Overview of documents EFSA APDESK requires from applicants

NAS Regulation EC No **1107/2009**	Regulation (EC) No 1107/2009 of the European Parliament and the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC
AIR III Commission Implementing Regulation EU No **844/2012**	Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market

This document addresses frequent questions received by the Applications Helpdesk relating to specific documents that should be submitted to EFSA as required by the relevant regulatory framework on active substances and products containing these substances. It complements information on the EFSA and European Commission websites.

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, Agencie and European Commission services, as appropriate.

NAS EC No **1107/2009**	**Preferred format**	**Timing**	**Submission route**
Dossier	CADDY XML	Within 14 days after notification of admissibility by RMS*	CD
Summary Dossier (Dossier without Doc J-K)	CADDY XML or pdf		
Sanitised Summary Dossier (Dossier without Doc J-K and with confidential information blackened) + j**ustification form** signed by applicant and including agreements on sanitisations by RMS	Pdf (full, stand alone, sanitised version)		
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

*Deadline agreed by Pesticide 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 EU No **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 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	Upon admissibility decision of the Application (Art. 8) by the RMS*	CD
Supplementary Dossier	CADDY XML		
Supplementary Summary Dossier	CADDY XML		
Sanitised Supplementary Summary Dossier (with blackened confidential information) **+ justification form** signed by applicant including agreements on sanitisations by RMS	Pdf (full, stand alone sanitised version) or Doc P in CADDY XML (files adequately named**)		
Updated Supplementary Complete Dossier and **Sanitised Supplementary Summary Dossier** (f*ormat still under discussion with EC*)	CADDY XML	ASAP after receiving the Draft Renewal Assessment Report from EFSA.	CD

*According to Art. 6, the Supplementary Dossiers have to be provided to EFSA at the same time as to the RMS. However, for reasons of simplification it was agreed in the Pesticides Steering Committee (11-12/06/2013) to postpone the submission to EFSA until after the admissibility decision of the dossiers by the RMS.

**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.