

Questions & Answers on licence application DIR 216 – commercial release of genetically modified 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. The purpose of the proposed release is to allow commercial production of this GM cotton Australia-wide, subject to restrictions in some Australian States and Territories for marketing reasons. The GM cotton and its products would enter general commerce, including use in human food and animal feed.

How has the GM cotton been modified?

The GM cotton permitted for release contains 4 inserted 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 cotton also contains 3 introduced genes for herbicide tolerance, conferring tolerance to glyphosate, glufosinate and dicamba herbicides.

The GM cottons also contain selectable marker genes derived from a common gut bacterium. These genes confer selective antibiotic resistance or 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 process for considering this application?

The licence application will be subject to comprehensive, science-based risk analysis. The process includes 2 rounds of stakeholder consultation. In the first round, the Regulator seeks advice from prescribed experts, agencies and authorities prior to preparing a draft Risk Assessment and Risk Management Plan (RARMP). The RARMP focuses on identifying risks to people and to the environment that may be posed by the commercial release. Following public release of the consultation RARMP, submissions will again be sought from stakeholders, including the public. The RARMP will then be finalised taking into account submissions received, and inform the Regulator's decision whether or not to issue a licence.

What other regulatory processes apply to this commercial product?

Food Standards Australia New Zealand has approved the use in food of material derived from this GM cotton, including food made from any offspring produced through conventional breeding. No further food approvals are required. The GM cotton would also be subject to regulation by the Australian Pesticides and Veterinary Medicines Authority (APVMA) and Department of Agriculture, Fisheries and Forestry (DAFF) if importing any GM seed into Australia.

How can I comment on this application?

The consultation version of the RARMP for this application is expected to be released for public comment in **July 2025**. Its release will be advertised in newspapers, and it will be available on the OGTR website along with a range of supporting information. While comment is not being sought from the public at this stage, you can obtain a copy of the full application by contacting the OGTR. Please quote the application number DIR 216. A summary of the application is available on the [OGTR website](#) or by contacting the OGTR.