



16 August 2017

## Summary of Licence Application DIR 157

### Introduction

An application has been made under the *Gene Technology Act 2000* (the Act) for Dealings involving the Intentional Release (DIR) of a genetically modified organism (GMO) into the Australian environment.

Application number:	DIR 157
Applicant:	Syngenta Australia Pty Ltd
Project Title:	Commercial release of cotton genetically modified for insect resistance (COT102) <sup>1</sup>
Parent organism:	Cotton ( <i>Gossypium hirsutum</i> L.)
Introduced gene and modified trait:	<b>One insect resistance gene:</b> <ul style="list-style-type: none"><li>• <i>vip3Aa19</i> gene from <i>Bacillus thuringiensis</i> (Bt)</li></ul> <b>One selectable marker gene:</b> <ul style="list-style-type: none"><li>• <i>aph4</i> from <i>Escherichia coli</i> for resistance to hygromycin B</li></ul>
Proposed release dates:	Ongoing from date of approval
Proposed locations:	Australia-wide

### The proposed dealings

Syngenta Australia Pty Ltd (Syngenta) proposes commercial cultivation of a genetically modified (GM) cotton line (COT102), which contains an introduced gene that confers insect resistance. This event is also known by the unique OECD identifier SYN-1R1Ø2-7.

The aim of the proposed release is for the commercial production of COT102 throughout Australia. If a licence is issued, COT102 would be grown and used in the same way that commercial cotton is currently grown and used, including as feed for animals, cottonseed oil for human food, and for fibre production, e.g. clothes and other cotton products. Food Standards Australia New Zealand has assessed and approved food made from COT102.

### Parent organism

The parent organism is cotton (*Gossypium hirsutum* L.), which is exotic to Australia and is grown as an agricultural crop in New South Wales, southern and central Queensland, and northern Victoria, and on a trial basis in northern Queensland, northern Western Australia and the Northern Territory. More than 99% of the Australian cotton crop is genetically modified for the traits of insect resistance, herbicide tolerance or both.

### The genetic modifications and their effect

COT102 contains a gene derived from a common soil bacterium, *Bacillus thuringiensis* (Bt). This gene produces a protein, Vip3A (vegetative insecticidal protein), which makes the cotton resistant to lepidopteran caterpillar pests, e.g. *Helicoverpa armigera* and *H. punctigera*.

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<sup>1</sup> The title of the application submitted by Syngenta is "Commercial release of *Gossypium hirsutum* genetically modified for COT102".

COT102 also contains the marker gene *aph4*, derived from the common gut bacterium *Escherichia coli*. This gene confers resistance to the antibiotic hygromycin and was used during plant transformation to select for genetically modified plant cells.

### **Method of genetic modification**

COT102 was produced using *Agrobacterium*–mediated transformation. This transformation method has been widely used in Australia and overseas for introducing genes into plants. More detailed information on methods of genetic modification can be found in the document *Methods of plant genetic modification* available from the [Risk Assessment References](#) page on the OGTR website.

### **Previous releases of the same or similar GMOs**

Field trials of COT102 have been conducted in Australia since 2002 under licences DIR 017/2002, DIR 025/2002, DIR 034/2003, DIR 036/2003, DIR 058/2005, DIR 065/2006, DIR 073/2007, DIR 101, DIR 120 and DIR 133. Some of these licences authorised trials of COT102 alone, and others authorised trials of COT102 crossed with other GM lines.

COT102 has been licenced for commercial release in Australia since 2014 under licences DIR 124, DIR 143 and DIR 145. These commercial licences approved COT102 in combination with other GM insect resistance traits and, in some cases, with GM herbicide tolerance traits.

There have been no credible reports of adverse effects on human health and safety or the environment resulting from any of these releases.

### **Assessment and consultation process for this DIR application**

The Act and the Gene Technology Regulations 2001 set out requirements for considering licence applications, including matters that the Regulator must take into account before deciding whether or not to issue a licence.

Since this application is for commercial purposes, the Regulator is required to seek advice from prescribed experts, agencies and authorities on matters relevant to the preparation of a Risk Assessment and Risk Management Plan (RARMP), in accordance with section 50 of the Act. This first round of consultation must include the Gene Technology Technical Advisory Committee, State and Territory Governments, prescribed Australian Government agencies, any local council that the Regulator considers appropriate and the Environment Minister.

While the Regulator is not required to seek public comment at this stage, copies of the application are available on request from the OGTR. Please quote application number DIR 157.

In a second round of consultation, the Regulator will seek comment on the consultation RARMP from the public as well as prescribed experts, agencies and authorities. The RARMP will then be finalised, taking into account matters raised relating to risks to human health and safety and the environment, and will inform the Regulator's decision whether or not to issue a licence.

At this stage, the RARMP is expected to be released for comment in **December 2017**. The public will be invited to provide submissions on the RARMP via advertisements in the media and direct mail to anyone registered on the OGTR mailing list. The RARMP and other related documents will be available on the OGTR website or from the OGTR.

More information on Australia's national scheme for regulation of gene technology and the assessment process can be found at the OGTR [website](#).

If you have any questions about the application or the assessment process, or wish to register on the mailing list, please contact the OGTR at:

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