

**Note for agreement by Member States's Competent Authorities in
the SCoPAFF: Phytopharmaceutical legislation section**

SANTE/2018/10591 rev.1

24 October 2018

Guidance on dermal absorption

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.

Introduction

The European Food Safety Authority (EFSA), following its standard procedures for development of guidance documents, including consultation of stakeholders and general public, has published the following guidance document:

EFSA, 2017. Guidance on dermal absorption. EFSA Journal 2017;15(6):4873 [60 pp.]. doi: 10.2903/j.efsa.2017.4873

This Guidance Document constitutes a revision of the first version of the 'guidance document on dermal absorption', issued in 2012 by the EFSA PPR Panel.

The 2017 EFSA Guidance Document has been adopted in the Standing Committee on Plants, Animals, Food and Feed on 25 May 2018.

A corrigendum (minor modification) has been adopted in the Standing Committee on Plants, Animals, Food and Feed on 24 October 2018.

Implementation schedule

The use of this revised guidance document is recommended for applicants and Member States for any applications for active substance and/or plant protection products submitted under Regulation (EC) No 1107/2009 after **25 August 2018**.

For the purpose of this guidance document a plant protection product is considered:

1. A "concentrate" when the active substance is present in the plant protection product at a concentration higher than 50 g/L (or 50g/Kg or 5%);
2. A "dilution" when the active substance is present in the plant protection product at a concentration lower than or equal to 50 g/L (or 50g/Kg or 5%).

The Member States may decide in the future to carry out further more precise analysis of the data and agree, if they consider it appropriate, a threshold value different from 5% to discriminate between a "concentrate" and a "dilution".