

REGULATION No 1107/2009
DECISION ON APPROVAL OF THE ACTIVE SUBSTANCE
PYDIFLUMETOFEN

Background

Pydiflumetofen is an active substance used in plant protection products, which are regulated under assimilated Regulation No 1107/2009. 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.

This document sets out the decision on the application for the approval of the active substance pydiflumetofen. It explains the process for assessing the application and the reasons for the decision. It summarises the information relevant to the decision, which is set out fully in the assessment documents.

Regulatory process

Syngenta Crop Protection AG submitted a dossier to the Health and Safety Executive (HSE) for the consideration of the new active substance pydiflumetofen in October 2020 for the first approval of this substance in Great Britain (GB) under assimilated Regulation No 1107/2009.

HSE, on behalf of GB ministers, started consideration of the application under section 1(1) of the Agriculture Act 1986, in the EU exit transition period. HSE assessed the application against the approval criteria in the then Retained Regulation No 1107/2009, which is now assimilated in GB law, and prepared a draft assessment report (DAR).

Independent scientific advice was sought, with the assessment considered at the 54th (18 October 2022), 58th (18 April 2023) and 63rd (23 January 2024) meetings of the UK Expert Committee on Pesticides (ECP). It was noted that the applicant was required to provide additional information on the oestrogen, androgen and steroidogenesis (EAS) modalities of Endocrine Disruption. This information was provided by Syngenta Crop Protection AG, evaluated by HSE and presented in an update to the DAR. Further advice on post approval environmental monitoring was sought at the 63rd meeting of the ECP (23 January 2024); this advice was finalised and delivered by correspondence.

On 30 October 2023, HSE published the DAR for public consultation for a period of 60 days. The consultation closed on 29 December 2023.

HSE considered the comments alongside the advice from the ECP, amended the DAR accordingly and prepared a 'Conclusion of the Authority' document. HSE's conclusion was that pydiflumetofen could be approved in GB; the conclusion is available here: [New active substances - HSE](#)

Decision

Pydiflumetofen is approved as a candidate for substitution in GB, for use in plant protection products. Defra and Devolved Government Ministers considered HSE's proposal and approved HSE making the decision on their behalf. The decision takes account of HSE's conclusion from the assessment and also consideration of the scope to manage the risks arising from use of plant protection products containing this active substance. Consequently, plant protection products containing pydiflumetofen can be authorised in GB, in accordance with the requirements of assimilated Regulation No 1107/2009.

Statement of Reason

The evaluation demonstrated that the approval criteria specified in Article 4 of assimilated Regulation No 1107/2009 may be expected to be met. The evaluation demonstrated that the criteria specified in Article 24 of assimilated Regulation No 1107/2009 are satisfied and pydiflumetofen meets the conditions for approval as a candidate for substitution.

Further Information

Technical information concerning pydiflumetofen, including its identity and reference values finalised as part of the assessment, are available in HSE's conclusion.

For the purposes of Article 62 of assimilated Regulation No 1107/2009, HSE will keep available information about the studies for which the applicant claimed data protection, and which were considered necessary for the assessment.

03 April 2024