



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food and feed safety, innovation
Pesticides and biocides

SANTE-2018- 10048–rev 5

April 2024

DRAFT WORKING DOCUMENT
ESTABLISHING
THE FIFTH RENEWAL PROGRAMME

This document has been conceived as a working document of the Commission Services. It does not represent the official position of the Commission. It does not intend to produce legally binding effects.

SUMMARY

This document provides an overview of indicative submission dates for supplementary dossiers for the renewal of 66 active substances expiring between 1 January 2022 and 31 December 2024. The document may be updated. It is recommended to refer to the dates in the acts adopted and published in the Official Journal, see <http://eur-lex.europa.eu>.

The renewal process and instructions how to apply is explained in Commission Implementing Regulation (EU) No 844/2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances.

Active substances in the renewal programme have been allocated to a rapporteur and co-rapporteur Member State and listed in Part C of Implementing Regulation (EU) No 686/2012 allocating to Member States, for the purposes of the renewal procedure, the evaluation of active substances.

In view of the time and resources necessary for completing the assessment of applications for the fifth renewal programme, a work programme has been established grouping together similar active substances and setting priorities on the basis of safety concerns for human and animal health or the environment. See Commission Implementing Decision C/2018/3434 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 (OJ C 195, 7.6.2018, p. 20).

UPDATE: Please note that the deadlines for the submission of supplementary dossiers have been advanced by 3 months by Commission Implementing [Regulation \(EU\) 2020/103](#) of 17 January 2020 amending Implementing Regulation (EU) 844/2012 as regards the harmonised classification of active substances. The new rules apply to all renewal procedures of those active substances for which the approval expires on or after 13 May 2023.

Prioritisation of active substances

Substances that are listed or approved as Candidates for Substitution as well as substances that may fail to satisfy the criteria listed in points 3.6.2 to 3.6.5 and point 3.7 of Annex II to Regulation 1107/2009 are prioritised in the work programme. They will undergo a full assessment and the expiry dates will not be postponed.

Alignment of substances with similar properties

In order to facilitate the peer review and assessment by the European Food Safety Authority (EFSA) some substances merit alignment because they share similar properties. For instance, fluxapyroxad, bixafen, sedaxane, penflufen and penthiopyrad should be assessed in parallel. Also disodium phosphonates and potassium phosphonates should be assessed in parallel. For these substances extensions are proposed in order to group them together and to manage the workload for the evaluating authorities. Based on their properties, it is also good to group eugenol, geraniol, and thymol together, *T. atroviride* and *T. asperellum* together, and benzovindiflupyr and isopyrazam together. However, these substances are already aligned in terms of expiry of approval, therefore, no extensions are proposed.

- fluxapyroxad 2 years 5 months
- bixafen 1 year 8 months
- penflufen 1 year 4 months
- sedaxane 1 year 4 months
- penthiopyrad 1 year 1 month

- potassium phosphonates 2 years 4 months
- disodium phosphonates 2 years

Managing workload

A peak in dossier submissions is identified in 2021. Some substances that are not Candidates for Substitution or that are not expected to fail the approval criteria will have their approval periods extended in order to manage the workload for the evaluating authorities. Further extensions are still possible at a later point in time *'where for reasons beyond the control of the applicant it appears that the approval is likely to expire before a decision has been taken on renewal'*. The approval periods of the following 14 substances will be extended for one year provided an application is submitted three years before the current expiry date.

- 1,4-Dimethylnaphthalene
- *Adoxophyes orana* GV strain BV-0001
- *Aureobasidium pullulans* (strains DSM 14940 and DSM 14941)
- *Bacillus pumilus* QST 2808
- benalaxyl-M
- *Candida oleophila* strain O
- *Paecilomyces fumosoroseus* strain Fe9901
- *Pseudomonas sp.* Strain DSMZ 13134
- pyridalyl
- pyriofenone
- pyroxsulam
- spiromesifen
- *Streptomyces lydicus* WYEC 108
- *Zucchini Yellow Mosaik Virus*, weak strain

NOTE!

An application for renewal must be submitted 3 years before the current deadline in order to renew the approval of the active substance. Only when an application is received will the Commission extend the approval period. If an application is not received, the current expiry date will remain.

GROUP 1
No change in expiry date

Substance	Expiry date	Application date	Dossier submission
Metam (incl. -potassium and -sodium)*	30/06/2022	30/06/2019	30/12/2019
Flumetralin*	11/12/2022	11/12/2019	11/06/2020
Glyphosate	15/12/2022	15/12/2019	15/06/2020
Esfenvalerate*	31/12/2022	31/12/2019	30/06/2020
Fenpyrazamine	31/12/2022	31/12/2019	30/06/2020
Benzovindiflupyr*	02/03/2023	02/03/2020	02/09/2020
Isopyrazam*†	31/03/2023	31/03/2020	30/09/2020
lambda-Cyhalothrin*	31/03/2023	31/03/2020	30/09/2020
Metsulfuron-methyl*	31/03/2023	31/03/2020	30/09/2020
Phosphane	31/03/2023	31/03/2020	30/09/2020
Cyflumetofen	31/05/2023	31/05/2020	31/08/2020
<i>Helicoverpa armigera</i> nucleopolyhedrovirus (HearNPV)	31/05/2023	31/05/2020	31/08/2020
<i>Spodoptera littoralis</i> nucleopolyhedrovirus	31/05/2023	31/05/2020	31/08/2020
<i>Trichoderma asperellum</i> (strain T34)	31/05/2023	31/05/2020	31/08/2020
<i>Trichoderma atroviride</i> strain I-1237	31/05/2023	31/05/2020	31/08/2020
Ametoctradin	31/07/2023	31/07/2020	31/10/2020
Mandipropamid	31/07/2023	31/07/2020	31/10/2020
<i>Bacillus firmus</i> I-1582†	30/09/2023	30/09/2020	30/12/2020
Halosulfuron methyl	30/09/2023	30/09/2020	30/12/2020
Maltodextrin	30/09/2023	30/09/2020	30/12/2020
Eugenol	30/11/2023	30/11/2020	28/02/2021
Geraniol	30/11/2023	30/11/2020	28/02/2021
Thymol	30/11/2023	30/11/2020	28/02/2021
Fluopyram	31/01/2024	31/01/2021	30/04/2021
Chlorantraniliprole	30/04/2024	30/04/2021	30/07/2021
Emamectin	30/04/2024	30/04/2021	30/07/2021
Orange oil	30/04/2024	30/04/2021	30/07/2021
Prosulfuron*	30/04/2024	30/04/2021	30/07/2021
Sodium silver thiosulphate	30/04/2024	30/04/2021	30/07/2021
Spirotetramat†	30/04/2024	30/04/2021	30/07/2021
Tembotrione	30/04/2024	30/04/2021	30/07/2021
Amisulbrom	30/06/2024	30/06/2021	30/09/2021
Ascorbic acid†	30/06/2024	30/06/2021	30/09/2021
S-Abscisic acid	30/06/2024	30/06/2021	30/09/2021
Spinetoram†	30/06/2024	30/06/2021	30/09/2021
Thiencarbazone	30/06/2024	30/06/2021	30/09/2021
Valifenalate (formerly Valiphenal)	30/06/2024	30/06/2021	30/09/2021
Acequinocyl	31/08/2024	31/08/2021	30/11/2021
Flubendiamide†	31/08/2024	31/08/2021	30/11/2021
Ipconazole	31/08/2024	31/08/2021	30/11/2021
Pendimethalin*	31/08/2024	31/08/2021	30/11/2021
Imazamox*	31/10/2024	31/10/2021	31/01/2022
Aminopyralid	31/12/2024	31/12/2021	31/03/2022
Metaflumizone†	31/12/2024	31/12/2021	31/03/2022
Metobromuron	31/12/2024	31/12/2021	31/03/2022

* Candidates for Substitution

†No application received. ** Approval withdrawn. ‡ Application withdrawn

GROUP 2
Active substances to be potentially extended

Substance	Initial expiry date	Potential new expiry date	Application date	Dossier submission
Fluxapyroxad	31/12/2022	31/05/2025	31/12/2019	31/08/2022
<i>Adoxophyes orana</i> GV strain BV-0001 ‡	31/01/2023	31/01/2024	31/01/2020	30/04/2021
<i>Zucchini Yellow Mosaik Virus</i> , weak strain †	31/05/2023	31/05/2024	31/05/2020	31/08/2021
<i>Candida oleophila</i> strain O	30/09/2023	30/09/2024	30/09/2020	30/12/2021
<i>Paecilomyces fumosoroseus</i> strain Fe9901	30/09/2023	30/09/2024	30/09/2020	30/12/2021
Spiromesifen †	30/09/2023	30/09/2024	30/09/2020	30/12/2021
Bixafen	30/09/2023	31/05/2025	30/09/2020	31/08/2022
Potassium phosphonates (formerly potassium phosphite)	30/09/2023	31/01/2026	30/09/2020	30/04/2023
<i>Pseudomonas sp.</i> Strain DSMZ 13134	31/01/2024	31/01/2025	31/01/2021	30/04/2022
<i>Aureobasidium pullulans</i> (strains DSM 14940 and DSM 14941)	31/01/2024	31/01/2025	31/01/2021	30/04/2022
Pyriofenone	31/01/2024	31/01/2025	31/01/2021	30/04/2022
Disodium phosphonate	31/01/2024	31/01/2026	31/01/2021	30/04/2023
Penflufen †	31/01/2024	31/05/2025	31/01/2021	31/08/2022
Sedaxane	31/01/2024	31/05/2025	31/01/2021	31/08/2022
Benalaxyl-M	30/04/2024	30/04/2025	30/04/2021	30/07/2022
Pyroxsulam	30/04/2024	30/04/2025	30/04/2021	30/07/2022
Penthiopyrad	30/04/2024	31/05/2025	30/04/2021	31/08/2022
1,4-Dimethylnaphthalene	30/06/2024	30/06/2025	30/06/2021	30/09/2022
Pyridalyl †	30/06/2024	30/06/2025	30/06/2021	30/09/2022
<i>Bacillus pumilus</i> QST 2808 †	31/08/2024	31/08/2025	31/08/2021	30/11/2022
<i>Streptomyces lydicus</i> WYEC 108	31/12/2024	31/12/2025	31/12/2021	31/03/2023

† No application received. ** Approval withdrawn. ‡ Application withdrawn