ASSIMILATED REGULATION No 1107/2009

DECISION TO WITHDRAW APPROVAL OF THE ACTIVE SUBSTANCE DIMETHOMORPH IN GB

Issue

1. This report sets out the decision to withdraw approval of the active substance dimethomorph in Great Britain (GB). 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

2. Dimethomorph is an active substance used in plant protection products, which are regulated under assimilated Regulation 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 the active meets the approval criteria of Article 4 of the Regulation and authorisation of a plant protection product is expected to be possible for at least one representative use.

Regulatory process

3. Dimethomorph is a pesticide active substance (fungicide) used in plant protection products. It was first approved on 01 October 2007. An application to renew the approval in Great Britian has been received. In the absence of a GB renewal programme, this submission has not been prioritised for assessment. The GB approval is currently set to expire on 31 July 2027.

4. On 20 May 2024, the European Commission decided not to renew the approval of dimethomorph in the European Union (EU) and Northern Ireland – Regulation (EU) 2024/1207[1]. The EU assessment highlighted a number of areas of concern. In particular, that dimethomorph should be classified as toxic to reproduction, category 1B and meets the criteria to be considered an endocrine disruptor in humans and wild mammals as non-target organisms for the oestrogen, androgen and steroidogenesis (EAS)-modalities. Negligible exposure could not be demonstrated since residues above the default value of 0,01 mg/kg were expected to occur for all representative uses and in rotational crops. Although this decision had no legal effect in GB, the approval criteria in assimilated Regulation No 1107/2009 in GB are the same as in the EU.

5. HSE considered that this decision represented new knowledge which indicated that dimethomorph may no longer satisfy the criteria for approval

[1] Implementing regulation - EU - 2024/1207 - EN - EUR-Lex

provided for in Article 4 of the Regulation. Therefore, HSE proposed a review of the GB approval of dimethomorph under Article 21(1) of the Regulation to Defra and the GB Devolved Governments. In accordance with the Agency Agreements which delegate work under the Regulation to HSE, the GB administrations gave their consent to this review in April 2025.

6. The GB review would consider both the classification as toxic to reproduction, category 1B (Point 3.6.4 of Annex II of the Regulation) and endocrine disruptor properties in humans and wild mammals for the EAS modalities Point 3.6.5 and 3.8.2 of Annex II of the Regulation).

7. At the time of the initiation of the review in April 2025, seven companies held authorisations for dimethomorph-containing products in the UK and were considered producers. These were BASF, Pan Agriculture, FMC, Arysta LifeScience, Clayton Plant Protection, Adama Agricultural Solutions, and Gowan UK. HSE informed these producers of the initiation of the review and the reasons for it. They were given one month to submit comments for consideration as part of the review. A summary of the comments received from BASF are included in Annex I of this document. Adama and FMC informed HSE they did not wish to submit any comments. No comments were received from Pan Agriculture, Arysta LifeScience, Clayton Plant Protection, and Gowan UK.

8. HSE undertook an independent, objective, and focused consideration of dimethomorph in light of current scientific and technical knowledge. This included a review of the scientific evidence that supported the EU decision and the comments received from producers. HSE concluded that dimethomorph fails to meet the approval criteria provided for in Article 4 of the Regulation with regards to both classification as toxic to reproduction category 1B and endocrine disruption in humans and so approval should be withdrawn in GB. A summary of HSE's scientific review is at Annex II.

9. HSE concluded that the failure to meet approval criteria as regards to both classification as toxic to reproduction category 1B and endocrine disruption in humans was sufficiently clear that it was unnecessary to obtain independent scientific advice. Moreover, a detailed consideration of any further areas of the risk assessment, including the endocrine disruption properties in wild mammals, was unnecessary. Given the concerns identified, it would be inappropriate to delay a GB decision whilst further detailed consideration of those other areas was carried out.

10. In accordance with Agency Agreements, HSE notified Defra and the GB Devolved Governments of its proposed decision that approval of dimethomorph should be withdrawn, the reasons for that decision, and the details of the grace period it proposed to set. Defra and the Devolved Governments gave their consent to HSE exercising the decision-making function in this case.

11. In August 2026, the decision was then consulted upon for its potential impact on trade via the World Trade Organisation's (WTO) Technical Barriers to Trade (TBT) agreement.

12. On 02 October 2026, HSE received confirmation that the WTO TBT process had concluded. HSE determined that the comments received during the WTO consultation did not materially alter its decision.

13. HSE considered all of the information in reaching its final decision, which was that the approval of dimethomorph for use in plant protection products should be withdrawn in GB. HSE notified the producers of the final decision, the reasons for it, and the grace period that would be set for authorised products, on 20 October 2026.

Decision

14. HSE has decided that approval of dimethomorph for use in plant protection products should be withdrawn in GB.

15. The decision reflects the overall conclusion from the HSE review and consideration of the scope to manage the risks arising from use of plant protection products containing this active substance.

16. Consequently, plant protection products containing dimethomorph can no longer be authorised in GB and existing authorisations must be withdrawn in accordance with the requirements of assimilated Regulation No 1107/2009.

17. The approval of dimethomorph will now expire on 30 November 2026, at which point the approval will end.

Statement of reasons

18. The reasons for the decision to withdraw dimethomorph in GB are that:

- It meets the criteria for ED (endocrine disruption) properties in humans via the EAS (oestrogen, androgen, and steroidogenesis) modalities.
- It has been classified as toxic to reproduction category 1B for effects on fertility.

Grace period

19. In accordance with Article 21(7) of the Regulation, and recognising the identified risks to human health & mammals, authorisations of existing products should be phased out so that:

- Sale and distribution of each product shall expire by 31 May 2027;

- Disposal, storage and use of existing stocks shall expire by 31 May 2028.

Further information

20. The GB Approvals register will be updated to reflect this decision.

16 October 2026

Annex I – Summary of comments received

Specialist Area	Company	Description	HSE comments
Toxicology	BASF	**DocID 2017/1033551**: BASF position paper on the proposed classification of dimethomorph.	Noted and considered
Toxicology	BASF	**DocID 2018/1202679**: BASF ED assessment of dimethomorph.	Noted and considered
Toxicology	BASF	**DocID 2022/2028205:** BASF rationale for self-classification for reproductive toxicity, where scientific reasoning leads to the conclusion to self-classify the compound as “Reprotoxic 2 H361fd” following GHS classification criteria regarding reproductive toxicity	Noted and considered

Annex II – Summary of HSE's consideration supporting the recommendation

The HSE review took account of the information that supported the EU decision to non-renew dimethomorph and comments provided by the producers.

Toxicology (Human Health)
Endocrine Disruption

A critical area of concern was identified in the EFSA conclusion[2] for dimethomorph:

- Meeting the criteria to be regarded as having endocrine disrupting properties in humans for the EAS (oestrogen, androgen and steroidogenesis) modalities

With regard to dimethomorph meeting the criteria for being an EAS endocrine disruptor in humans HSE's toxicology consideration reaches the same conclusion as in the EU assessment. HSE has considered the reported endocrine adversity in the male rat and noted the additional findings on testis and prostate weights in dogs. HSE has given significant weight to the findings in the extended one generation reproductive toxicity (EOGRT) study in rats, which contributed to the classification of dimethomorph for toxic to reproduction 1B (Repr. 1B) (H360F) under the GB CLP Regulation. Delayed preputial separation, decreased anogenital distance (AGD) in males, and decreased seminal vesicle weights across generations and cohorts were not associated with marked parental toxicity, nor explained by a generalised slowed development of the pups. In addition, whilst the available two-generation study did not report delayed preputial separation nor a reduction in fertility in the second generation, it is noted the study did not investigate AGD and sexual maturity and dosed the animals only up to 70 mg/kg bw/day. The effects in the EOGRT study were observed from the mid-dose of 70 mg/kg bw/day, but much more markedly at the top dose of 144 mg/kg bw/day. The available two-generation study is therefore considered insufficient to assess whether the delayed puberty observed in the EOGRT study would have impacted fertility in the second generation (due to the low doses tested). When the adversity is considered alongside the anti-androgenic activity seen in vitro and in silico, HSE agrees there is a plausible mechanism of anti-androgenicity driving the adversity observed in vivo. Overall, therefore, HSE agrees that there is a pattern of endocrine adversity mainly in male rats, supported by some endocrine effects in male dogs, for which a plausible anti-androgenic mode of action (MoA) cannot be excluded. On this basis, HSE agrees that dimethomorph is an endocrine disruptor (ED) in humans, specifically acting via the A-modality.

Overall, having carefully considered the information that formed part of the EU evaluation of the toxicology of dimethomorph and the producers' comments, HSE has concluded that the human health ED exclusion criterion of the Regulation has been met and that regulatory action is warranted.

Classification as toxic for reproduction category 1B (H360F)

A critical area of concern was identified in the EFSA conclusion for dimethomorph:

[2] Peer review of the pesticide risk assessment of the active substance dimethomorph

- Meeting the criteria to be classified as toxic for reproduction category 1B.

With regards to dimethomorph meeting the criteria to be classified as toxic for reproduction category 1B (H360F) under the GB CLP Regulation, HSE's toxicology consideration reaches the same conclusion as the EU assessment. No new data for dimethomorph nor any new arguments that have not already been considered in the GB CLP technical report were submitted. As such, there is no justification to change the current position on the GB mandatory classification for effects on fertility of dimethomorph. The existing MCL (mandatory classification and labelling) listing of Repr. 1B; H360F (May damage fertility) is maintained.

Overall, having carefully considered the information that formed part of the EU evaluation of the toxicology of dimethomorph and the producers' comments, HSE has concluded that classification as toxic for reproduction category 1B for effects on fertility is warranted, the exclusion criterion of the Regulation has been met and that regulatory action is warranted.