Questions & Answers on licence application DIR 216 – commercial release of genetically modified (GM) cotton

What is this application for?

Bayer CropScience Pty Ltd (Bayer) is seeking approval for the commercial release of cotton genetically modified for insect resistance and herbicide tolerance known as Bollgard® 3 ThryvOn® cotton with XtendFlex® Technology.

How has the GM cotton been modified?

The GM cotton contains 4 introduced genes from a common soil bacteria that confer insect resistance to common pests of cotton. Three genes provide protection against bollworms and one provides protection against certain bugs, aphids and thrips.

The GM cotton also contains 3 introduced genes for tolerance to herbicides glyphosate, glufosinate, and dicamba. These genes enable the GM cotton plants to grow in the presence of these herbicides, which can be used to control weeds in the GM cotton crop.

In addition, the GM cotton contains selectable marker genes derived from a common gut bacterium. These genes confer selective antibiotic resistance or enable expression of a reporter gene. They were used to select plants during laboratory development of the GM cotton and do not have any function when plants are grown in the field.

What is the purpose of the release?

The purpose of the proposed release is to allow commercial production of this GM cotton in all cotton growing areas of Australia, subject to restrictions in some Australian States and Territories for marketing reasons. Commercial cotton production occurs mainly in New South Wales and Queensland, and has recently expanded into northern Victoria, Western Australia and the Northern Territory. The GM cotton and its products would enter general commerce including use in human food and animal feed.

Has this GM cotton received any other approvals in Australia?

Food Standards Australia New Zealand (FSANZ) is responsible for food safety. FSANZ has approved the use of food derived from each parent of this GM cotton, including food made from any offspring produced through conventional breeding. This covers approval for this GM cotton, no further food approvals are required.

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has regulatory responsibility for agricultural chemicals, including insecticidal substances and herbicide use. This GM cotton would require APVMA registration before it can be grown commercially in Australia.

What controls are proposed for this release?

The licence application proposes an ongoing commercial release, with no restrictions on how the GM cotton is grown or used. The Gene Technology Regulator has prepared a consultation Risk Assessment and Risk Management Plan (RARMP), which finds that the proposed commercial release of this GM cotton poses negligible risk to the health and safety of people or the environment. However, licence conditions drafted in the consultation RARMP ensure that there is ongoing oversight of the release.

How can I comment on this application?

The full consultation RARMP and a summary of the RARMP for application DIR 216 are available on the OGTR website, the consultation hub or via the contacts listed below. You are invited to submit your written comments (including via the consultation hub or by email) on the consultation version of the RARMP, related to any risks to the health and safety of people or to the environment from the proposed release. Comments must be received by the close of the consultation period on **9 September 2025**.

What are the next steps in the evaluation process?

The RARMP will be finalised, taking into account submissions related to the protection of people or the environment. A de-identified summary of all comments received and consideration of those comments is

included in the Appendices to the final RARMP. The finalised RARMP will inform the Regulator's decision on whether or not to issue a licence.

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