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 4

ASSESSMENT AND RENEWAL REPORT AND REGULATION

Article 11

Assessment by the rapporteur Member State and the co-rapporteur Member State

1 Where the application is admissible in accordance with Article 8, the rapporteur Member State shall, after consulting the co-rapporteur Member State, at the latest 13 months after the date of submission of the application for renewal in accordance with Article 5(1), submit to the Commission and to the Authority, a report assessing whether the active substance can still be expected to meet the approval criteria, as provided for in Article 4 of Regulation (EC) No 1107/2009 (‘the draft renewal assessment report’).

2 The draft renewal assessment report shall include the following:

a a recommendation with regard to the renewal of the approval, including any necessary conditions and restrictions;

b a recommendation on whether the substance is to be considered a ‘low-risk’ substance;

c a recommendation on whether the substance is to be considered a candidate for substitution;

d a proposal to set maximum residue levels or a justification in case such proposal is not relevant;

e a suggestion for the classification, or its confirmation, where applicable or reclassification of the active substance in accordance with the criteria of Regulation (EC) No 1272/2008, as specified in and consistent with the dossier to be submitted pursuant to paragraph 9 of this Article;

f a conclusion on which of the studies included in the renewal dossier are relevant for the assessment;

g a recommendation as to the parts of the report on which a consultation of experts is to be organised in accordance with Article 13(1);

h where relevant, the points on which the co-rapporteur Member State did not agree with the assessment by the rapporteur Member State or, where applicable, the points where there is no agreement between Member States forming a group of Member States acting jointly as rapporteur Member State; and

i the results of the public consultation performed pursuant to Article 10 and how they have been taken into account.

3 The rapporteur Member State shall make an independent, objective and transparent assessment in the light of current scientific and technical knowledge using guidance documents applicable at the date of the submission of the application for renewal. It shall take into account all the information submitted as part of the application for renewal, including the dossiers submitted for the approval and subsequent renewals of approval. The rapporteur Member State

shall also identify and consider, where appropriate, risk mitigation measures and take into account the written comments received during the public consultation pursuant to Article 10). Where despite the best efforts made the applicant could not submit the full text and summary of each test and study report which were part of the approval dossier or subsequent renewal dossiers and required in accordance with points (e) and (f) of Article 6(2), the rapporteur Member State shall ensure that the respective studies are evaluated and taken into account in their overall assessment.

4 In its assessment, the rapporteur Member State shall first establish whether the approval criteria set out in points 3.6.2, 3.6.3, 3.6.4 and 3.7 of Annex II to Regulation (EC) No 1107/2009 are satisfied.

Where those criteria are not satisfied, the draft renewal assessment report shall be limited to the parts of the assessment corresponding to them, unless Article 4(7) of Regulation (EC) No 1107/2009 applies.

5 Where the rapporteur Member State requires additional information, it shall set a period for the applicant to supply that information. That period shall not lead to an extension of the period of 13 months provided for in paragraph 1. Any confidentiality request pursuant to Article 63 of Regulation (EC) No 1107/2009 shall be addressed to the Authority in accordance with Article 6(7) of this Regulation.

6 The rapporteur Member State may consult the Authority and request additional technical or scientific information from other Member States. Such consultations and requests shall not lead to an extension of the period of 13 months provided for in paragraph 1.

7 Information submitted by the applicant without having been requested, or provided after the expiry of the period set for its submission in accordance with paragraph 5 of this Article, shall not be taken into account, unless it is submitted in accordance with Article 56 of Regulation (EC) No 1107/2009.

8 When submitting the draft renewal assessment report to the Commission and the Authority, the rapporteur Member State shall request the applicant to submit the renewal dossier, updated to include the additional information requested by the rapporteur Member State in accordance with paragraph 5 of this Article or submitted in accordance with Article 56 of Regulation (EC) No 1107/2009, without delay, via the central submission system referred to in Article 7 of this Regulation.

Any confidentiality requests pursuant to Article 63 of Regulation (EC) No 1107/2009 shall be addressed to the Authority in accordance with Article 6(7) of this Regulation.

9 The rapporteur Member State shall at the latest at the time of submission of the draft renewal assessment report submit a proposal to the European Chemicals Agency pursuant to Article 37(1) of Regulation (EC) No 1272/2008 and in accordance with the Agency's requirements to obtain an opinion on a harmonised classification of the active substance at least for the following hazard classes:

a explosives;
b acute toxicity;
c skin corrosion/irritation;
d serious eye damage/eye irritation;
e respiratory or skin sensitisation;
f germ cell mutagenicity;
g carcinogenicity;
h reproductive toxicity;

i specific target organ toxicity – single exposure;

j specific target organ toxicity – repeated exposure;

k hazardous to the aquatic environment.

The rapporteur Member State shall duly justify its view that the criteria for classification for one or more of these hazard classes are not fulfilled.

Where a proposal for classification of an active substance has already been submitted to the Agency and its assessment is ongoing, the rapporteur Member State shall submit an additional proposal for classification, limited to any hazard classes listed in the first subparagraph that are not covered by the pending proposal unless new information has become available that was not part of the pending dossier as regards those listed hazard classes.

For the hazard classes, which are already covered by an existing opinion of the Committee for Risk Assessment of the Agency set up pursuant to point (c) of Article 76(1) of Regulation (EC) No 1907/2006, whether or not this opinion has formed the basis of a decision concerning an entry for harmonised classification and labelling of a substance in Annex VI to Regulation (EC) No 1272/2008, it is sufficient that the rapporteur Member State duly justifies in its submission to the Agency that the existing opinion, or where it has already formed the basis of a decision concerning the inclusion in Annex VI, the existing classification remains valid as regards the hazard classes listed in the first subparagraph of this paragraph. The Agency may provide its views regarding the rapporteur Member State's submission.

10 The Committee for Risk Assessment shall endeavour to adopt the opinion referred to in Article 37(4) of Regulation (EC) No 1272/2008 within 13 months from the submission referred to in the first subparagraph of paragraph 9 of this Article.

Article 12

Comments on the draft renewal assessment report

1 The Authority shall examine whether the draft renewal assessment report received from the rapporteur Member State contains all the relevant information in the agreed format and circulate it to the applicant and to the other Member States at the latest three months after its receipt.

2 Upon receipt of the draft renewal assessment report pursuant to paragraph 1 of this Article, the applicant may, within a period of two weeks, submit a request to the Authority for certain information in the draft renewal assessment report originating from its application to be kept confidential pursuant to Article 63 of Regulation (EC) No 1107/2009 and in accordance with Article 6(7) of this Regulation.

The Authority shall make the draft renewal assessment report publicly available with the exception of the information for which the confidentiality request has been accepted as justified.

3 The Authority shall allow a period of 60 days from the date the draft report is made available to the public for the submission of written comments. Such comments shall be communicated to the Authority, which shall collate and forward those comments, together with its own comments, to the rapporteur Member States or group of Member States acting jointly as rapporteur Member State and where relevant the co-rapporteur Member State. The Authority shall provide its view to the Commission on whether it is not necessary in the light of the comments received to continue the procedure in accordance with Article 13.

4 The Authority shall make the updated renewal dossier available to the public at the same time as making the draft renewal assessment report available in accordance with Article 10.

Article 13

Conclusion by the Authority

1 The Authority shall establish a conclusion in the light of current scientific and technical knowledge using guidance documents applicable at the date of the submission of the application for renewal and in the light of the opinion of the Committee for Risk Assessment on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Authority shall, where appropriate, organise a consultation of experts, including experts from the rapporteur Member State and co-rapporteur Member State.

The Authority shall draft the conclusion provided for in the first subparagraph within five months from the expiry of the period referred to in Article 12(3) of this Regulation, or within two weeks from the adoption of the opinion of the Committee for Risk Assessment referred to in Article 37(4) of Regulation (EC) No 1272/2008, if any adopted, whichever occurs later.

Where appropriate, the Authority shall address in its draft conclusion the risk mitigation options identified in the draft renewal assessment report or during the peer review.

The Commission may inform the Authority without delay after the period referred to in Article 12(3) has expired that a conclusion is not necessary.

2 Where the Authority considers that additional information from the applicant is necessary, it shall, in consultation with the rapporteur Member State, set a period not exceeding one month for the applicant to supply such information to the Member States, the Commission and the Authority. The rapporteur Member State shall, within 60 days from the date of receipt of the additional information evaluate the information received and send its evaluation to the Authority.

Where the first subparagraph applies, the period referred to in paragraph 1 shall be extended by the two periods referred to in that subparagraph.

3 The Authority may ask the Commission to consult a European Union reference laboratory designated, pursuant to Regulation (EU) 2017/625 of the European Parliament and of the Council[(1)] for the purposes of verifying whether the analytical method for the determination of the residues proposed by the applicant is satisfactory and complies with the requirements provided for in point (g) of Article 29(1) of Regulation (EC) No 1107/2009. The applicant shall, if requested by the European Union reference laboratory, provide samples and analytical standards.

4 The Authority shall communicate the draft conclusion to the applicant, the Member States and the Commission and give the applicant a possibility to submit comments within a period of two weeks.

Where in its draft conclusion the Authority identifies critical issues and/or critical data gaps such that it is expected that there is no representative use of at least one plant protection product containing the active substance for which the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 would be fulfilled, and which the applicant could not have known about at the time of submission of the application

and did not have the possibility to address following a request for additional information in accordance with Article 13(2), the applicant may also submit additional information on those issues to the Member States, the Commission and the Authority within the two-week period.

Comments and new information shall be considered by the Authority in cooperation with the rapporteur Member State and the co-rapporteur Member State. The Authority shall finalise the conclusion within 75 days from the expiry of the two-week period referred to in the first subparagraph.

In cases where the Authority drafted the conclusion before the expiry of the five months period referred to in the first paragraph of this Article the remaining time may be added to the 75 days mentioned in the previous subparagraph.

5 The Authority shall communicate its final conclusion to the applicant, the Member States and the Commission.

6 After giving the applicant two weeks to request certain information in the conclusion originating from its application to be kept confidential, pursuant to Article 63 of Regulation (EC) No 1107/2009, and in accordance with Article 6(7) of this Regulation, the Authority shall make its conclusion available to the public, excluding any information in respect of which confidentiality has been granted by the Authority.

7 Information submitted by the applicant without having been requested, or provided after the expiry of the period set for its submission in accordance with the first subparagraph of paragraph 2 and the second subparagraph of paragraph 4 of this Article shall not be taken into account, unless it is submitted in accordance with Article 56 of Regulation (EC) No 1107/2009.

Article 14

Renewal report and renewal Regulation

1 The Commission shall present to the Committee referred to in Article 79(1) of Regulation (EC) No 1107/2009 a draft renewal report and a draft Regulation within six months from the date of receipt of the conclusion of the Authority or in cases where there is no such conclusion of the Authority, from the expiry of the period referred to in Article 12(3) of this Regulation.

The draft renewal report and the draft Regulation shall take into account the draft renewal assessment report, the comments referred to in Article 12(3) of this Regulation and the conclusion of the Authority, where such a conclusion has been submitted, and the opinion of the Committee for Risk Assessment, if any, referred to in Article 37(4) of Regulation (EC) No 1272/2008.

The applicant shall be given the possibility to submit comments on the draft renewal report within a period of 14 days.

2 On the basis of the renewal report and taking into account comments submitted by the applicant within the period referred to in the third subparagraph of paragraph 1 of this Article as well as other factors legitimate to the matter under consideration and the precautionary principle where the conditions laid down in Article 7(1) of Regulation (EC) No 178/2002 are relevant, the Commission shall adopt a Regulation in accordance with Article 20(1) of Regulation (EC) No 1107/2009.

(**1**) Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (OJ L 95, 7.4.2017, p. 1).

Changes to legislation:
There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1740, CHAPTER 4.