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**COMMISSION REGULATION (EU) .../...**

**of **XXX****

**defining data requirements for the approval of safeners and synergists and establishing a work programme for the gradual review of safeners and synergists on the market in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council**

# COMMISSION REGULATION (EU) .../...

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**defining data requirements for the approval of safeners and synergists and establishing a work programme for the gradual review of safeners and synergists on the market in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council**

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<sup>1</sup>, and in particular Article 25(3) and Article 26 thereof,

Whereas:

- (1) Article 25(1) of Regulation (EC) No 1107/2009 provides that safeners and synergists are to be approved when the criteria for the approval of active substances, laid down in Article 4 of that Regulation, are fulfilled. Furthermore, Article 25(2) of that Regulation provides that the general rules applicable to the procedure for the approval of active substances, or the renewal thereof, set out in Articles 5 to 21 of that Regulation apply to safeners and synergists as well. In addition, Article 25(3) of that Regulation provides that similar data requirements to those applicable for the approval of active substances should be defined for the approval of safeners and synergists.
- (2) In addition, and as required by Article 26 of Regulation (EC) No 1107/2009, a work programme for the gradual review of safeners and synergists already on the market should be established. To ensure alignment with the derogation provided for in Article 81(1) of Regulation (EU) No 1107/2009, these procedures should allow these safeners and synergists to be reviewed within five years of the adoption of that work programme.
- (3) In order to ensure that all safeners and synergists already on the market can be reviewed, it is appropriate to first establish a list of the safeners and synergists already on the market and procedures for potential applicants to notify their interest in submitting applications for the approval of these safeners and synergists, the deadline for submitting such applications and the procedures for the evaluation of the admissibility of applications.
- (4) To ensure coherence with the specific conditions for scientific assessments established under Regulation (EC) No 178/2002 of the European Parliament and of the Council<sup>2</sup>,

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<sup>1</sup> 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 (OJ L 309, 24.11.2009, p. 1, ELI: <http://data.europa.eu/eli/reg/2009/1107/2022-11-21>).

<sup>2</sup> 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

it is appropriate to envisage similar provisions for safeners and synergists. Consequently, rules delineating how the precise procedures for pre-submission consultations with the European Food Safety Authority ('the Authority') pertaining to envisaged tests and studies aimed at securing approval for safeners and synergists and for the requisite notifications regarding studies initiated or conducted by prospective applicants to substantiate their applications should be established.

- (5) Similar data requirements to those applicable for the approval of active substances should be defined for the approval of safeners and synergists. In addition to the data requirements applicable to the approval of active substances, it is in particular important to require supplementary data related to the demonstration of efficacy of the safeners and synergists.
- (6) In view of the substantive links between the empowerments in Article 25(3) of Regulation (EC) No 1107/2009 concerning the definition of data requirements for the approval of safeners and synergists and in Article 26 of that Regulation concerning the establishment of a work programme for the gradual review of safeners and synergists already on the market, in particular the applicability of the same data requirements, it is appropriate to lay down those rules jointly in the same act.
- (7) 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*

#### *Article 1* *Subject matter*

This Regulation establishes:

- (a) the work programme for the gradual review of the safeners and synergists already used in plant protection products on [*Office of Publications, please insert date of entry into force of this Regulation*] and procedures relating to that programme';
- (b) the data requirements that an application for the approval of safener or synergist needs to fulfil.

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Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1, ELI: <http://data.europa.eu/eli/reg/2002/178/oj>).

## CHAPTER 2

### **ESTABLISHMENT OF THE WORK PROGRAMME FOR THE GRADUAL REVIEW OF SAFENERS AND SYNERGISTS ALREADY ON THE MARKET, LIST THEREOF AND PROCEDURES FOR THEIR GRADUAL REVIEW**

#### *Article 2*

#### ***Establishment of the work programme***

The work programme for the gradual review of the safeners and synergists already used in plant protection products on ... *[Office of Publications, please insert date of entry into force of this Regulation]*, set out in Annex I, is hereby established.

#### *Article 3*

#### ***List of safeners and synergists already on the market***

- (1) By ... *[Office of Publications, please insert date 1 month from the date of the entry into force of this Regulation]*, the Commission shall publish, by electronic means and in a manner accessible to the general public, a list of all substances or preparations known to the Commission as being used as safeners or synergists contained in at least one plant protection product authorised for the placing on the market in at least one Member State on ... *[Office of Publications, please insert date of entry into force of this Regulation]*.
- (2) By ... *[Office of Publications, please insert date 6 months from the entry in force of this Regulation]*, any interested party may submit a notification of further substances or preparations potentially used as safeners or synergists in plant protection products authorised for the placing on the market in at least one Member State on ... *[Office of Publications, please insert date of entry into force of this Regulation]*.
- (3) The notification referred to in paragraph 2 shall include the information referred to in Sections 1.3, 1.4, 1.6 and 1.7 of Part A of the Annex to Commission Regulation (EU) No 283/2013<sup>3</sup> and evidence that the notified substance or preparation is used as a safener or synergist in at least one plant protection product authorised in at least one Member State.  
  
The notification shall be submitted electronically to the Commission at the following address: [sante-secteur-ppp@ec.europa.eu](mailto:sante-secteur-ppp@ec.europa.eu).
- (4) The Commission shall provide Member States and the Authority with a summary of the notifications received.  
  
Member States and the Authority may provide their comments to the Commission within two months from the date of being informed by the Commission.
- (5) The Commission shall update the list referred to in paragraph 1, taking into account the safeners and synergists contained in plant protection products authorised for the placing on the market in Member States on ... *[Office of Publications, please insert*

<sup>3</sup> 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, ELI: <http://data.europa.eu/eli/reg/2013/283/oj>).

date of entry into force of this Regulation] by [Office of Publications, please insert date 9 months from the entry into force of this Regulation].

#### *Article 4*

##### ***Request for inclusion in the work programme for gradual review***

- (1) Any interested party wishing to submit an application, in accordance with Article 7 of Regulation (EC) No 1107/2009, for the approval of a safener or synergist included in the list referred to in Article 3(1), may submit a request for inclusion of that safener or synergist in the work programme for gradual review by ... [Office of Publications, please insert 12 months from the entry into force of this Regulation].

The request shall be submitted electronically to the Commission at the following address: [sante-secteur-ppp@ec.europa.eu](mailto:sante-secteur-ppp@ec.europa.eu), and contain the information listed in Annex II.

- (2) Within one month from receipt of a request for inclusion of a safener or synergist in the work programme for the gradual review, the Commission shall indicate, in the list referred to in Article 3(1) of this Regulation, that a request pursuant to the paragraph 1 of this Article has been made for the respective substance or preparation. It shall also inform those parties requesting the inclusion of a safener or synergist in the gradual review, of the contact details of other parties requesting the inclusion in the review of the same safener or synergist.

#### *Article 5*

##### ***Non-inclusion of a safener or a synergist in the work programme for gradual review***

Where no request for inclusion in the work programme for gradual review is received for a safener or synergist listed in the list referred to in Article 3(1) within the deadline set out in Article 4(1), the Commission shall adopt a decision stating that the respective safener or synergist is not included in the work programme for gradual review.

#### *Article 6*

##### ***Applicants and sharing of data, establishment of the work programme, notification of intended studies and pre-submission advice***

- (1) From ... [Office of Publications, please insert date 13 months from the date of entry into force of this Regulation], for any substance or preparation for which the Commission has indicated in the list of safeners and synergists referred to in Article 3(1) that a request for inclusion in the work programme for gradual review has been received, the person or persons requesting the inclusion of a safener or synergist shall be considered individually or collectively as the applicant for the approval of that safener or synergist within the meaning of Articles 7 to 13 of Regulation (EC) No 1107/2009.
- (2) Applicants for the approval of the same safener or synergist shall undertake all reasonable efforts to submit a joint application, or to share relevant scientific data.
- (3) By ... [Office of Publications, please insert date 18 months from the date of entry into force of this Regulation], following consultation with Member States, the Commission shall adopt the work programme by amending Annex I to this Regulation, specifying the safeners and synergists included in the work programme and designating for each of them a rapporteur Member State and co-rapporteur Member State.

- (4) Following the amendment of Annex I of this Regulation, in accordance with the previous paragraph, applicants for the approval of a safener or a synergist shall, without delay, in accordance with Article 32b(2) of Regulation (EC) No 178/2002 notify the Authority of the title and the scope of any study commissioned or carried out by them to support an application for the approval of a safener or a synergist, as well as the laboratory or testing facility carrying out that study, and its starting and planned completion dates.
- (5) Applicants for the approval of a safener or a synergist may, in accordance with Article 32a(1) of Regulation (EC) No 178/2002, request pre-submission advice from the Authority until the complete submission of their application. The Authority shall inform the rapporteur Member State of the request and they shall jointly provide general advice.

#### *Article 7*

##### ***Submission and content of the application for approval of safeners and synergists in the work programme for gradual review***

- (1) By ... [*Office of publications, please insert date 48 months from the date of entry into force*], applicants for the approval of a safener or a synergist shall, individually or collectively, submit the application for approval of the safeners and synergists to the rapporteur Member State. The application shall be in standard IUCLID data format and be submitted via the central submission system as specified in Article 7 of Implementing Regulation (EU) 2020/1740<sup>4</sup>.
- (2) The application shall contain the data as required for safeners and synergists pursuant to Article 9.

#### *Article 8*

##### ***Procedure for the evaluation of the admissibility of applications for safeners and synergists***

- (1) The rapporteur Member State shall deem an application admissible if it satisfies the following criteria:
- (a) it has been submitted by the date set out, in accordance with the format and using the central submission system referred to in Article 7(1);
  - (b) it contains all the elements set out in Article 9;
  - (c) it contains all studies, in full, that have been previously notified in accordance with Article 32b of Regulation (EC) No 178/2002;
  - (d) the relevant fee as set by the rapporteur Member State in accordance with Article 74 of Regulation (EC) No 1107/2009 has been paid.
- (2) The rapporteur Member State shall, within 45 days following the date specified in Article 7(1), inform the applicant, the co-rapporteur Member State, the Commission, and the Authority of the date of receipt of the application and of its admissibility.

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<sup>4</sup> 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 (OJ L 392, 23.11.2020, p. 20, ELI: [http://data.europa.eu/eli/reg\\_impl/2020/1740/oj](http://data.europa.eu/eli/reg_impl/2020/1740/oj)).

- (3) If the application is not submitted by the date set out in Article 7(1), the rapporteur Member State shall promptly inform the applicant, the co-rapporteur Member State, the Commission, the other Member States and the Authority that the application is deemed inadmissible due to a missed deadline.
- (4) If an application is submitted by the date set out in Article 7(1), but does not satisfy the criteria set out in paragraph 1, point (b) or (d), the rapporteur Member State shall notify the applicant within one month from the date of receipt of the application of the specific elements that are missing and set a 14-day period for the submission of the missing elements via the central submission system referred to in Article 7(1).
- (5) If an application is submitted by the date set out in Article 7(1), but the application does not satisfy the criteria set out in paragraph 1, point (c), the rapporteur Member State shall, in cooperation with the Authority, inform the applicant within one month from the date of receipt of the application. The applicant shall be given a 14-day period to provide a valid justification for this non-compliance.
- (6) If the missing elements referred to in paragraph 4 or the valid justification referred to in paragraph 5 are not provided within the 14-day period, the application shall be deemed inadmissible and Article 32b(5) of Regulation (EC) No 178/2002 shall apply.
- (7) In case of such inadmissibility, the rapporteur Member State shall promptly inform the applicant, the co-rapporteur Member State, the Commission, the other Member States, and the Authority that the application is deemed inadmissible and of the reasons for the inadmissibility.
- (8) The assessment of the admissibility of a resubmitted application shall only commence after the six-month period mentioned in Article 32b(5) of Regulation (EC) No 178/2002 has elapsed following the notification of the necessary studies and/or submission of studies, as applicable.

### *CHAPTER 3*

#### *DEFINITION OF DATA REQUIREMENTS FOR SAFENERS AND SYNERGISTS*

##### *Article 9*

##### ***Data requirements for safeners and synergists***

- (1) In addition to the data requirements set out in Article 8 of Regulation (EC) No 1107/2009, an application for the approval of a safeners or synergist shall include:
  - (a) the data as required for active substances pursuant to Regulation (EU) No 283/2013, and the supplementary data listed in Annex III to this Regulation;
  - (b) the data as required for plant protection products pursuant to Regulation (EU) No 284/2013, and the supplementary data listed in Annex III to this Regulation;
  - (c) where relevant, the identification and proposal of a residue definition for the purposes of risk assessment and for enforcement purposes;

- (d) where relevant, a proposal for classification in one or more hazard classes in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council<sup>5</sup>;
  - (e) where relevant, a justification for any IUCLID Validation Assistant check failures;
  - (f) the summaries and results of scientific peer-reviewed open literature, as referred in Article 8(5) of Regulation (EC) No 1107/2009;
  - (g) an assessment according to the current scientific and technical knowledge of all information submitted;
  - (h) the identification and proposal for any necessary and appropriate risk mitigation measures;
  - (i) all relevant information related to the notification of the studies as required in accordance with Article 32b of Regulation (EC) No 178/2002.
- (2) When obtaining an authorisation for a plant protection product containing a safener or a synergist, the applicants may submit a request, pursuant to Article 59 of Regulation (EC) No 1107/2009, aimed at obtaining data protection for their test and study reports.
- (3) When submitting the application for the approval of a safener or a synergist, the applicants may submit a request, pursuant to Article 63 of Regulation (EC) No 1107/2009, to treat certain information, including certain parts of the dossier, as confidential and shall identify the confidential and non-confidential versions of the information submitted.

## *CHAPTER 4*

### *FINAL PROVISIONS*

#### *Article 10*

#### ***Entry into force***

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

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

Done at Brussels,

*For the Commission*

*The President*

***Ursula VON DER LEYEN***

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<sup>5</sup> 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, ELI: <http://data.europa.eu/eli/reg/2008/1272/o>).