



SANCO/5634/2009 rev. 6.1
Dated December 2013

Guidance document on the procedures for submission and assessment of confirmatory information following approval of an active substance in accordance with Regulation (EC) No 1107/2009

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This document has been conceived as a guidance document of the Commission Services. It does not represent the official position of the Commission. It does not intend to produce legally binding effects. Only the European Court of Justice has jurisdiction to give preliminary rulings concerning the validity and interpretation of acts of the institutions of the EU pursuant to Article 267 of the Treaty.

Revision history

When	What
Rev. 6.1 of 13.12.2013	Reflect the procedure regarding the submission and assessment of confirmatory information submitted under Regulation (EC) No 1107/2009. An additional step (EFSA's conclusion on the comments) is introduced in the procedure (see chapter 5).

1. IMPLEMENTATION SCHEDULE

This amended version of the guidance document should be implemented as from 1 March 2014.

2. INTRODUCTION & BACKGROUND

Under Regulation (EC) No 1107/2009 an approval may be subject to the request for submission of further confirmatory information, where new requirements are established during the evaluation process or as a result of new scientific and technical knowledge (Article 6(f)). In exceptional cases an active substance may be approved with a request for the submission of information where *(a) the data requirements have been amended or refined after the submission of the dossier; or (b) the information is considered to be confirmatory in nature, as required to increase confidence in the decision* (Annex II, point 2.2).

Such a request for confirmatory information should be specified in the approval decision. Where the approval provides for the submission of further confirmatory information, the Regulation shall provide the time limit (usually 2 years after entry into force of the approval Regulation) to submit the information to the Member States, the Commission and the Authority.

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to all the data gaps listed in the EFSA conclusions (LIST OF STUDIES TO BE GENERATED, STILL ONGOING OR AVAILABLE BUT NOT PEER REVIEWED).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

3. PROCEDURES IMMEDIATELY FOLLOWING APPROVAL

All authorisation holders should be informed (by concerned Member States, which are those where an authorisation is held) that confirmatory information is required, highlighting -when this is stated in the approval Regulation- that this is a requirement for the applicant(s)¹ at whose request the active substance was approved.

¹ When in this document reference is made to applicant (singular), it may refer to applicants (plural) as well to take into account that different applicants can have supported the approval of the active substance.

4. PROCEDURES FOR SUBMISSION OF CONFIRMATORY INFORMATION

The applicant should submit the confirmatory information to the Member States, the Commission and the Authority at the latest by the deadline prescribed in the approval Regulation. In addition the applicant should highlight that the Rapporteur Member State/Designated Member States (RMS/DMS) will evaluate the information on behalf of all MS. The RMS should confirm at the time of voting that it will undertake the assessment of the confirmatory information. If not, another designated MS (DMS) should be allocated.

The applicant's submission should make clear how the information submitted addresses the outstanding issues (e.g. via a summary document). The applicant should restrict its submission and assessment specifically to the areas required as confirmatory information. He 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 applicant's submission should refer to the uses considered for the approval decision and in the Review Report.

The information and the summary document should be submitted in electronic format (or hard copy if requested).

Whilst the submission of confirmatory information under Directive 91/414/EEC was (in many cases) required at the same time as the administrative deadline for submission of Step 2 re-registration [Annex III] submissions, this will (in most cases) not be the case under Regulation (EC) No 1107/2009 where the submission of information for the re-authorisation for the product should be done within 3 months from the renewal of the approval of the active substance.

In all cases applicants should *not* combine the two submissions, nor should they combine the submission of confirmatory information with the submission of an application to amend the approval conditions. There should be clear separation between the confirmatory information, submissions for re-authorisation² (noting they may reflect different uses/GAPs), and submission of an application to amend the approval conditions. However, the applicant should clearly cross reference the data and information submitted in all cases, to prevent duplication of assessment by the competent authority(s).

In the event that the applicant does not submit the confirmatory information then the COM will need to determine the appropriate action, which could be a withdrawal or a restriction of the approval of the active substance.

The act of submission or non-submission of confirmatory information will not be treated as confidential. The applicant may request that the information

² Re-authorisation 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.

submitted be treated as confidential. Provisions pertaining to the confidential treatment of information under Regulation (EC) No 1107/2009 will apply. In principle the submitted information as referred to in Article 63 of Regulation (EC) No 1107/2009 will remain confidential.

5. PROCEDURES FOR ASSESSMENT OF CONFIRMATORY INFORMATION

Assessment by RMS/DMS

The confirmatory information is linked to the approval of the active substance.. Generally guidance in place at the time of publication of the approval Regulation should be used however more recent guidance can also be used if appropriate.

The RMS/DMS should prepare an addendum³ or revised DAR⁴, focussing only on the specific areas of assessment addressed by the confirmatory information and against the uses considered for the approval and in the Review Report. An amended Draft Assessment Report should be prepared for all active substances for which the assessment report was submitted to the Commission as from 1 May 2013, taking into account the *Guidance Document on rules for revision of assessment reports* (SANCO/10180/2013).

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

Ideally the RMS/DMS (assessing the confirmatory information) should be the same MS as the Zonal Rapporteur member States (ZRMS)/DMS⁵ (for the re-authorisation of products).

Based on the assessment of the confirmatory information COM and MS should consider whether at least one safe use (normally a use considered for approval) 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 approval should continue. Each MS would then need to consider carefully whether or not it can grant authorisations based on their own risk assessment and risk management measures. If the assessment of the confirmatory information shows no safe use a decision for withdrawal or restriction of the approval should be taken.

³ For all active substances for which the assessment report was submitted to the Commission before 1 May 2013 still an addendum can be prepared.

⁴ When in this document reference is made to 'Draft Assessment Report', it applies as well to 'Draft Renewal Assessment Report' and 'Renewal Assessment Report'.

⁵ The ZRMS/DMS conducts the core assessment of product submissions on behalf of other MS in the zone - see SANCO Guidance on worksharing SANCO/6896/2009

In general the submission and assessment of confirmatory information should not delay product authorisations. Assessments of new products should be undertaken on request, and without referral to the pending confirmatory information.

Commenting period.

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

The comments from the applicant, 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 its conclusion i.e. comment addressed or open point and, as necessary, indicate its view in relation to next steps (e.g. recommendation for consideration at MS level). This process should be completed within 6 weeks and the reporting table should then be sent to EFSA. EFSA will add its conclusion in column 4 within 4 weeks (after receipt of the reporting table) and sent the final reporting table to COM and the RMS. The RMS is responsible for uploading the document on CIRCABC and sending it to the applicant for information.

Where necessary an amended addendum or revised DAR should be prepared and placed on CIRCABC. The RMS/DMS shall invite the applicant to identify any confidential information, and remove such information where the request for removal is justified. This amended addendum or revised DAR, without the confidential information, should be sent to EFSA who should then publish the latest version of the addendum or revised DAR on the EFSA website.

It would be useful if EFSA briefly indicates the main open points and its overall view whether an EFSA peer review might be necessary when sending the completed Reporting Table to COM and RMS. In addition it should be indicated where there is a difference of opinion with the conclusion of the RMS.

Role of COM and EFSA

If the RMS/DMS or EFSA raises 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, and –when available- the EFSA conclusion, COM will refer the decision to the next meeting of the Standing Committee to be noted. An accompanying amended review report will be produced, highlighting whether the information provided was 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 information is acceptable, the approval will continue either un-amended or amended to reflect any changes in conditions or restrictions resulting from the assessment of the confirmatory information. If the confirmatory information fails to address the points raised in the approval Regulation or where it appears that the criteria for approval are no longer met, then the approval of the active substance may be withdrawn or restricted.

In the event that there may be a need to amend critical end-points related to the approval criteria (e.g. 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 active substance data post approval' should be followed. A revised Review Report and/or a revised EFSA conclusion are required in this case.

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

7. IMPACT ON OTHER AUTHORISATION HOLDERS & DATA PROTECTION

When it is stated in the approval Regulation that the applicant at whose request the active substance has been approved, should submit the confirmatory information, then another interested party including authorisation holders cannot provide the outstanding confirmatory information instead of the original applicant.

The role of applicant may be transferred to another company if both parties agree to the transfer. This should be done before the deadline for the submission of the confirmatory information.

In the case a third party wishes to be considered as an applicant and a transfer of the role of applicant is not possible, a new application for the approval of the active substance should be made.

In the latter case, it is clear that the dossier should contain the requested confirmatory information.

Active substance **confirmatory information** submitted under Directive 91/414/EEC for NAS or EAS (assessed post approval)

This information is generally not protected because in most cases no formal decision will be taken to maintain (or vary) the approval. Should however the approval be amended as a result of the evaluation of the confirmatory information (or *critical* end points change as a result) data protection will be 5 years from the date of the amended approval.

Active substance **confirmatory information** submitted for NAS or EAS (assessed post approval) for approvals issued under Regulation (EC) No 1107/2009

The situation arises when confirmatory information is submitted after the granting of an authorisation. In the case confirmatory information is necessary to review the authorisation, that information will be protected for 30 months from the date of the amended authorisation or from the date of the decision to maintain the authorisation in each MS.

8 SCHEMATIC OF CONFIRMATORY INFORMATION PROCESS

