

Overview of documents EFSA Applications Helpdesk requires from applicants for pesticide active substances

<u>NAS</u> <u>Regulation EC 1107/2009</u>	In this section you can find the documents that applicants submitting an application for the approval of new active substances should present to EFSA in the various phases of the procedure, as per Regulation EC 1107/2009
<u>AIR III and IV</u> <u>Commission Implementing Regulation EU 844/2012</u>	Active substances which have been approved are re-evaluated before their expiry date under the renewal programme ("AIR"). In this part, you can find the documents that applicants need to submit to EFSA for the renewal of approval of active substances under Regulation EU 844/2012

This document addresses frequent questions received by the Applications Helpdesk relating to specific documents that should be submitted to **EFSA** (it does not concern the submission of documents to any other party, e.g. European Commission, Rapporteur Member States and Member States) as required by the relevant regulatory framework on active substances and products containing these substances. It complements information on the EFSA and [European Commission website](#).

The document provides informal general guidance. It is not legally binding and provides supplementary information to the prevailing legislative requirements.

Applicants are advised to direct specific queries relating to their application to the [Applications Helpdesk service](#), which will consult with the relevant EFSA Scientific Unit, Agencies and European Commission services, as appropriate.

NAS Reg. EC 1107/2009	Preferred format	Timing	Submission route
Dossier Sanitised Summary Dossier (dossier without Doc J-K and with confidential information blackened) + justification form signed by applicant and including agreements on sanitisations and countersignature by RMS	CADDY XML Pdf (full, stand alone, sanitised version)	Within 14 days after notification of admissibility by RMS ¹	CD
Updated Dossier (dossier updated with new info as requested by the RMS during the assessment)	CADDY XML	ASAP after receiving the Draft Assessment Report from EFSA	CD

¹ Deadline agreed by Pesticides Steering Committee (October 2011) for the Sanitised Summary Dossier, EFSA suggests that the dossier, summary dossier and sanitised summary dossier are sent at the same time, in a single package.

AIR III and IV Reg. EU 844/2012	Format	Timing	Submission route
Application + request for confidentiality	pdf	Together with submission to RMS	CD or email
Sanitised application (application with blackening of confidential information) + Justification form signed by applicant including agreements on sanitisations and countersignature by RMS	pdf	Within 14 days upon the decision by the RMS that the application has been submitted by the date provided for (Art. 1) and that it contains all the elements provided for in Art. 2	CD or email
Original dossier from first Annex I inclusion and subsequent renewals [Art. 8(5)]	CADDY, CADDY XML or pdf		
Supplementary Dossier	CADDY XML		
Sanitised Supplementary Summary Dossier (dossier without Doc J-K and with confidential information blackened) + Justification form signed by applicant including agreements on sanitisations by RMS	Pdf, presented as: <ul style="list-style-type: none"> - full dossier (including files non-sanitised) - standalone files (sanitised) using up to date and reliable redacting software programmes ³ Doc P, in CADDY XML (files adequately named ⁴)		
Updated Supplementary Dossier Updates should be highlighted	CADDY XML	ASAP after receiving the Draft Renewal Assessment Report from EFSA	CD
Updated Sanitised Supplementary Summary Dossier (Updated dossier without Doc J-K and with confidential	Pdf, presented as: <ul style="list-style-type: none"> - full dossier (including files non-sanitised) - standalone files (sanitised) 	ASAP after receiving the Draft Renewal Assessment Report from EFSA	CD

² For detailed information consult the [EC Guidance Document on the renewal of approval of active substances Reg. EU 844/2012](#)

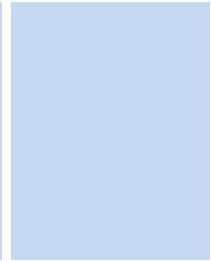
³ Word format is not recommended, as sanitisation is not performed effectively

⁴ As the pdf files need to be copied from the CADDY XML documents directory, they need to be identifiable as Doc P and therefore be named adequately

information blackened)
+ Updated justification form for EFSA Approval. Updates should be highlighted **both** in the sanitised dossier and in the justification form

using up to date and reliable redacting software programmes⁵

Doc P, in CADDY XML (files adequately named⁶)



⁵ Word format is not recommended, as sanitisation is not performed effectively

⁶ As the pdf files need to be copied from the CADDY XML documents directory, they need to be identifiable as Doc P and therefore be named adequately