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Directorate E – Safety of the food chain  
Unit E.3 - Chemicals, contaminants, pesticides

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## **GUIDANCE DOCUMENT ON THE EVALUATION OF NEW ACTIVE SUBSTANCE DATA POST APPROVAL**

This document has been conceived as a working document of the Commission Services, which was elaborated in co-operation with the Member States. It does not intend to produce legally binding effects and by its nature does not prejudice any measure taken by a Member State within the implementation prerogatives under Regulation (EC) No 1107/2009, nor any case law developed with regard to this provision. This document also does not preclude the possibility that the European Court of Justice may give one or another provision direct effect in Member States.

### Revision history

When	What
Rev. 7 of 21.11.2011	Simplification of text by deleting repetitive paragraphs Update of document to reflect situation under Regulation (EC) No 1107/2009 Inclusion of chapter 5 on data protection
Rev. 8 of 24.01.2012	Some further editorial amendments

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## 1. Introduction

This guidance document aims to give a systematic overview on the different reasons for submissions of further active substance data after its approval and the handling of such data with respect to (a) authorisation of plant protection products (Regulation (EC) No 1107/2009, Article 29) and (b) potential consequences for the approval of an active substance such as an amendment of the list of end-points or a review of the approval of the respective active substance according to Article 21 of the Regulation (EC) No 1107/2009.

For data submitted in the framework of (a) confirmatory data (GD SANCO/5634/2009), (b) technical specification (GD SANCO/6075/2009) and (c) equivalence assessment (GD SANCO/10597/2003) reference is also made to the respective Guidance Documents.

The aim is:

- to establish a harmonised approach in this area in order to avoid unnecessary duplication of effort,
- to improve co-operation between the Competent Authorities of the MSs to get a harmonised data background for the national and/or zonal authorisation of the plant protection products and MRL setting.

In general, this guidance has been developed in relation to the re-registration of plant protection products containing active substances approved, but could equally apply to the consideration of new data for the authorisation of new products. It was also originally developed with regard to new active substance data, but could equally apply to the evaluation of key product data in some cases.

## 2. Implementation schedule

This document has been finalised in the Standing Committee on the Food Chain and Animal Health on 15.7.2005 and amended on 24.01.2012. It should be implemented as from 24.01.2012 (date of noting of the amended version by the Standing Committee on the Food Chain and Animal Health).

## 3. Background

There are a number of reasons why it can be necessary to submit further active substance data or why new information can become available to Competent Authorities of the MS after approval of an active substance and before its next scheduled renewal:

- For re-registration of products (as well as for authorisation of new products) to support other uses than the representative uses for approval of the active substance.
- Registration holders or applicants who were not notifiers for the approval of the active substance and do not have access to certain data may have to provide

data to cover certain data points (with the exception of vertebrate studies) in order to fulfil conditions for a complete dossier for re-registration of products (as well as for authorisation of new products). All these active substance studies are considered for compliance (step 1 procedure); the procedures are laid down in “GD on the Procedures relating to the authorisation of plant protection products following inclusion of an existing active substance in Annex I of Council Directive 91/414/EEC” (SANCO 10796/2003”).

- Following the implementation of new guidance or new data requirements.
- To amend an endpoint in order to achieve an acceptable risk.
- New data submitted in accordance with Article 56 of Regulation (EC) No 1107/2009.
- Information submitted by third parties needs to be considered on a case-by-case approach.

#### 4. Assessment procedure

General points:

The timing to evaluate the submitted data or information will depend on a number of factors. When data are evaluated, standard procedures are required such that several Member States do not duplicate the evaluation.

The authorisation/re-registration of products following approval should be undertaken in accordance with the scientific and technical knowledge in place at the time of submission of the dossier for the authorisation/re-registration (see Article 29(1) of the Regulation (EC) No 1107/2009).

In principal the end-points established during the assessment for approval of the active substance must be used for the authorisation/re-registration of products post-approval. If new active substance data lead to a change of end-points as a result of a peer reviewed EU procedure, the end-points need to be updated accordingly and the updated version then must be used.

New active substance data not to be evaluated immediately (prior to renewal):

New active substance data made available by an applicant after the approval of an active substance are not to be evaluated immediately (prior to renewal); these data will be considered in the next “scheduled” peer reviewed EU procedure for this active substance, i.e. when the approval is reviewed (renewal of approval of the active substance) or in the procedure of MRL-setting according to Regulation (EC) No 396/2005.

This procedure applies to:

- Data submitted by applicants who are not the notifier for approval - compliance check (step 1 procedure);
- Active substance data listed in the EFSA conclusion other than confirmatory data;

- Additional active substance data submitted by the notifier not essential for authorisation.

#### New active substance data to be evaluated immediately (prior to renewal):

##### *4.1 New active substance data submitted as part of an application for authorisation/re-registration.*

Such data need to be essential for that evaluation, e.g. to support uses other than the representative uses for the active substance approval. These data will be evaluated by the MS/zRMS receiving that application. This would include any additional residue data required to set an EU MRL for a new crop. The assessments should be made available by the MS/zRMS in the format of the registration report (Sanco/6895/2009) via CIRCA, and Member States informed by e-mail that the assessment is available. The assessment will need to be made available within the timelines specified in Regulation (EC) No 1107/2009, Article 33 or 43 for the authorisation or renewal of the authorisation of the product, respectively.

##### *4.2 New active substance data resulting in a change of endpoints other than ADI, AOEL, ARfD or residue definition for commodities of plant and animal origin.*

For new active substance data which result in an end-point (with the exception of ADI, AOEL, ARfD and the residue definitions for commodities of plant and animal origin) which leads to a more favourable risk assessment compared to the end-point listed in the LoEP and a safe use can only be demonstrated by using the new end-point, MS/zRMS can use this new end-point (provided that the studies are valid) for the risk assessment/management. The assessments should be made available by the MS/zRMS in the format of the registration report (Sanco/6895/2009) via CIRCA, and Member States informed by e-mail that the assessment is available. The LoEP will not be amended until the active substance approval is renewed. In this case, the changed endpoint is only valid for the applicant supplying the data.

##### *4.3 New active substance data resulting in a change of ADI, AOEL, ARfD or residue definition for commodities of plant and animal origin.*

In all cases where the ADI, AOEL, ARfD and/or the residue definitions for commodities of plant and animal origin need to be changed in order to obtain an authorisation or in other cases where the evaluation of new active substance data lead to a necessary change of the active substance approval, a proposal and/or addendum to amend these end-points would be forwarded to the Commission by the MS/zRMS. Proposal and/or addendum is then circulated to all MS and EFSA for commenting and/or peer review. If accepted, the revised end-point(s) will be submitted to the Standing Committee on the Food Chain and Animal Health for formal adoption. If adopted the active substance approval and LoEP will be amended. A revised review report and/or a revised EFSA conclusion will be published. MS/zRMS can use the new ADI, ARfD, AOEL and/or the residue definitions for commodities of plant and animal origin only after formal adoption in the Standing Committee, and the amended endpoints will apply to all submission from applicants.

##### *4.4 New data/information submitted in accordance with Article 56 of Regulation (EC) No 1107/2009.*

The procedures as described in the corresponding Article are to be followed.

## **5. Data protection**

Data protection provisions will apply at the national level when the new data are compliant with Article 59(1) and are necessary to grant an authorisation or a re-registration in the individual MS. Data protection will not apply when new data is submitted in accordance with Article 56 of Regulation (EC) No 1107/2009.

## **6. Outcomes**

There is a number of possible outcomes at EU level derived from the evaluation of further active substance data after approval:

- The conditions for approval have to be amended or the active substance has to be withdrawn.
- No change is required either for Review Report or for Implementing Regulation.
- A revised or new Review Report is required without changing the approval Regulation.

Where changes to the Review Report or implementing Regulation are required, the decision must be taken at EU level (Standing Committee (SCFCAH)). EFSA will be involved on a case by case basis and -if appropriate- EFSA will prepare an amended EFSA-conclusion.