



Office of the Gene Technology Regulator

THERAPEUTIC GOODS ADMINISTRATION

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# MEDIA RELEASE

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## **GENE TECHNOLOGY REGULATOR REFUSES COMMERCIAL RELEASE OF GM COTTON IN NORTHERN AUSTRALIA, BUT GIVES APPROVAL ELSEWHERE**

The Commonwealth Gene Technology Regulator, Dr Sue Meek, has rejected an application by Monsanto Australia Limited for commercial release of two types of genetically modified cotton in northern Australia because of uncertainty about their potential to become a weed problem.

"However, I have given Monsanto approval to undertake commercial release of the GM cotton in southern Australia, south of 22 degrees South," she said.

Dr Meek, said today she had, as foreshadowed in the public consultation on this application, only authorised Monsanto to conduct further field trials of Bollgard II and Bollgard II/ Roundup Ready cotton under strict, limited and controlled conditions north of latitude 22 degrees South.

She said the field trials in northern Australia would enable the collection of more data on the behaviour of genetically modified cotton in this unique region of the Australian environment.

"Any future commercial release in the north would require a new license application and would only be approved if data from the field trials conclusively demonstrated that any risks to human health and safety and the environment could be effectively managed," she said.

Bollgard II cotton has had two insecticidal genes inserted, which produce proteins that are lethal for certain significant cotton pests. Bollgard II is derived from INGARD cotton, which only has one of these genes, and as such Bollgard II is expected to be less susceptible to insect predation and less likely to promote the development of resistance.

Bollgard II/ Roundup Ready cotton has been produced by conventional breeding of Bollgard II with Roundup Ready cotton which contains a gene that confers tolerance to glyphosate, the active ingredient of the herbicide Roundup. Both types have been trialled previously under limited and controlled conditions in northern and southern Australia under the former voluntary and present regulatory systems for gene technology.

"While INGARD and Roundup Ready cotton were approved for commercial release, in Australia in 1996 and 2000 respectively, under the former voluntary system that was overseen by the Genetic Manipulation Advisory Committee, the releases were restricted to the southern cotton-growing regions of NSW and Queensland where they do not pose a weed problem," she said.

Dr Meek said that the evaluation process and the final decision on this application reflect the regulatory system's cautious approach to the approval of intentional releases of GMOs into the environment.

"Because of continuing concern about the risks of weediness associated with the commercial release of GM cotton in northern Australia, I issued an invitation to the public to comment on Monsanto's application, via the internet and extensive press advertising, as well as the usual process of requesting comment on the Risk Assessment and Risk Management Plan that is prepared for every license application.

"This is the first time that the provision in the *Gene Technology Act 2000* Act for **two** rounds of public consultation where there may be significant risk to human health and safety and/ or the environment has been applied," she said.

"After considering all of the submissions from the public, other key stakeholders and expert groups and the available data, my initial assessment was confirmed and, for this reason, I have restricted the commercial release to southern Australia

Dr Meek said that the decision also demonstrated responsiveness to feedback from the consultation process.

Following the public consultation phase, the Regulator revised the Risk Assessment and Risk Management Plan to restrict the commercial release in southern Australia to south of 22 degrees South rather than slightly further north (20 degrees South) as initially proposed.

"This was in response to submissions which suggested that since some significant river systems in Queensland are located between 20 and 22 degrees South and flow north-west from that area, they could potentially carry viable GM material into the area where only limited and controlled release will be allowed," Dr Meek said.

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