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(4) Therefore, Implementing Regulation (EU) No 844/2012 should be repealed and replaced by this Regulation for the sake of clarity.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

([1]) OJ L 31, 1.2.2002, p. 1.

([2]) OJ L 309, 24.11.2009, p. 1.

([3]) 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 (OJ L 252, 19.9.2012, p. 26).

([4]) Commission Implementing Regulation (EU) 2018/1659 of 7 November 2018 amending Implementing Regulation (EU) No 844/2012 in view of the scientific criteria for the determination of endocrine disrupting properties introduced by Regulation (EU) 2018/605 (OJ L 278, 8.11.2018, p. 3); Commission Implementing Regulation (EU) 2019/724 of 10 May 2019 amending Implementing Regulation (EU) No 686/2012 as regards the nomination of rapporteur Member States and co-rapporteur Member States for the active substances glyphosate, lambda-cyhalothrin, imazamox and pendimethalin and amending Implementing Regulation (EU) No 844/2012 as regards the possibility that a group of Member States assumes jointly the role of the rapporteur Member (OJ L 124, 13.5.2019, p. 32) and Commission Implementing Regulation (EU) 2020/103 of 17 January 2020 amending Implementing Regulation (EU) No 844/2012 as regards the harmonised classification of active substances (OJ L 19, 24.1.2020, p. 1).

([5]) Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and the sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC (OJ L 231, 6.9.2019, p. 1).

(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.

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[6] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

(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 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;

([7]) 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).

(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 ([8]), 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 ([9]), 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 ([10]);

(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.

([8]) 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).

([9]) 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).

([10]) 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).

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.

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 ([11]) 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

([11]) 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).

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.

CHAPTER 5

REPLACEMENT OF THE APPLICANT, FEES AND CHARGES

Article 15

Replacement of the applicant

An applicant may be replaced by another producer in respect of all of its rights and obligations under this Regulation by informing the rapporteur Member State, by a joint declaration made by both of them. In that case, both shall, at the same time, inform of the replacement the co-rapporteur Member State, the Commission, the other Member States, the Authority and any other applicants that have submitted an application for renewal for the same active substance.

Article 16

Fees and charges

1. Member States may require payment of fees and charges in accordance with Article 74 of Regulation (EC) No 1107/2009 to recover the costs associated with any work they carry out within the scope of this Regulation.

2. In case of simultaneous applications for renewal for more than one active substance, for which at least part of the risk assessment can be considered applicable to all of the active substance applications for renewal, fees shall be proportionate and applied taking into consideration that a common risk assessment might be performed.

The first subparagraph shall in particular apply to such simultaneous applications for renewal concerning strains of microorganisms with genetic, biological and/or ecological similarity, or to pheromones with similar chemical structures acting on the same taxonomic group of target organisms.

CHAPTER 6

FINAL PROVISIONS

Article 17

Repeal

Implementing Regulation (EU) No 844/2012 is repealed.

However, it shall continue to apply to the procedure for the renewal of the approval of the active substances:

(1) whose approval period ends before 27 March 2024;

(2) 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.

Article 18

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 27 March 2021.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 20 November 2020.

For the Commission
The President
Ursula VON DER LEYEN