

Office of the Gene Technology Regulator

Via email: [ogtr@health.gov.au](mailto:ogtr@health.gov.au)

16 December 2016

## Technical review of the Gene Technology Regulations 2001:

### Options for regulating new technologies

Dear Sir/Madam,

Cotton Australia welcomes the opportunity to provide comment and, as the industry representative body, speak on behalf of cotton growers regarding the *Technical Review of the Gene Technology Regulations 2001: Options for regulating new technologies*.

The cotton industry is an integral part of the Australian economy, worth over \$1.25 billion in export earnings for the 2014-15 season, and employing on average 10,000 people. The industry's vision is *Australian cotton, carefully grown, naturally world's best*.

#### Executive Summary

The Australian cotton industry strongly supports the application of gene technology innovations to deliver productivity and sustainability gains to growers. Transgenic cotton currently accounts for over 99% of the total area planted to cotton in Australia and has contributed to a 96% decrease in insecticide use over the last 20 years. To ensure continued investment in innovation, Cotton Australia strongly supports a robust system for science-based and risk-aligned regulation that protects human and environmental health and provides a clear and predictable path to market.

The currently regulatory system for gene technologies is not sufficiently flexible to accommodate advances in breeding techniques. A review of the current regulatory system and related legislation is essential to ensure that Australia's scientists and cotton growers are best positioned to utilise these technological advances.

Cotton Australia has reviewed the proposed recommendations put forward by the OGTR and wishes to indicate strong support for Option 4: Exclude certain new technologies from regulation based on the outcomes they produce, which should be implemented as follows;

**Recommendation 1.** Schedule 1A of the Gene Technology Regulations to be immediately reviewed and amended to include SDN-1, oligo-directed mutagenesis, and SDN-2.

**Recommendation 2.** Review of the national gene technology framework to consider the properties of the final organism as the regulatory trigger.

**Recommendation 3.** Australian Regulators to continue involvement in international fora seeking to harmonise regulation of new technologies.

## Technical review of the Gene Technology Regulations 2001:

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#### Introduction

The Australian cotton industry strongly supports the application of gene technology innovations to deliver productivity and sustainability gains to growers. Transgenic cotton now accounts for over 99% of the total planted cotton area in Australia.

Commercialisation of transgenic insecticidal (Bt) cotton, in conjunction with integrated pest management and best management programs, has delivered a 96% reduction in insecticide since 1996. This has greatly improved the productivity and sustainability of the Australian cotton industry and has recently allowed Australian cotton growers to access premium markets for sustainably produced fibre.

New gene technologies have potential to rapidly transform the productivity and sustainability of Australian cotton industry. These technologies can be used to deliver new varieties with superior yield and quality parameters, address landscape-wide issues such as pest management and pesticide resistance and, add value to cotton by-products such as cotton seed.

New breeding techniques could also be applied to overcome significant technical challenges in plant breeding for polyploid plants, such as cotton. These advances are not technically possible using conventional breeding and are currently prohibited by cost if regulated as genetically modified organisms.

To ensure continued investment in innovative solutions for Australian agriculture, Cotton Australia strongly supports a robust system for science-based and risk-aligned regulation that protects human health and the environment as part of a clear and predictable path to market. This support is consistent with our position put forward to the Productivity Commission in August 2016.

The currently regulatory system for gene technologies is not sufficiently flexible to accommodate advances in gene technology and thus requires review.

There now exists a continuum of techniques between those traditionally considered to mimic natural processes and those which result in a genetically modified organism. Additionally, new techniques are able to deliver significant advances in plant productivity and quality with a risk profile that is commensurate with natural processes and, should be regulated accordingly. As such, organisms that are indistinguishable from those produced through natural processes, conventional breeding or methods already exempt from regulation, should similarly be exempt from regulation.

#### Option 4 is the model preferred by Cotton Australia

Cotton Australia supports Option 4 as the preferred model: Exclude certain new technologies from regulation on the basis of the outcomes they produce.

Cotton Australia considers the current arrangements to be proficient in delivering science-based and risk-aligned regulation for conventionally bred or, genetically modified organisms. Under this framework, organisms produced through natural processes, conventional breeding or chemical/radiation mutagenesis have been determined to not pose significant risk to warrant regulation by the Office of the Gene Technology Regulator. Organisms that are genetically indistinguishable from those produced through natural processes, conventional breeding or chemical/radiation mutagenesis present the same risks to human health and the environment, and thus should be similarly exempt from regulation, regardless of how they were derived.

To effectively implement Option 4, Cotton Australia supports an immediate review of the Gene Technology (GT) Regulations to amend Schedule 1A to include SDN-1, oligo-directed mutagenesis and SDN-2. To address long-term inadequacies of the current regulatory model, Cotton Australia advocates for reconsideration of the Gene Technology Act to change the regulatory trigger to focus on the properties of the final organism.

Trade implications should be considered as part of the review process for the Gene Technology Regulations. Cotton Australia supports the Office of the Gene Technology Regulator to take leadership on this issue and remain involved in international fora seeking to harmonise regulation of new technologies domestically and internationally.

### Cotton Australia Recommendations

**Recommendation 1.** Schedule 1A of the Gene Technology Regulations to be immediately reviewed and amended to include SDN-1, oligo-directed mutagenesis, and SDN-2.

**Recommendation 2.** Review of the national gene technology framework to consider the properties of the final organism as the regulatory trigger.

**Recommendation 3.** Australian Regulators to continue involvement in international fora seeking to harmonise regulation of new technologies.

### Cotton Australia does not support Options 1, 2 or 3

Cotton Australia does not support Option 1: No amendments to the GT Regulations. This option does not provide sufficient clarity as to whether or not new technologies are regulated, does not provide a clear and predictable path to market and thus, may impede innovation for Australian agriculture.

Cotton Australia does not support Option 2: Regulate certain new technologies. Regulation of SDN-1, oligo-directed mutagenesis and SDN-2 is not consistent with the exclusion of chemical and radiation mutagenesis techniques from the Scheme and is not commensurate with the risk posed by organisms derived using these gene technologies.

Cotton Australia does not support Option 3: Regulate some new technologies based upon the process used. Regulation of organisms produced by oligo-directed mutagenesis and SDN-2 as genetically modified organisms is not commensurate with the risk that these organisms pose.



*Advancing Australian Cotton*

## **Conclusion**

Cotton Australia considers that the national framework should be reviewed to facilitate outcome-based regulation of gene technologies. This will ensure a science-based and risk-aligned regulatory system which provides a transparent and predictable path-to-market to encourage investment in innovative solutions for Australian agriculture.

Cotton Australia welcomes any opportunity to provide further information on its position. For more information, contact Nicola Cottee, Policy Officer on (02) 9669 5222 or .

Yours sincerely,

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Cotton Australia

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