



Case study – Protecting public health: the cancellation of chlorthal dimethyl

The cancellation of chlorthal dimethyl products in 2024 demonstrates the APVMA's commitment to being a trusted, transparent and fair regulator, and to acting in the best interests of the Australian community in accordance with its legislative obligations.

Chlorthal dimethyl is a herbicide that had been registered for use on vegetable and strawberry crops, lawns, cotton, and public spaces such as golf courses. Prior to cancellation, approximately 38 tonnes were used annually in Australia, with applications often occurring at high rates via groundboom spraying.

In August 2024, the United States Environmental Protection Agency cancelled all registrations for chlorthal dimethyl following new toxicological evidence identifying developmental thyroid effects in animal studies. In September 2024, New Zealand's Environmental Protection Authority imposed significant restrictions on its use. Around the same time, the APVMA received the pivotal toxicology study underpinning the US decision.

Consistent with its posture of making data-driven and evidence-based decisions, the APVMA undertook an urgent assessment of the study. The assessment identified a substantially lower no-observable-adverse-effect level (NOAEL) than previously relied upon, indicating a risk of disruption to foetal thyroid hormone levels. These effects have the potential to result in low birth weight, impaired neurological development, reduced cognitive outcomes and motor impairments, some of which may be irreversible.

Applying a risk-based approach focused on protecting human health, the APVMA determined that, under Australian conditions of use, the identified risks represented an imminent and serious risk to unborn children, particularly for pregnant farm workers, handlers and people living near treated areas.

On 9 October 2024, the APVMA exercised its statutory powers to act swiftly where there was evidence of serious risk, cancelling the registration of all chlorthal dimethyl products with immediate effect. No phase-out period was provided, as:

- the risk of serious harm was imminent,
- no practical or effective risk-mitigation measures were available to enable continued safe use, and
- existing product labels did not adequately warn users of the identified risks.

The decision was published in the Gazette on 10 October 2024. In total, 12 products were cancelled, and a compulsory recall was initiated to remove product from the supply chain and from farms. Product holders were notified in November 2024, and a formal recall notice was published in the APVMA Special Gazette on 6 December 2024.

Consistent with its commitment to clear, transparent and timely communication, the APVMA worked closely with state and territory regulators, industry peak bodies and other stakeholders to explain the regulatory decision, clarify the immediate 'stop use' requirements, and support effective implementation of the recall.

This regulatory action aligned Australia's controls with international regulatory developments and eliminated the potential for further harmful exposure. By applying contemporary science, acting proportionately and decisively, and communicating clearly, the APVMA demonstrated how its regulatory posture is applied in practice to protect public health and maintain confidence in Australia's agvet chemical regulatory system.