Commission Implementing Regulation (EU) 2020/1740 of 20 November 2020 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, and repealing Commission Implementing Regulation (EU) No 844/2012 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1740

of 20 November 2020

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, and repealing Commission Implementing Regulation (EU) No 844/2012

(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 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety[(1)], and in particular Article 39f thereof,

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[(2)], and in particular Article 19 thereof,

Whereas:

(1) Article 14(1) of Regulation (EC) No 1107/2009 provides that on application the approval of an active substance may be renewed if it is established that the approval criteria in Article 4 of that Regulation are fulfilled.

(2) Commission Implementing Regulation (EU) No 844/2012[(3)] sets out the provisions necessary for the implementation of the procedure for the renewal of approval of active substances. In particular, it sets out rules for the different steps of the renewal procedure from the preparation to the submission of the application for the renewal of the approval of an active substance (‘the application for renewal’), its content and format, on confidentiality and public disclosure of the application for renewal, and on the adoption of a regulation on the renewal or non-renewal of the approval of active substances.

(3) Implementing Regulation (EU) No 844/2012 has been substantially amended three times[(4)]. Further amendments are to be made to it following the adoption of Regulation (EU) 2019/1381 of the European Parliament and the Council[(5)].

(4) Therefore, Implementing Regulation (EU) No 844/2012 should be repealed and replaced by this Regulation for the sake of clarity.

(5) It is appropriate to set out new provisions necessary for the implementation of the renewal procedure, in particular the periods for the different steps of the renewal procedure.

(6) Regulation (EU) 2019/1381 amended, among others, Regulations (EC) No 178/2002 and (EC) No 1107/2009. Those amendments strengthen the transparency and the sustainability of the Union risk assessment in all areas of the food chain where the European Food Safety Authority ('the Authority') conducts a scientific risk assessment.

(7) Regulation (EU) 2019/1381 introduced provisions that are pertinent for the renewal procedure for active substances provided for in Regulation (EC) No 1107/2009. Those include, amongst others, the provision of pre-submission advice on intended tests and studies for the purposes of a renewal, preceded by a specific notification by the potential applicant and consultation of third parties, the provision of general pre-submission advice on the rules applicable to the application for renewal, and its content, a notification obligation imposed on business operators, laboratories and testing facilities when studies are commissioned or carried out by them to support an application, the public disclosure of all scientific data, studies and other information supporting an admissible application by the Authority, and a consultation of third parties on the submitted scientific data, studies and other information supporting an admissible application. To ensure proper implementation of those provisions in the context of the procedure for the renewal of approval of active substances, detailed rules should be set out.

(8) An application for renewal should include the necessary data and risk assessments and demonstrate why any new data and risk assessments are necessary.

(9) In order to implement the requirement set out in point (c) of Article 38(1) of Regulation (EC) No 178/2002 as amended by Regulation (EU) 2019/1381, its Article 39f(2) provides for the adoption of standard data formats to allow documents to be submitted, searched, copied and printed, while ensuring compliance with regulatory requirements set out in Union law. Consequently, it is necessary to adopt a standard data format.

(10) Rules should be set out as regards the establishment of the admissibility of the application for renewal by the rapporteur Member State.

(11) Where all applications for renewal submitted are inadmissible, the Commission should adopt a Regulation on the non-renewal of the active substance concerned to provide clarity on the status of the active substance.

(12) Regulation (EU) 2019/1381 also introduced additional requirements relating to transparency and confidentiality as well as specific procedural requirements for the submission of confidentiality requests in relation to information submitted by an applicant. To ensure a proper implementation of those requirements, the conditions for the assessment of confidentiality requests in the context of applications for renewal should be set out. That assessment should be performed by the Authority in accordance

with Regulation (EU) 2019/1381 once the relevant application for renewal has been considered admissible by the rapporteur Member State.

(13) 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 prepared by the rapporteur Member States and co-rapporteur Member State, or by Member States acting jointly as rapporteur.

(14) In accordance with Article 36(2) of Regulation (EC) No 1272/2008 of the European Parliament and of the Council[6], active substances within the meaning of Regulation (EC) No 1107/2009 are normally to be subject to harmonised classification and labelling. It is therefore appropriate to set detailed rules of procedure regarding the submission of proposals to the European Chemicals Agency in accordance with Article 37(1) of Regulation (EC) No 1272/2008 by the rapporteur Member State during the renewal of approval of active substances pursuant to Article 14 of Regulation (EC) No 1107/2009.

(15) The Authority should organise consultations of experts and provide conclusions, except where the Commission informs it that a conclusion is not necessary.

(16) Rules should be set out as regards the renewal report and the adoption of a regulation on the renewal or non-renewal of the approval of the active substance.

(17) Given that this Regulation implements certain provisions of Regulation (EU) 2019/1381, which applies from 27 March 2021 , this Regulation should apply from the same date. Since applications for renewal pursuant to this Regulation are to be submitted at least three years before the expiry of the approval period of an active substance, this Regulation should apply with respect to the renewal of the approval of active substances for which the approval period ends on or after 27 March 2024, even if an application for renewal has already been submitted in accordance with Implementing Regulation (EU) No 844/2012.

(18) Transitional measures should be provided for active substances for which the approval period ends before 27 March 2024 to ensure that the renewal procedure for those substances can continue. Implementing Regulation (EU) No 844/2012 should continue to apply to active substances whose approval period on the date of application of this Regulation expires before 27 March 2024 or for which a Regulation, adopted in accordance with Article 17 of Regulation (EC) No 1107/2009 on or after 27 March 2021, extends the approval period to 27 March 2024 or a later date.

(19) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

CHAPTER 1

SUBJECT MATTER AND SCOPE

Article 1

Subject matter

This Regulation establishes rules on the procedure for the renewal of the approval of active substances within the meaning of Regulation (EC) No 1107/2009.

Article 2

Scope

This Regulation shall apply to the renewal of the approval of active substances whose approval period ends on or after 27 March 2024.

However, it shall not apply to the renewal of the approval of the active substances for which a Regulation, adopted in accordance with Article 17 of Regulation (EC) No 1107/2009 on or after 27 March 2021, extends the approval period to 27 March 2024 or a later date.

CHAPTER 2

NOTIFICATION AND ADVICE PRIOR TO THE SUBMISSION OF THE APPLICATION FOR RENEWAL

Article 3

Notification of intended studies and advice on intended studies

1 Notifications of studies intended to be conducted to support a future application for renewal in accordance with Article 32c(1) of Regulation (EC) No 178/2002 shall be submitted sufficiently ahead of the date for submission of the application for renewal in accordance with Article 5(1) of this Regulation in order to allow public consultation to be performed and comprehensive advice to be provided by the Authority and the studies required in support of a future application for renewal to be carried out in a timely and proper manner.

2 The pre-submission advice by the Authority pursuant to Article 32c(1) of Regulation (EC) No 178/2002 shall be provided with the participation of the rapporteur Member State and the co-rapporteur Member State, taking into account any existing experience and knowledge relevant for the active substance, including, where appropriate, available studies from the earlier approval or renewal of approval.

Article 4

General pre-submission advice

1 A potential applicant may request from the staff of the Authority general pre-submission advice at any time before the submission of the application for renewal. The Authority shall inform the rapporteur Member State of the request and together they shall decide if the co-rapporteur Member State is required to participate in providing the general pre-submission advice.

2 Where several potential applicants request general pre-submission advice, the Authority shall suggest that they submit a joint application for renewal and disclose their contact details to each other for that purpose.

CHAPTER 3

SUBMISSION AND ADMISSIBILITY OF THE APPLICATION FOR RENEWAL

Article 5

Submission of the application for renewal

1 An application for renewal shall be submitted electronically via a central submission system using the format as set out in Article 7 by a producer of the active substance no later than three years before the expiry of the approval.

The rapporteur Member State as set out in the second column of the Annex to Commission Implementing Regulation (EU) No 686/2012[7] or each of the Member States in a group of Member States acting jointly as rapporteur Member State as set out in the fourth column of that Annex, the co-rapporteur Member State as set out in the third column of that Annex, the other Member States, the Authority and the Commission shall be informed via the central submission system referred to in Article 7.

Where a group of Member States jointly assumes the role of the rapporteur Member State, as set out in the fourth column of the tables in Part B and Part C of the Annex to Implementing Regulation (EU) No 686/2012, no co-rapporteur Member State shall be appointed. In this case, all references to ‘the rapporteur Member State’ in this Regulation shall be deemed to be references to ‘the group of Member States acting jointly as rapporteur Member State’.

Prior to the expiry of the deadline for submission of the application for renewal, the Member States acting jointly as rapporteur Member State shall agree on the repartition of all tasks and workload.

Member States forming part of the group of Member States acting jointly as rapporteur Member State shall endeavour to reach consensus during the evaluation.

2 A joint application for renewal may be submitted by an association of producers designated by the producers.

Where there is more than one applicant requesting the renewal of the approval of the same active substance, those applicants shall take all reasonable steps to submit their