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)

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[(1)] 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 dossiers jointly. Where contrary to the advice of the Authority as referred to in Article 4 such dossiers are not submitted jointly by all the applicants concerned, the reasons for that shall be set out in the dossiers.

Article 6

Content of the application for renewal

1 An application for renewal shall consist of a renewal dossier in the format as set out in Article 7.

2 The renewal dossier shall include the following:

a the name and address of the applicant responsible for the application for renewal and for the obligations under this Regulation;

b where the applicant is joined by one or more other applicants, the name and address of that or those other applicants and, if applicable, the name of the association of producers mentioned in Article 5(2);

c information with respect to one or more representative uses on a widely grown crop in each zone of at least one plant protection product containing the active substance, demonstrating that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are fulfilled;

d data and risk assessments which are necessary:

(i) to reflect changes in legal requirements since the approval or last renewal of the approval of the active substance concerned;

(ii) to reflect changes in scientific and technical knowledge since the approval or last renewal of the approval of the active substance concerned;

(iii) to reflect changes to representative uses; or

(iv) because the application is for an amended renewal;

e for each of the data requirements for the active substance, as set out in Commission Regulation (EU) No 283/2013[(2)], the full text of each test or study report and summaries thereof, including those that were part of the approval dossier or subsequent renewal dossiers;

f for each of the data requirements for the plant protection product, as set out in Commission Regulation (EU) No 284/2013[(3)], the full text of each test or study report and summaries thereof, including where relevant, those that were part of the approval dossier or subsequent renewal dossiers;

g where relevant, documented evidence as referred to in Article 4(7) of Regulation (EC) No 1107/2009;

h for each test or study involving vertebrate animals, a description of the steps taken to avoid animal testing on vertebrate animals;

i where relevant, a copy of an application for maximum residue levels as referred to in Article 7 of Regulation (EC) No 396/2005 of the European Parliament and of the Council[(4)];

j a proposal for classification where it is considered that the substance has to be classified or reclassified in accordance with Regulation (EC) No 1272/2008;

k a checklist demonstrating that the renewal dossier is complete in view of the uses applied for and indicating which data are new;

l the summaries and results of scientific peer-reviewed open literature, as referred in Article 8(5) of Regulation (EC) No 1107/2009;

m an assessment according to the current scientific and technical knowledge of all information submitted, including, where relevant, a reassessment of studies and information that were part of the approval dossier or subsequent renewal dossiers;

n a consideration and proposal for any necessary and appropriate risk mitigation measures;

o all relevant information related to the notification of the studies in accordance with Article 32b of Regulation (EC) No 178/2002.

The information referred to in point (o) of the first subparagraph shall be clearly identifiable.

The renewal dossier shall not contain any reports of tests or studies involving the deliberate administration of the active substance or the plant protection product containing it to humans.

3 Applicants shall make their best efforts to obtain access to and provide the studies which were part of the approval dossier or subsequent renewal dossiers as required under points (e) and (f) of paragraph 2.

The Member State that acted as rapporteur for the previous approval and/or subsequent renewal dossiers or the Authority shall endeavour to make available such studies where the applicant provides evidence that its attempts to obtain access from the study owner have failed.

4 If the information submitted in accordance with point (c) of paragraph 2 does not cover all zones or does not concern a widely grown crop, a justification shall be submitted.

5 The uses referred to in point (c) of paragraph 2 shall, where appropriate, include the uses evaluated for the approval or subsequent renewals. At least one plant protection product referred to in point (c) of paragraph 2 shall contain no other active substance, where such a product exists for a representative use.

6 The applicant shall identify and list the new data it submits, including any new studies involving vertebrate animals in a separate list. It shall demonstrate that the new data is necessary in accordance with the first subparagraph of Article 15(2) of Regulation (EC) No 1107/2009 and, where applicable, refer to advice received during the pre-submission phase in accordance with Articles 32a and 32c of Regulation (EC) No 178/2002.

7 When requesting certain information to be kept confidential in accordance with Article 63(1), (2) and (2a) of Regulation (EC) No 1107/2009, the applicant shall identify the confidential and a non-confidential versions of the information submitted.

8 The applicant may submit any data protection claims pursuant to Article 59 of Regulation (EC) No 1107/2009.

Article 7

Format and software for the submission of the application for renewal

1 The Authority shall establish and make available online a central submission system. The Authority shall ensure that the central submission system facilitates the verification of admissibility performed by Member States in accordance with Article 8.

2 The standard data formats proposed by the Authority as part of the IUCLID software package pursuant to Article 39f of Regulation (EC) No 178/2002 are hereby adopted.

3 The application for renewal shall be submitted via the central submission system using the IUCLID software package.

4 The applicant, when requesting certain information to be kept confidential in accordance with Article 63(1), (2) and (2a) of Regulation (EC) No 1107/2009, shall indicate such information using the relevant IUCLID functionality.

The Authority shall assess such a request only if the application is considered admissible in accordance with Article 8 of this Regulation.

Article 8

Admissibility of the application for renewal

1 The rapporteur Member State shall consider an application for renewal admissible, provided that all the following requirements are met:

a the application for renewal has been submitted within the period provided for in Article 5(1) and in accordance with the format and using the software provided for in Article 7;

b the application for renewal contains all the elements provided for in Article 6;

c the application for renewal contains all studies, in full, that have been previously notified in accordance with Article 32b of Regulation (EC) No 178/2002 and no additional ones apart from those contained in the approval dossier or subsequent renewal dossiers or conducted before the obligation under Article 32b of Regulation (EC) No 178/2002 applied, unless a valid justification is provided;

d the relevant fee has been paid.

2 The rapporteur Member State shall, within a period of one month from the date provided for in Article 5(1), inform the applicant, the co-rapporteur Member State, the Commission and the Authority of the date of receipt of the application for renewal and of its admissibility.

3 Where an application for renewal has been submitted in accordance with point (a) of paragraph 1, but one or more elements provided for in point (b) or (d) of paragraph 1 are missing, the rapporteur Member State shall, within a period of one month from the date of receipt of the application for renewal, inform the applicant which elements are missing and set a period of 14 days for the submission of those elements via the central submission system referred to in Article 7. Upon expiry of that period, the rapporteur Member State shall, without delay, proceed in accordance with either paragraph 4 or paragraph 5.

4 Where the application for renewal does not comply with point (c) of paragraph 1, the rapporteur Member State shall, in coordination with the Authority, within a period of one month from date of receipt of the application for renewal, inform the applicant accordingly and set a period of 14 days for providing a valid justification for this non-compliance. Upon expiry of that period and where a valid justification has not been provided, the application for renewal shall be considered inadmissible and Article 32b(4) or Article 32b(5) of Regulation (EC) No 178/2002 shall apply. The assessment of the admissibility of a resubmitted application for renewal shall only commence after the expiry of the six-month period mentioned in Article 32b(4) or Article 32b(5) of Regulation (EC) No 178/2002 following the notification of the relevant studies and/or submission of studies as necessary and provided that that point in time is no later than three years before the expiry of the approval of the active substance. If that point in time is later than three years before the expiry of the approval of the active substance, the resubmitted application for renewal shall be considered inadmissible.

5 Where the application for renewal has not been submitted within the period referred to in point (a) of paragraph 1, or where at the end of the 14-day period set for the submission of the missing elements in accordance with paragraphs 3 and 4 the application for renewal still does not contain all the elements provided for in Article 6, the rapporteur Member State shall, without delay, inform the applicant, the co-rapporteur Member State, the Commission, the other Member States and the Authority that the application for renewal is inadmissible and of the reasons for inadmissibility.

Article 9

Adoption of a non-renewal Regulation

Where all applications for renewal submitted for an active substance are inadmissible in accordance with Article 8, a Regulation on the non-renewal of the approval of that active substance shall be adopted in accordance with point (b) of Article 20(1) of Regulation (EC) No 1107/2009.

Article 10

Public access to the information in the application for renewal and consultation of third parties

The Authority shall allow a period of 60 days from the date the application for renewal is made public in accordance with point (c) of Article 38(1) of Regulation (EC) No 178/2002 for the submission of written comments on that information and on whether other relevant scientific data or studies are available on the subject matter concerned by the application for renewal. This paragraph does not apply to the submission of any supplementary information submitted by the applicant during the evaluation process.

(**1**) Commission Implementing Regulation (EU) No 686/2012 of 26 July 2012 allocating to Member States, for the purposes of the renewal procedure, the evaluation of the active substances (OJ L 200, 27.7.2012, p. 5).

(**2**) Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 93, 3.4.2013, p. 1).

(**3**) Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 93, 3.4.2013, p. 85).

(**4**) Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

Changes to legislation:
There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1740, CHAPTER 3.