SANCO/12592/2012 –rev. 1.2

6 October 2017

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

This document was first finalised in the Standing Committee on the Food Chain and Animal Health on 20 November 2012. This revised template was agreed by the Standing Committee on Plants, Animals, Food and Feed on 6 October 2017. It should be used for combined assessment and CLH reports prepared for active substances covered by Commission Regulation (EU) No 844/2012 *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* and for active substances for which an application for the approval has been submitted as from 6 October 2017.

APPENDIX

See on SANTE's website for pesticides:

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