SANCO/12592/2012 –rev. 2

22 March 2019

Combined Template to be used for

Assessment Reports according to Regulation (EC) No 1107/2009 and Proposals for Harmonised Classification and Labelling according to Regulation (EC) No 1272/2008

Agreed by Member States' Competent Authorities in the SCoPAFF: Phytopharmaceutical legislation section

This document is drafted in the interest of consistency of the implementation of Regulation (EC) No 1107/2009 and with the aim of finding an agreement between Member States' Competent Authorities for plant protection products, the European Food Safety Authority and the European Commission on a harmonised approach. Please note, however, it does not represent the official position of the Commission and that Member States are not legally obliged to follow the approach set out in this document, since only the Court of Justice of the European Union can give authoritative interpretations on the contents of Union law.

Contents

Background

This revised template is intended to (i) align the current structure of the assessment report with the dossier and the revised data requirements, (ii) align the structure and the content of the assessment report with the report for proposed harmonised classification according to Regulation (EC) No 1272/2008. It also aims to reduce duplication of information in different parts of the assessment report and to separate out the active substance part from product related exposure and risk. In this way transparency and consistency in the documentation submitted and assessed in light of an application for an approval or renewal of approval of an active substance will be increased.

Furthermore it is envisaged that this structure will support the risk envelope approach for products and that it will facilitate the setting of Maximum Residue Levels (MRLs), the preparation of a "Conclusion on the peer review of the pesticide risk assessment of an active substance" as prepared by the European Food Safety Authority (EFSA), as well as an "Opinion on proposal for harmonised classification and labelling" (CLH report) as prepared by the Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA).

An Assessment Report shall consists of the following parts: Volume 1, Volume 2, Volume 3 Active Substance part, Volume 3 Plant Protection Product part(s), Volume 4, as well as a List of Endpoints as a stand-alone document separated in an Active Substance part and Plant Protection Product part(s).

Implementation schedule

When	Applicability	What
Rev 0 of 20 November 2012		Original version
Revision 1.2 of 6 October 2017	For applications for (renewal of) approval submitted after 6 October 2017	Updated to align the structure and the content of the assessment report with the report for proposed harmonised classification according to Regulation (EC) No 1272/2008
Revision 2 of 22 March 2019	For *Assessment Reports* submitted by Member States to EFSA from 1 April 2019 as a minimum the revised Volume 1 should be used and the statement should be added to each section cover page. The revised templates are fully applicable for *dossiers* submitted from 1 April 2019.	Updated to: • Add a statement to each section cover page to explain how information is presented • Amend the sections in Volume 1 where the summary of the assessment of endocrine disrupting properties is made • Revise the format of the table of lists of tests and studies (Volumes 2 and 3)

APPENDIX

The full template can be found on DG SANTE's pesticides webpages at the following link:

https://ec.europa.eu/food/plant/pesticides/approval_active_substances/guidance_documents_en