COMMISSION IMPLEMENTING DECISION

of 6 June 2018

on the establishment of a work programme for the assessment of applications for the renewal of approvals of active substances expiring in 2022, 2023 and 2024 in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council

(Text with EEA relevance)

(2018/C 195/07)

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 18 thereof,

Whereas:

- (1) A large number of active substances approved under Regulation (EC) No 1107/2009 and listed in Parts B and E of the Annex to Commission Implementing Regulation (EC) No 540/2011 (²) have an expiry date set between 1 January 2022 and 31 December 2024. Part C of the Annex to Commission Implementing Regulation (EU) No 686/2012 (³) lists those active substances and allocates to the Member States the evaluation of those active substances, naming for each active substance a rapporteur and a co-rapporteur Member State for the purposes of the renewal procedure.
- (2) In view of the time and resources necessary for completing the assessment of applications for the renewal of approvals of the active substances concerned by the Member States and by the European Food Safety Authority (the Authority), it is necessary to establish a work programme grouping together similar active substances and setting priorities on the basis of safety concerns for human and animal health or the environment as provided for in Article 18 of Regulation (EC) No 1107/2009.
- (3) It is appropriate to provide for the identification of substances, for which, given their properties, it is expected that they may fail to satisfy the approval criteria set out in points 3.6.2 to 3.6.5 and point 3.7 of Annex II to Regulation (EC) No 1107/2009 and to prioritise their assessment.
- (4) Among the active substances listed in Part C of the Annex to Implementing Regulation (EU) No 686/2012 it is appropriate to identify those substances that are listed in Part E of the Annex to Implementing Regulation (EC) No 540/2011 as candidates for substitution, for which, given their properties, the approval periods do not exceed seven years. It is also appropriate to identify substances that are listed in the Annex to Commission Implementing Regulation (EU) 2015/408 (4) as candidates for substitution. The programme should prioritise their assessment.
- (5) Active substances fluxapyroxad, bixafen, sedaxane, penflufen and penthiopyrad share similar properties. Active substances disodium phosphonates and potassium phosphonates share similar properties. The active substances eugenol, geraniol and thymol share similar properties. The active substances *Trichoderma atroviride* (strain I-1237) and *Trichoderma asperellum* (strain T34) share similar properties. The active substances benzovindiflupyr and isopyrazam also share similar properties. As it is appropriate to align the timing of the assessment and the peer-review process carried out by the Authority of substances with similar properties, the dossiers for these substances should be submitted to their respective rapporteur Member States within the same time frame.
- (6) Given the available resources of the authorities conducting the assessment of applications for the renewal of approvals, it cannot be excluded that as a result of the prioritisation of the assessment of substances provided for by this Decision the approval of some other active substances may expire before a decision has been taken on the renewal of the approval of such substances. In such cases, the approval period of such active substances should be extended in due time in accordance with Article 17 of Regulation (EC) No 1107/2009.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²) Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

⁽³⁾ 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 whose approval expires by 31 December 2018 at the latest (OJ L 200, 27.7.2012, p. 5).

⁽⁴⁾ Commission Implementing Regulation (EU) 2015/408 of 11 March 2015 on implementing Article 80(7) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and establishing a list of candidates for substitution (OJ L 67, 12.3.2015, p. 18).

(7) In addition to providing for the grouping together of similar active substances based on priorities for their assessment, Article 18 of Regulation (EC) No 1107/2009 also provides that the work programme is to include specific elements. Implementing Regulations (EU) No 844/2012 and (EU) No 686/2012 are, respectively, implementing points (a) to (e) and point (f) of the second paragraph of Article 18 of Regulation (EC) No 1107/2009,

HAS DECIDED AS FOLLOWS:

Sole Article

The work programme as set out in the Annex to this Decision is hereby adopted.

Done at Brussels, 6 June 2018.

For the Commission

Vytenis ANDRIUKAITIS

Member of the Commission

ANNEX

- (1) The work programme concerns active substances approved under Regulation (EC) No 1107/2009 which are listed in Part C of the Annex to Implementing Regulation (EU) No 686/2012.
- (2) The priorities for the assessment of applications for the renewal of approvals of the active substances and grouping together similar active substances, as provided for in Article 18 of Regulation (EC) No 1107/2009, are as follows:
 - (a) The assessment of applications for the renewal of approvals of active substances for which, given their properties, it is expected that they may fail to satisfy the approval criteria set out in points 3.6.2 to 3.6.5 and point 3.7 of Annex II to Regulation (EC) No 1107/2009, shall be prioritised. Accordingly, such assessments shall be carried out without delay or with as little delay as possible.
 - (b) The assessment of applications for the renewal of approvals of active substances listed in Part E of the Annex to Regulation (EC) No 540/2011 as candidates for substitution which, given their properties, are approved for no more than seven years, shall be prioritised. Also the assessment of applications for the renewal of approvals of active substances listed in the Annex to Implementing Regulation 2015/408 shall be prioritised. Accordingly, such assessments shall be carried out without delay or with as little delay as possible.
 - (c) Taking into account the similarities in their respective properties, where the dates of dossier submission are different, the approval period shall be extended where appropriate and in due time in accordance with Article 17 of Regulation (EC) No 1107/2009 in order to align the timing of their assessment and the peer-review process carried out by the Authority for the following substances:
 - (i) fluxapyroxad, bixafen, sedaxane, penflufen and penthiopyrad;
 - (ii) disodium phosphonates and potassium phosphonates;
 - (iii) eugenol, geraniol and thymol;
 - (iv) Trichoderma atroviride (strain I 1237) and Trichoderma asperellum (strain T34);
 - (v) benzovindiflupyr and isopyrazam.
 - (d) Where the approval of some active substances not covered by points (a) and (b) is likely to expire before a decision has been taken on the renewal of the approval of such substances for reasons beyond the control of the applicant, the approval period of those active substances shall be extended in due time in accordance with Article 17 of Regulation (EC) No 1107/2009.