

February 2025

Summary of Licence Application DIR 216

Bayer CropScience Pty Ltd has made an application under the *Gene Technology Act 2000* (the Act) for Dealings involving the Intentional Release (DIR) of genetically modified organisms (GMOs) into the Australian environment.

Project Title	Commercial release of cotton genetically modified for insect resistance and herbicide tolerance (Bollgard® 3 ThryvOn™ cotton with XtendFlex® Technology)¹
Parent organism	Cotton (Gossypium hirsutum)
Genetic modifications	
Introduced genes	Four introduced genes from the common soil bacteria <i>Bacillus thuringiensis</i> (Bt) conferring insect resistance.
	Three introduced genes from common bacteria conferring tolerance to glyphosate, glufosinate and dicamba herbicides.
	Three introduced antibiotic resistance marker genes and one visual reporter gene.
Genetic modification method	Agrobacterium-mediated transformation, biolistics and conventional breeding
Principal purpose	Commercial release of GM cotton
Proposed location	Australia-wide
Proposed period of release	Ongoing from issue of licence

Next steps

The Gene Technology legislation sets out what the Regulator must do, as well as what the Regulator can or must consider, before deciding whether or not to issue a licence for this application.

After seeking advice from prescribed experts, agencies and authorities, the Regulator's staff will prepare a consultation version of the Risk Assessment and Risk Management Plan (RARMP) considering aspects of the application in accordance with the legislation.

The Regulator will seek comment on the consultation RARMP from the public, as well as a wide range of experts, agencies and authorities. The public and experts will be invited to provide submissions on the risks to human health and safety, and on risks to the environment from the proposed release.

At this stage, the consultation RARMP is expected to be released for comment in July 2025.

After consultation, the Regulator's staff will finalise the RARMP, taking into account advice on relevant matters. The finalised RARMP will form the basis of the Regulator's decision whether or not to issue a licence. The consultation and final versions of the RARMP and associated documents will be available on the <u>OGTR website</u> when they are released.

¹ The title of the project as supplied by the applicant is "Commercial release of cotton genetically modified for insect resistance and herbicide tolerance"

Other information available from the OGTR website:

- documents on genetic modification methods and selectable marker genes
- information on Australia's national scheme for regulation of gene technology and
- information on the DIR application process.

Please use the contact details below if you:

- would like a copy of the application. Please include the identifier DIR 216
- have any questions about the application or the legislated evaluation process
- wish to register on the mailing list.

The Office of the Gene Technology Regulator, MDP 54, GPO Box 9848, Canberra ACT 2601

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