

(English version)

**Question for written answer E-001417/24
to the Commission
Oihane Agirregoitia Martínez (Renew)
(24 July 2024)**

Subject: Feasibility of an emergency renewal for a biocidal active substance after the given deadline

Article 13 of Regulation (EU) No 528/2012 sets out that applications to renew the approval of biocidal active substances must be made at least 550 days before the approval expires.

The Spanish company marketing diflubenzuron — a preventive and curative anti-termite treatment for wood — in Europe has not been able to apply for the renewal of its approval, which expires on 31 January 2025, before this deadline. This is because the current authorisation holder did not warn the company that they would not be requesting a renewal. Withdrawing diflubenzuron from the market would mean that the only available alternative would be hexaflumuron, a persistent, bioaccumulative and toxic substance (PBT) and, as such, a ‘candidate for exclusion’.

Thus, owing to the delay in the substance's assessment prior to its renewal or exclusion, this deadline, a mere formality, will result in a much safer substance being taken off the European market, while a much less safe substance will remain authorised until 31 March 2027.

In the light of the above:

Would it be possible to submit an application for the extraordinary emergency renewal of diflubenzuron's approval in the interests of better public health and environmental protection, given that it is not a PBT substance?

Submitted: 24.7.2024

**Answer given by Ms Kyriakides on behalf of the European Commission
(10 September 2024)**

Biocidal active substances are strictly regulated under the Biocidal Products Regulation ⁽¹⁾ (BPR) and this includes adherence to specific timelines for the submission of applications for renewal of approval.

The set deadline is meant to allow the completion of the evaluation of the renewal application before the expiry of the approval and to ensure there is no disruption for the making available on the market of authorised products containing that active substance. If no application for renewal is submitted within the set deadline, this cannot be ensured.

Companies can however apply for a new approval, which will be obtained in case the evaluation shows that the safety and efficacy requirements are still met. Interested companies should do so as soon as possible to minimise the time during which products will have to be removed from the market.

The BPR does not envisage any emergency procedure for the renewal of active substances. Member States can however specifically permit biocidal products that do not fulfil the conditions for authorisation laid down in the BPR to be temporarily made available on the market in case of danger to human health or the environment, provided that no other products or means to control that danger are available.

It must be noted that diflubenzuron is an active substance approved as insecticide (product-type 18) and not direct treatment of wood (product-type 8). Products containing diflubenzuron are used, among others, for the control of subterranean termites via bait stations.

Several active substances used for direct wood preservation are approved and products containing them have been authorised for wood treatment against termites.

⁽¹⁾ Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, OJ L 167, 27.6.2012, p. 1-123.