Summary of Licence Application DIR 228

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[1]
Parent organism	Cotton (*Gossypium hirsutum*)
Genetic modification	
Introduced gene	Introduced gene conferring insect resistance: • *mCry51Aa2* gene from the common soil bacteria *Bacillus thuringiensis* (Bt)
Principal purpose	Commercial release of GM cotton
Previous releases	DIR-147, DIR-203 and DIR-216
Proposed location	Australia-wide
Proposed period of release	Ongoing from issue of licence

Other regulatory approvals

If a licence is issued, the GM cotton would enter general commerce, including use in human food and animal feed. Food Standards Australia New Zealand (FSANZ) has assessed and approved food made from this GM cotton. This approval includes food made from any offspring produced through conventional breeding, and therefore no further food approvals are required for the GM cotton MON 88702.

The applicant has applied to the Australian Pesticides and Veterinary Medicines Authority (APVMA) for approval of the active constituent Cry51Aa2 and for the cultivation of ThryvOn™ cotton (MON 88702) in a stacked combination with Bollgard® 3 (MON 15985 x COT102) for use as an insecticidal substance.

The applicant may need an approval from the Department of Agriculture, Fisheries and Forestry (DAFF) if importing any GM seed into Australia.

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 December 2026.

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

[1] The title of the project as supplied by the applicant is "Commercial release of *Gossypium hirsutum* genetically modified for insect resistance in Australia "

licence. The consultation and final versions of the RARMP and associated documents will be available on the OGTR website when they are released.

Other information available from the OGTR website:

- 'Questions and Answers' document for this application
- 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 228.
- have any questions about the application or the legislated evaluation process or
- wish to register on the mailing list.

The Office of the Gene Technology Regulator, MDP 54, GPO Box 9848, Canberra ACT 2601
Telephone: 1800 181 030
Email: ogtr@health.gov.au