# ECPA Technical Guidance Paper

# No: 2012/2

***Technical guidance for applicants regarding the submission of efficacy information for product re-registration following inclusion of an existing active substance into Annex I.***

## Introduction

This Technical Guidance Paper has been developed to provide guidance for applicants in preparing the submission of efficacy information for Annex III submission following renewal of inclusion of an existing active substance in Annex I. It does not address the question of new active substances and reference should be made to TGP 2012/1.

Following the successful renewal of inclusion of an existing active substance in Annex I it is a requirement that the registration holder (applicant) re-submits for registration all products containing the active substance. This may either be done at a Member State level or under Regulation EC No 1107/2009, at a zonal level. The requirement can clearly place a burden on applicants and evaluators and this TGP sets out to provide guidance on what information needs to be submitted and under what circumstances. It aims to ensure that evaluators can have confidence that they have access to all necessary information without having to re-evaluate information that has already been provided and evaluated in the past.

There will be a number of situations that can apply with regard to a product since the active substance was last included in Annex I. However, these can be broken down into 2 main groups; those where there has been no change since the last Annex I inclusion and those where changes have occurred. These changes may either be in the data requirements, GAP e.g. lower rate of use or product label e.g. tank-mixes. This grouping is represented graphically in **Error! Reference source not found.** which also describes in outline the process for the submission and evaluation of new information.

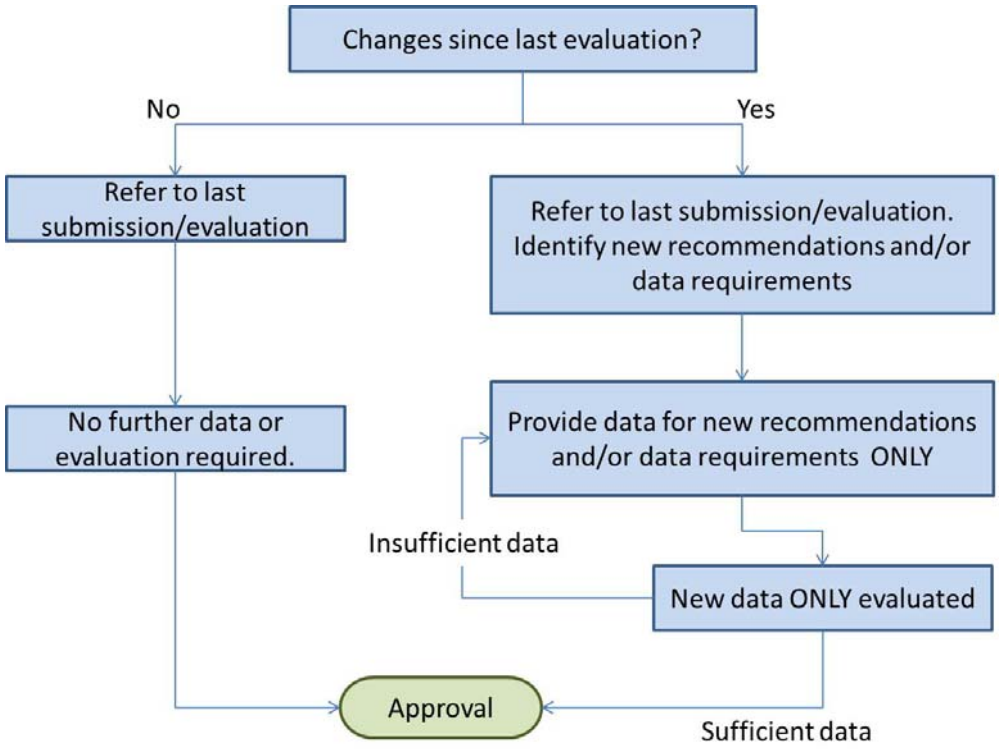


**Figure 1 Process for submission of efficacy information post Annex I inclusion of existing active substances.**

This is also described in Table 1 which describes the potential situations and the appropriate action to be taken.

**Table 1 Potential situations and action taken to address efficacy information requirements post Annex I inclusion of existing active substances.**

| Situation | 1. No changes since last evaluation | 2. New data requirements only | 3. Changes to product label only e.g. lower use rate | 4. New data requirements AND changes to product label |
|---|---|---|---|---|
| Action taken | No information required | Provide data to satisfy new requirements only. For all other requirements refer to previously evaluated data. | Provide data to satisfy changes to product label only. For all other label content refer to historical references. | Provide data to satisfy new requirements AND data to satisfy changes to product label. For all other requirements and label content refer to historical references. |
| Format | Statement | dRR & BAD | dRR & BAD | dRR & BAD |

It should be noted that where information needs to be submitted it should be in the format of a dRR as described in TGP 2011/1.

The remainder of this TGP describes in detail what should be submitted under the different situations.

**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 blue provides **general information/support.**
- Text in black 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.

## 1. No change to the data requirements or product label.

This is the simplest circumstance following the renewal of inclusion of an existing active substance in Annex I.

It is not necessary to submit any new data or other information regarding the product. A statement referring to the existing label and the information that was submitted historically is sufficient.

**Example**

This document addresses 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.

Since the previous inclusion of <*insert active substance*> into Annex I (<*insert directive number*>) there have been no changes to the product label and there are no additional data requirements relating to the product. Therefore no further information is submitted and reference should be made to the existing label (Appendix 1) and previous efficacy submission <*insert reference to previous dRR/BAD*>.

## 2. New data requirements ONLY.

It may be the case that, since the product was registered following the last inclusion of the active substance into Annex I, new data requirements have come into existence that were not present at the time. These requirements may be changes to existing requirements or be entirely new. It is important that these requirements are fully addressed to ensure the evaluator has at their disposal all the information required to make a full evaluation. However, it is **not** necessary to submit information for requirements that have not changed or are not new. For these requirements it is sufficient to make reference to the previous data submission and evaluation even where these were not made in the most current format.

The format used to submit the new information should be as a dRR as described in TGP 2011/1.

**Example**

This document addresses 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.

Since the previous inclusion of <*insert active substance*> into Annex I (<*insert directive number*>) there have been no changes to the product label. There have been changes to the data requirements relating to the product and these are listed in Table 2.

**Table 2 Changes to the data requirements since last inclusion in Annex I**

| Item | Change |
|---|---|
| IIIA 6.1.2 Minimum effective dose tests | New requirement – minimum effective dose |
| III 6.2.8 Possible development of resistance or cross-resistance | Change in requirement - reporting of cases of resistance. |

Information is therefore only provided in the remainder of this document in relation to these specific changes. No further information is submitted and reference should be made to the existing label (Appendix 1) and previous efficacy submission <*insert reference to previous dRR/BAD*>.

## 3. Changes to product label ONLY.

If, since the product was registered following the last inclusion of the active substance into Annex I, the product label has changed these need to be addressed. If the changes have already been made and approved there is no requirement to submit the information to support the use again. This is similar to situation 1 – the information has been, submitted and the use already approved – all the applicant needs to do is reference the relevant submission.

Situation 3 really applies to cases where the applicant wishes to make changes to the label **at the time of submission**. These changes may include, but is not limited to, any of the following:

New targets
New crops
Tank-mix recommendations
Recommendation to use an adjuvant.
Claim for rainfastness.
Change in number of applications
Change of dose rate
Change regarding resistance situation/recommendations.

It is important that these changes are all fully addressed to ensure the evaluator has at their disposal all the information required to make a full evaluation. However, it is **not** necessary to submit information for requirements that label statements that have not changed or are not new. For these requirements it is sufficient to make reference to the previous data submission and evaluation.

The format used to submit the information should be as a dRR as described in TGP 2011/1.

**Example**

This document addresses 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.

Since the previous inclusion of <*insert active substance*> into Annex I (<*insert directive number*>) there have been no changes to data requirements relevant to the product. There are a number of proposed changes to the label recommendations and these are listed in Table 3.

**Table 3 Proposed changes to the product label.**

| **Item** | **Change** |
|---|---|
| Additional crops | Inclusion of spinach, lettuce and watercress |
| Rainfastness | Claim for rainfastness after one hour |
| Use of an adjuvant | Recommendation for use of Codacide Oil in mixture for the control of *Pegomya* spp. |

Information is therefore only provided in the remainder of this document in relation to these specific label recommendations. No further information is submitted and reference should be made to the existing label (Appendix 1) and previous efficacy submissions <*insert reference to previous dRR/BAD*>.

## 4. Changes to data requirements AND product label.

This the most complex situation where there have been changes to the data requirements since the last inclusion of the active substance in Annex I **and** the applicant is proposing changes to the product recommendations.

In this case the approach taken to submitting information should be a combination of situations 2 and 3 described previously. It is important to note that there is **no** requirement to provide information for requirements that have not changed or for label recommendations that are not new but have been previously evaluated (even if these occurred since the last Annex I listing). Reference should be made to the original submission(s) and current label.