

Commission Implementing Regulation (EU) No 844/2012 of 18 September 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 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 844/2012

of 18 September 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

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC<sup>(1)</sup>, and in particular Article 19 thereof,

Whereas:

- (1) Regulation (EC) No 1107/2009 provides that the approval of an active substance may be renewed upon expiry.
- (2) It is appropriate to set out the provisions necessary for the implementation of the renewal procedure.
- (3) In particular, periods should be set for the different steps of the renewal procedure to ensure that it functions properly.
- (4) Rules should be set out as regards confidentiality and the publication of the application for renewal, the supplementary dossiers and their updates.
- (5) Rules should also be set out as regards the submission of the application for renewal and its contents and format. The applicant should be obliged to justify the submission of new information and to list separately studies concerning vertebrate animals that they intend to submit.
- (6) Rules should be set out as regards the checking of the application by the rapporteur Member State.
- (7) In order to ensure the proper functioning of the renewal procedure, the rapporteur Member State should, at the applicant's request, organise prior to the submission of the supplementary dossier, a meeting to discuss the application.

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**Status:** Point in time view as at 31/12/2020.

**Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 844/2012, Introductory Text. (See end of Document for details)

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- (8) The supplementary dossiers submitted for renewal should, in particular, include necessary new data and new risk assessments and demonstrate why such data and risk assessments are necessary.
- (9) Rules should be set out as regards the establishment of the admissibility of the application by the rapporteur Member State.
- (10) Where all applications submitted are inadmissible, the Commission should adopt a Regulation on the non-renewal of the active substance concerned.
- (11) Rules should be set out to ensure an independent, objective and transparent assessment of the active substance.
- (12) The applicant, the Member States, with the exception of the rapporteur Member State, and the public should be given the opportunity to submit comments on the draft renewal assessment report.
- (13) The European Food Safety Authority should provide conclusions and organise consultations of experts, except where the Commission informs it that a conclusion is not necessary.
- (14) Rules should be set out as regards the renewal report and the adoption of a regulation on the renewal of the approval of the active substance.
- (15) Commission Regulation (EU) No 1141/2010 of 7 December 2010 laying down the procedure for the renewal of the inclusion of a second group of active substances in Annex I to Council Directive 91/414/EEC and establishing the list of those substances<sup>(2)</sup> should continue to apply with respect to the renewal of the approval of the active substances listed in Annex I thereto.
- (16) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

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- (1) [OJ L 309, 24.11.2009, p. 1.](#)
- (2) [OJ L 322, 8.12.2010, p. 10.](#)

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