Cholecalciferol Public Consultation

Please note that this consultation has been extended to 25th April 2024

A public consultation on the active substance cholecalciferol is currently being undertaken by the European Chemicals Agency (ECHA) in the context of the renewal of this active substance for use in the EU under the Biocidal Products Regulation (BPR).

Cholecalciferol (CAS No. 67-97-0) for product-type 14 (Rodenticides) is currently undergoing a review in the context of renewing the active substance for approval for use in biocidal products.

The active substance cholecalciferol is considered as having endocrine disrupting properties that may cause adverse effects in humans, and therefore meets the exclusion criterion set out in point (d) of Article 5(1) of Regulation (EU) No 528/2012. Active substances meeting the exclusion criteria should not be approved/renewed unless it is shown that at least one of the conditions for derogation set out in Article 5(2) of that Regulation is met.

In that context, a consultation is therefore made in order to gather information to demonstrate whether or not one or several of the following conditions for derogation are met:

(a) the risk to humans, animals or the environment from exposure to the active substance in a biocidal product, under realistic worst case conditions of use, is negligible, in particular where the product is used in closed systems or under other conditions which aim at excluding contact with humans and release into the environment;

(b) it is shown by evidence that the active substance is essential to prevent or control a serious danger to human health, animal health or the environment; or

(c) not approving the active substance would have a disproportionate negative impact on society when compared with the risk to human health, animal health or the environment arising from the use of the substance.

The availability of alternative active substances or technologies shall also be a key consideration.

ECHA has launched the public consultation on the derogation to the exclusion criteria for cholecalciferol (PT14):

https://echa.europa.eu/derogation-to-the-exclusion-criteria-current-consultations#

Member States and interested parties are invited to contribute to this consultation to indicate if they consider that one or several of the conditions set out under Article 5(2) of the BPR are met, or if none of these conditions are met, for which exact uses, and to provide justifications.

The Commission together with Member States will take into account the information collected in order to decide whether or not to renew the approval of this active substance for this product-type.

It is important that you read carefully the section ***"How to submit a contribution to the public consultation?",*** and follow the instructions given therein to send a contribution.

This consultation is open for a period of 60 days from its start, **contributions shall therefore be sent by 25th April 2024 at the latest.**