



Annexes to the Guidance document on the presentation and evaluation of dossiers according to annex III of Directive 91/414/EEC in the format of a (draft) Registration Report¹

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
Revision of 20.03.2015	<ul style="list-style-type: none">- Cover sheet is adapted,- The numbering is aligned according to the numbering of the DAR (SANCO/12592/2012),- The content is aligned with guidance document SANCO/12580/2012 rev. 3.1 (reference lists) and Regulation (EU) No 284/2013 (data requirements),- New document B.0 containing general information has been added,- A summary should be added at beginning of each part and study evaluation in the appendix,- An overview on the data gaps should be included in the summary in the beginning of each section,- The presentation of the different GAPs has been streamlined.
Revision 1 of 07.10. 2016	<ul style="list-style-type: none">- Part B6 (Mammalian Toxicology) is updated according to the latest guidance² on exposure assessment of operators, workers, bystanders and residents

¹ The Guidance Document itself is currently in the process of updating and at that stage the title will be amended and the reference to Directive 91/414/EEC will be deleted.

² EFSA 2014. Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products. EFSA Journal 2014;12(10):3874, 55 pp.

Implementation schedule

This document has been finalised in the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF) on 20 March 2015. Revision 1 was finalised in the SCoPAFF on 7 October 2016. The present templates (revision 1) should be used for applications for authorisation, amendment of authorisation and renewal of authorisation of plant protection products containing chemical active substances as from 1 January 2017.

Previous revisions of the templates may be used for applications for re-authorisation of plant protection products containing active substances renewed in accordance with Regulation (EU) No 1141/2010. However, applicants may choose to already use the present templates (March 2015) for these re-authorisations.