II

(Non-legislative acts)

REGULATIONS

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

(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 ([1]), and in particular Article 19 and Article 78(2) thereof,

Whereas:

(1) Commission Implementing Regulation (EU) No 844/2012 ([2]) sets out the provisions necessary for the implementation of the renewal procedure for active substances under Regulation (EC) No 1107/2009.

(2) In accordance with Article 36(2) of Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([3]), 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 ('the 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.

(3) Additional time in the framework of the procedure for renewal should be made available to the rapporteur Member State for preparing the draft renewal assessment report and the dossier submitted to the Agency, and to the European Food Safety Authority ('the Authority') for preparing its conclusion. The period available to the applicants between the submission of the application for renewal and the submission of the supplementary dossiers should therefore be reduced by three months and that period of three months should be reallocated to the periods available to the rapporteur Member State and the Authority.

(4) It is appropriate that, in general, the rapporteur Member State submits a dossier in accordance with Article 37(1) of Regulation (EC) No 1272/2008 for at least those hazard classes that are relevant to identify whether an active substance can be considered as a low-risk active substance according to Article 22 of Regulation (EC) No 1107/2009 in conjunction with point 5.1.1 of Annex II to that Regulation, which also include the hazard classes relevant for the cut-off criteria set in points 3.6.2 to 3.6.4 and 3.7 of Annex II to Regulation (EC) No 1107/2009. The rapporteur Member State should duly justify why no harmonised classification and labelling is warranted for hazard classes for which it considers that the criteria for harmonised classification and labelling set by Regulation (EC) No 1272/2008 are not fulfilled.

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

([2]) 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 the Council concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26).

([3]) 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).

(5) However, where a proposal has already been submitted to the Agency and its assessment is ongoing, the rapporteur Member State should limit the proposal to any of those hazard classes that are not covered by the pending proposal, unless it considers that new information is available that was not part of the pending dossier.

(6) Moreover, for those of the hazard classes listed in point 5.1.1 of Annex II to Regulation (EC) No 1107/2009, which are already covered by an existing opinion of the Committee for Risk Assessment of the Agency, it is sufficient that the rapporteur Member State duly justifies that the existing opinion of the Committee for Risk Assessment remains valid. The Agency may provide its views regarding the rapporteur Member State's submission.

(7) Indicative timelines should be defined to ensure that the opinion of the Committee for Risk Assessment of the Agency is available to the Authority prior to the adoption of its conclusion under Article 13 of Regulation (EU) No 844/2012.

(8) A transitional period should be provided for so that applicants can take account of the reduced period for dossier preparation between the application for renewal and the submission of the supplementary dossiers. Procedures for which supplementary dossiers have already been submitted should not be affected.

(9) 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:

Article 1

Regulation (EU) No 844/2012 is amended as follows:

(1) in Article 6, paragraph 3 is replaced by the following:

'3. The supplementary dossiers shall be submitted no later than 33 months before the expiry of the approval.';

(2) in Article 7(1), point (j) is replaced by the following:

'(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 of the European Parliament and of the Council (*);

(*) 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.).';

(3) Article 11 is amended as follows:

(a) in paragraph 1, '12 months' is replaced by '13 months';

(b) in paragraph 2, point (e) is replaced by the following:

'(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;';

(c) in paragraph 5, second sentence, '12 months' is replaced by '13 months';

(d) in paragraph 6, second sentence, '12 months' is replaced by '13 months';

(e) the following paragraph 9 is added:

'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 ('the 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:

— explosives,

— acute toxicity,

— skin corrosion/irritation,

— serious eye damage/eye irritation,

— respiratory or skin sensitisation,

— germ cell mutagenicity,

— carcinogenicity,

— reproductive toxicity,

— specific target organ toxicity – single exposure,

— specific target organ toxicity – repeated exposure;

— 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 above that are not covered by the pending proposal unless new information has become available that was not part of the pending dossier as regards the hazard classes listed above.

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 Article 76(1)(c) 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 of 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. The Agency may provide its views regarding the rapporteur Member State's submission.';

(4) the following Article 11b is inserted after Article 11a:

'*Article 11b*

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 Article 11(9).';

(5) in Article 12, paragraph 1 is replaced by the following:

'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.'

(6) in Article 13(1), the first sentence is replaced by the following:

'Within five months from the expiry of the period referred to in Article 12(3), 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, the Authority shall adopt a conclusion in the light of current scientific and technical knowledge using guidance documents applicable at the date of the submission of the supplementary dossiers 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.';

(7) in Article 14(1), the second subparagraph is replaced by the following:

'The renewal report and the draft Regulation shall take into account the draft renewal assessment report of the rapporteur Member State, 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.'

Article 2

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 to renewal procedures of those active substances for which the approval period expires on or after 13 May 2023.

It shall, however, not apply to renewal procedures of such active substances for which supplementary dossiers have already been submitted before the date of adoption of this Regulation.

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

Done at Brussels, 17 January 2020.

For the Commission
The President
Ursula VON DER LEYEN