The products are not recommended in <crop(s)>. For the control of some targets the use of an adjuvant is recommended to ensure reliability.

4. SUPPORTED USES

A list of the representative uses should be provided for example in the form of a table. A justification should be given as to why these uses are considered to be representative. This may include different application methods, timings of application, frequency of application, such that a relevant risk envelope can be established.
Applicants are encouraged to include as representative uses examples of uses for the same target and crop where the recommended dose differs between Member States.

Table 4 identifies representative uses which have been selected to support the inclusion of <active substance> in Annex I. These use are considered representative as they <justify how the uses are representative>.

5. HARMFUL ORGANISMS CONTROLLED AND CROPS TREATED

Briefly summarise the range of rates used and the most important pest species controlled.

<Active substance> containing products are used at rates as shown in Table 4 and control the most important pest species; <main target species>.

6. METHOD OF APPLICATION

Briefly describe the type and method of application e.g. foliar spray, broadcast, directed etc.

<Active substance> containing products are applied as <describe application type and method>.

It may be possible to combine the content of Sections 4-6 in a single table.

7. MODE OF ACTION - EFFECTS ON HARMFUL ORGANISMS

Provide a brief summary of the mode of action and the classification of the active substance. Where available, reference should be made to the relevant Resistance Action Committee classification

<Active substance> is a <herbicide, insecticide, fungicide> used in agriculture for control of <pest groups> in <crop(s)>. <Active substance> is a <contact /residual, systemic> <type>belonging to the group of the <pesticide group> substances.

Alternatively a table could be used:

Table 1. Properties of <active substance>

Active substance:	<Active substance>
Chemical group:	<Chemical group>
Biological Action	<herbicide, insecticide, fungicide, plant growth regulator>
Mode of Action:	<MOA>
Plant translocation:	<contact /residual, systemic, etc.>
Resistance Group:	<HRAC/IRAC/FRAC> <group label>

Example 1

<Active substance> is taken up by the meristem tissues of the shoot and root. The principal effect is achieved by uptake via the hypocotyl. Uptake of <active substance> into plants from pre-emergence application usually results in death of <target>at <application window>.The primary site of action is <site of action> which passes through the herbicide containing soil layer before emergence at the soil surface. With post emergence applications <active substance> enters the plant through the foliage and moves towards the growing point. With both pre emergence and post emergence applications the meristem is killed quickly leading to plant death. <Active substance> is known to inhibit the production of long chain fatty acids in lipid synthesis resulting in alteration of cell membranes and disruption of cell processes e.g. cell division and hormone regulation. Although the specific site of action is not known, it is thought to affect more than one step in the lipid synthesis process. <Active substance> is classified by HRAC in <HRAC GROUP>

Example 2

<Active substance> is taken up by target pests primarily by ingestion but with some secondary uptake by contact with treated surfaces. . All larval stages and adults are

susceptible to <active substance>. No effect has been recorded on eggs laid on treated surfaces or where application is made directly to eggs. Effects on the susceptible stages of target pests are seen soon after ingestion (less than 6 hours) with death occurring within 24 hours. <Active substance> is taken up by the plant and is fully systemic, moving in both the xylem and phloem transport systems. The primary site of action in target pests is <site of action> which is shared with other members of the <chemical group> chemical group. <Active substance> is classified by IRAC in <IRAC GROUP>.

8. SUMMARY OF EFFECTIVENESS AND CROP SAFETY DATA SUPPORTING EFFICACY

There are 2 scenarios for the submission of this concise summary as part of an Annex I submission:

a) A representative formulation is being considered under the product authorisation process at the same time as the active substance is being considered.
b) A representative formulation is available but the active substance is being evaluated in advance of authorisation of any products.

In either case it is not necessary to submit a Biological Assessment Dossier to support the Annex I submission as this will be provided in the Annex III submission in support of the product.

A brief summary of preliminary data may be provided and, it may be beneficial to provide a very high level summary of the effectiveness and crop safety of the representative formulation used according to the representative uses described in the GAP, Table 4. This is most easily presented in the form of a table:

Table 2. Summary data showing effectiveness of <active substance>. Applied as a <application method> using <representative formulation>

Crop	Target(s)	Rate (g/ha)	No. applications	No. trials (by zone if appropriate)	Control achieved (%)	
					At reduced rate <fraction of full rate n>	At 1n rate
<crop1>	<target1> <target2>	<rate> <rate>	<#> <#>	Central <#> Central <#>	<##>	<##> <##>
<crop2>	<target1>	<rate>	<#>	Central <#> South <#>	<##>	<##> <##>
<crop3>	Etc.					
<crop4>						
Etc.						

Table 3. Summary data showing crop safety of <active substance>. Applied as a <application method> using <representative formulation>

Crop	Rate (g/ha)	No. applications	No. trials (by zone if appropriate)	Phytotoxicity observed (%)	
				At 1n rate	At higher rate <multiple of full rate n>
<crop1>	<rate>	<#>	Central <#>	<##>	<##>
<crop2>	<rate>	<#>	Central <#> South <#>	<##> <##>	<##>
Etc.					

Table 4. Representative uses for products containing <active substance>

Crop and/ or situation (a)	Country(s)	F G or I (b)	Pests or Group of pests controlled (c)	Application				Application rate per treatment		
				method kind (d)	growth stage & season (e)	number (f)	Minimum interval between applications	kg as/hL (g)	water L/ha (g)	kg as/ha (g)

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) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(e) Growth stage (BBCH) at treatment (range if applicable) including where relevant, information on season at time of application
(f) The minimum and maximum number of application possible under practical conditions of use
(g) Minimum and maximum if applicable.