

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.

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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 <i>Assessment Reports</i> 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 <i>dossiers</i> submitted from 1 April 2019.	Updated to: <ul style="list-style-type: none"> • 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)
Revision 3 of 22 March 2024	As of April 2024, any	Updated template consequent to new and/or

	<p>new Assessment Reports shall be prepared using the revised Volume 1. For ongoing assessments, Member States should use the revised Volume 1, where possible.</p>	<p>revised sections in view of the new hazard classes introduced by Commission Delegated Regulation 2023/707 of 19 December 2022 amending the CLP Regulation (EC) No 1272/2008 as regards hazard classes and criteria for the classification, labelling and packaging of substances and mixtures. In particular, the new sections on PBT, vPvB, PMT, vPvM (cf sections 2.10 and 2.11) were extracted and directly taken over from the updated standalone ECHA CLH report template, as published on ECHA website (<u>CLH report template (with explanations)</u>), and reproduced in the combined template without any modification. With regard to the new hazard classes on endocrine disruption for human health or the environment, the existing ED template following the structure of the ECHA/EFSA ED Guidance has been maintained, with the addition of the classification-specific elements taken over from the ECHA standalone template, as a pragmatic approach (cf section 2.12).</p> <p>No updates made to any other section.</p>
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APPENDIX

The full template can be found in the database on “Guidelines and supporting documents on Active Substances and Plant Protection Products”:

<https://webgate.ec.europa.eu/dyna2/pgd/>