



EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Safety of the Food Chain
Chemicals, contaminants, pesticides

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Guidance document on the procedures for submission and assessment of confirmatory data following inclusion of an active substance in Annex I of Council Directive 91/414/EEC¹

COMMISSION GUIDANCE DOCUMENT - DOES NOT NECESSARILY
REPRESENT THE VIEWS OF THE COMMISSION SERVICES

This document has been conceived as a guidance document by the Commission Services, and 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 Annex II, III and VI of Council Directive 91/414/EEC, nor any case law developed with regard to this provision. Nor does this document preclude the possibility that the European Court of Justice may give one or another provision direct effect in the Member States.

¹ A separate guidance will be developed for the procedure regarding submission and assessment of confirmatory information submitted under Regulation (EC) No 1107/2009.

1. IMPLEMENTATION SCHEDULE

This amended version of the guidance document should be implemented as from 15th July 2011.

2. INTRODUCTION & BACKGROUND

A number of active substances are included on Annex I of Directive 91/414/EEC with a requirement for confirmatory data *specified in Part B of the Inclusion Directive*.

Part B of the inclusion directive requires the notifier at whose request the active substance was included in Annex I, to submit the relevant confirmatory data to the Commission by a prescribed deadline (usually 2 years after entry into force of the Inclusion Directive). The confirmatory data may be either Annex II data (e.g. mancozeb DNT study), or more commonly Annex III data and risk assessments (e.g. bird and mammal risk assessment). The confirmatory data may also be required to fully establish the reference technical specification (where the deadline for submission would preferably be at entry into force).

It should be noted that the confirmatory data do not necessarily include all the data gaps listed in the EFSA conclusions (LIST OF STUDIES TO BE GENERATED, STILL ONGOING OR AVAILABLE BUT NOT PEER REVIEWED).

This guidance document describes the procedures for submission and assessment of these confirmatory data.

3. PROCEDURES IMMEDIATELY FOLLOWING INCLUSION

All authorisation holders should be informed (by concerned Member States, that is those where an authorisation is held) that confirmatory data are required, highlighting that this is a requirement for the notifier at whose request the active substance was placed onto Annex I.

4. PROCEDURES FOR SUBMISSION OF CONFIRMATORY DATA

The notifier (at whose request the active substance has been included in Annex I) must submit the confirmatory data (Annex II and/or Annex III and risk assessment) to COM and the original RMS at the latest by the deadline prescribed in the Directive. The RMS should confirm at the time of voting that they will undertake the assessment of the confirmatory data and, if not, another designated MS (DMS) should be allocated.

The notifier's submission must make clear how the data submitted address the outstanding issues (e.g. via a summary document). The notifier should restrict their submission and assessment specifically to the areas required as confirmatory data in Part B of the Inclusion Directive. They should not address other 'data gaps' listed in the EFSA conclusions (List of studies to be generated, still ongoing or available but not peer reviewed)

The notifier's submission should refer to the uses considered for the Annex I inclusion and in the Review Report.

The data and summary document must be submitted in electronic format (or hard copy if requested).

In addition the notifier must also copy the confirmatory data to all MS and EFSA, by the required deadline, highlighting that the RMS/DMS will evaluate the data on behalf of all MS.

Whilst the submission of confirmatory data is (in many cases) required at the same time as the administrative deadline for submission of Step 2 re-registration [Annex III] submissions, notifiers should *not* combine the two submissions, nor should they combine the submission of confirmatory data with the submission of other data destined to amend the Annex I inclusion conditions. There must be clear separation between the confirmatory data, Step 2 submissions² (noting they may reflect different uses/GAPs), and submission of data in order to amend the Annex I inclusion conditions. However, the notifier should clearly cross reference the data submitted in all cases, to prevent duplication of assessment by the competent authority(s).

In the event that confirmatory data are not submitted by the notifier then the COM will need to determine the appropriate action, which would normally be non-inclusion of the active substance.

The act of submission or non-submission of confirmatory data should not be treated as confidential. Whether or not the data has been submitted can be disclosed to other parties and the list of submitted studies may also be disclosed but the submitted data itself related to confidential sections of the dossier shall remain confidential.

5. PROCEDURES FOR ASSESSMENT OF CONFIRMATORY DATA

Assessment by RMS/DMS

The RMS/DMS should prepare a DAR addendum, focussing only on the specific areas of assessment addressed by the confirmatory data and against the uses considered for the Annex I inclusion and in the Review Report. Generally guidance in place at the time of publication of the Inclusion

² Note from 2/10/2010, Annex III Step 2 re-registration submissions should be in the format of a draft registration report – see Guidance document on the presentation and assessment of Annex III dossiers SANCO/6895/2009.

Directive should be used however more recent guidance can also be used if appropriate.

The DAR addendum should be placed on CIRCA within **6 months** of the deadline for submission of the confirmatory data. Evaluations should be uploaded under the active substance as described in SANCO/04846/2009. If confidential data are included in the assessment, conventional confidential distribution methods should be used.

The rapid assessment by the RMS/DMS is crucial for maintaining the Annex I inclusion and because the evaluation of the confirmatory data may impact on the Step 2 assessment. For example, key end-points may be derived or the risk envelope influenced by the results of the confirmatory data assessment. Ideally the RMS/DMS (assessing the confirmatory data) should be the same MS as the ZRMS/DMS³ (for the Step 2 re-registration) and the projects should be co-ordinated to ensure no duplication of assessment and prompt delivery. Where the RMS/DMS is not the same as the ZRMS/DMS, the two MS should liaise closely to ensure no duplication of assessment and prompt delivery.

Based on the assessment of the confirmatory data COM and MS should consider whether at least one safe use (normally a use considered for Annex I inclusion) has been identified, such that a MS can grant an authorisation applying -if necessary- risk management and risk mitigation measures appropriate to their national conditions. If this is the case, the inclusion should continue. Each MS would then need to consider carefully whether or not they can grant authorisations based on their own risk assessment and risk management measures. If the assessment of the confirmatory data shows no safe use a decision for non-inclusion should be taken.

Where the confirmatory data relate to the technical specification, the assessment should, wherever possible, be conducted to quicker timescales consistent with the Step 1 process, to prevent delays in the revocation of non-compliant sources at the compliance deadline. In addition the provisions as given in SANCO/6075/2009 should be taken into consideration.

Commenting period.

At the same time as placing the assessment on CIRCA, the RMS/DMS will inform via an e-mail the notifier, other MS using the EAS/NAS contact points, COM and EFSA of the conclusion as to the acceptability of the confirmatory data (highlighting any concerns raised) and asking for comments within 6 weeks, using the standard header 'Outcome of RMS/DMS assessment of confirmatory data for [active substance]'. The EFSA standard commenting table template should be included. The assessment should also be sent to the notifier.

³ The ZRMS/DMS conducts the core assessment of Annex III submissions on behalf of other MS in the zone - see SANCO Guidance on worksharing SANCO/6896/2009

The comments from the notifier, other MS and EFSA should be compiled in the same format as comments on the original DAR (using the EFSA standard commenting table template) and sent to COM and RMS/DMS by the 6 week commenting deadline.

The RMS/DMS is responsible for collating the comments in the Reporting Table format. The RMS/DMS should insert their response to each comment in column 3 of the Reporting Table. The RMS should identify in column 4 of the table their conclusion i.e. comment addressed or open point and, as necessary, indicate their view in relation to next steps (e.g. need for peer review; recommendation for consideration at MS level). This process should be completed within 6 weeks and the reporting table should then be sent to COM, placed on CIRCA and sent to the notifier for information.

Where necessary a revised DAR addendum should be prepared and placed on CIRCA and sent to EFSA who should publish the DAR addendum on the confirmatory data alongside the original DAR on the EFSA website. Before sending the DAR addendum to EFSA, the RMS/DMS shall invite the notifier to identify any confidential information, and remove such information where the request for removal is justified.

It would be useful if the RMS briefly indicated the main open points and their overall view of whether or not a EFSA peer review might be necessary when sending the completed Reporting Table (together with any updated Addendum/endpoints list) to COM (e.g. where conflicting comments are received from MS).

Role of COM

If RMS/DMS/MS or EFSA raise concerns or differences of opinion, then COM will determine whether to instigate a formal EFSA peer review. Where a peer review is required, COM shall set a timeline for the finalisation of the EFSA Conclusion after consultation with EFSA.

6. OUTCOMES OF ASSESSMENT

Based on the outcome of the RMS/DMS assessment, and taking account of comments received from other MS and EFSA, COM will refer the decision to the next available Standing Committee to be noted. An accompanying amended review report will be produced, highlighting whether the data provided were acceptable and any further issues raised. Where necessary, the review report will identify all endpoints that need to be amended and list the new values.

If the confirmatory data are acceptable, the Annex I inclusion will continue either un-amended or amended to reflect any changes in conditions or restrictions resulting from the assessment of the confirmatory data. If the confirmatory data fail to address the points raised in Part B of the inclusion directive or where it appears that the criteria for Annex I inclusion are no

longer met, then the inclusion of the active substance may be withdrawn or amended.

In the event that there may be a need to amend critical end-points (ADI, AOEL, ARfD and/or the residue definitions for commodities of plant and animal origin) the established procedures in SANCO 10328/2004 'Guidance document on the evaluation of new Annex II data post Annex I inclusion of an active substance' should be followed. A revised Review Report and/or a revised EFSA conclusion is required in this case.

RMS/DMS should advise the notifier of the final conclusions.

7. IMPACT ON OTHER AUTHORISATION HOLDERS & DATA PROTECTION

As stated in Part B of the Inclusion Directive, the requirement to submit confirmatory data is incumbent upon the *notifier* (who requested Annex I inclusion).

Since in most cases no formal decision will be taken to maintain (or vary) the inclusion, Article 13 3 d does not apply, and no EU data protection will be afforded to the data. Thus other approval holders have no obligation to provide the data and MS need take no further action once the outcome of the assessment is noted by the Standing Committee. However, if the inclusion directive is amended as a result of the assessment of the confirmatory data then data protection would apply to those studies which have been considered essential to amend the inclusion directive and would be 5 years from the date of the amended inclusion.

Data protection for Annex III confirmatory data will be dealt with at a national level.

8 SCHEMATIC OF CONFIRMATORY DATA PROCESS

