

Health and Safety Executive (HSE)

REGULATION No 1107/2009

DECISION TO WITHDRAW APPROVAL OF THE ACTIVE SUBSTANCE

ALPHA-CYPERMETHRIN (AKA ALPHAMETHRIN)

Issue

This report sets out the decision to withdraw approval of the active substance alpha-cypermethrin. It explains the process for reviewing the approval and the reasons for the decision. It summarises the information relevant to the decision and the grace periods that apply.

Background

Alpha-Cypermethrin (aka alphamethrin) is an active substance used in plant protection products, which are regulated under retained Regulation (EC) No 1107/2009 (“the Regulation”). The Regulation requires that active substances must be approved for such use. Approval is given if, in the light of current scientific and technical knowledge, authorisation of a plant protection product is expected to be possible for at least one representative use.

Regulatory process

Alpha-cypermethrin was renewed in the European Union (EU) under Commission Implementing Regulation (EU) 2019/1690. At that time the United Kingdom (UK) was part of the EU and this renewal decision applied in the UK. The renewal included a requirement that the applicant submit certain confirmatory information to the European Commission. This included submitting information regarding the toxicological profile of certain metabolites by 30 October 2020.

In October 2020 the producer that supported the renewal of alpha-cypermethrin, BASF, informed the European Commission that it would not submit any confirmatory information in support of this active substance.

In May 2021 the European Commission determined that it was therefore appropriate to withdraw approval of alpha-cypermethrin in the EU and in Northern Ireland, where EU law continues to apply under the UK’s withdrawal agreement with the EU. Although this decision had no legal effect in Great Britain (GB), the confirmatory information requirement in Commission Implementing Regulation (EU) 2019/1690 applied in GB.

In respect of GB, the producer of the active substance did not submit any of the required confirmatory information to the Health and Safety Executive (HSE), the competent authority for plant protection products in GB.

On 23 June 2021, HSE initiated a review of the approval of alpha-cypermethrin under Article 21(2)(c) of the Regulation. This included contacting the producer of alpha-cypermethrin (BASF) asking them to provide comments. On 2 July 2021, BASF confirmed the non-submission of the confirmatory data.

Having considered this comment alongside the other information and matters relevant to the review, HSE has decided, in line with Agency Agreements, to withdraw approval of alpha-cypermethrin in GB.

Decision

HSE referred its conclusion and intended decision to GB administrations as required under the terms of legal delegations of functions via the Agency Agreements between HSE and the individual administrations. GB administrations approved HSE exercising the decision-making function in this case and HSE has decided that approval of alpha-cypermethrin for use in plant protection products should be withdrawn in GB.

Consequently, plant protection products containing alpha-cypermethrin cannot be authorised in GB and existing authorisations must be withdrawn in accordance with the requirements of the Regulation.

Statement of reasons

The decision reflects the non-submission of confirmatory information that was required to be submitted as a condition of the renewal of approval of alpha-cypermethrin (aka alphamethrin). Non-compliance with a condition of approval undermines the integrity of the regulatory system. Moreover, without that information, it was not possible to confirm that plant protection products containing this active substance continued to meet the standards required for authorisation.

Grace period

In accordance with Art. 21 (7) of the Regulation, authorisations of existing products should be phased out so that:

- advertisement, sale and supply of each product are allowed until 06 October 2023;
- storage, disposal and use are allowed until 06 October 2024.

Further information

The GB Approvals Register has been updated to reflect this decision.

[06 April 2023]