

## AUSTRALIAN GOVERNMENT SUBMISSION – May 2012

Ref SCBD/BS/MPDM/jh/67587, Notification 2012-016

### **Information on living modified organisms that are not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health**

#### **Australian experience of environmental releases of living modified organisms (LMOs)**

Since June 2001 regulatory oversight of environmental releases of LMOs has come under the Australian *Gene Technology Act 2000*<sup>1</sup>. As of 1 May 2012, Australia's Gene Technology Regulator<sup>2</sup> (the Regulator) has issued 93 licences for the intentional release of LMOs into the environment (Appendix A, <http://www.ogtr.gov.au>). This includes 13 general releases and 80 licences for limited and controlled releases (confined trials).

Each of these authorisations for release to the Australian environment was based on case by case risk assessment – the Regulator must prepare a risk assessment and risk management plan (RARMP) for each application to release an LMO into the Australian environment (see below for further details).

Details of all licences issued for environmental release of LMOs, including the full risk assessment and risk management plan, and licence conditions, are available from the Record of GMO and GM Product Dealings on the website of the Office of the Gene Technology Regulator - <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/ir-1>

Prior to June 2001, the environmental release of LMOs was subject to voluntary oversight by the Genetic Manipulation Advisory Committee (GMAC). Advice to proceed was given for 107 proposed field trials of genetically modified plants and four general releases (two carnation and two cotton).

#### **Current status of LMOs approved for unconfined general release (ie with no management/confinement conditions)**

A number of LMOs have been authorised for environmental release by the Gene Technology Regulator with no specific management or confinement conditions, based on an environmental risk assessment. Table 1 lists the eight approvals authorising LMOs for unrestricted release in Australia as of 1 May 2012. These authorisations include one entry on the GMO Register for genetically modified carnations, six licences for commercial cultivation of genetically modified cotton, canola and rose, and one licence for a genetically modified vaccine for people.

The Regulator has concluded that these LMOs are able to be used in the same manner as their conventional counterparts, including cultivation throughout Australia's landscape of diverse ecosystems and land use types. They were assessed on a case by case basis as not likely to have an adverse affect on the health and safety of people or the environment.

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<sup>1</sup> <http://www.comlaw.gov.au/Details/C2011C00539>, Australia's national biosafety law

<sup>2</sup> Australia's competent authority

### ***GM carnation***

Four LMO carnation lines, genetically modified for altered flower colour, have been placed on the Australian GMO Register<sup>3</sup> (see Table 1). These LMO carnations were first approved for general release by GMAC in 1995, commercially released in 1996, re-assessed and licensed by the Regulator in 2003, and included on the GMO Register in 2007 based on a further risk assessment by the Regulator which concluded that they are not likely to have any adverse effects on the health and safety of people or the environment and that no conditions on their release were necessary.

### ***GM cotton and canola***

Following environmental risk assessment, insect resistant and herbicide tolerant LMO cotton, and herbicide tolerant LMO canola have been authorised for unrestricted release in Australia (Table 1). LMO cotton has been grown commercially in Australia since 1996 and is now estimated to comprise more than 90% of the cotton crop. LMO canola has been grown commercially in Australia since 2008.

**Table 1: LMOs approved for unrestricted release in Australia**

| <b>LMO</b>   | <b>Modified trait</b>   | <b>OECD unique identifier(s)</b>  | <b>Australian approval and risk assessment</b> |
|--|---|---|--|
| <b>Carnation</b><br><i>Dianthus caryophyllus</i> L.  | Modified colour<br>Selectable marker (herbicide)  | FLO-4Ø644-4;<br>FLO-4Ø619-7;<br>FLO-11363-1;<br>FLO-4Ø685-1   | <a href="#">Register 001/2004</a>              |
| <b>Rose</b><br><i>Rosa X hybrida</i>   | Modified flower colour<br>Selectable marker (antibiotic)  | IFD-52401-4   | <a href="#">Licence DIR<sup>4</sup> 090</a>    |
| <b>Cotton</b><br><i>Gossypium hirsutum</i> L.<br>Bollgard II® cotton,<br>Roundup Ready® cotton,<br>Roundup Ready Flex®<br>cotton, Bollgard II® x<br>Roundup Ready® cotton,<br>Bollgard II®xRoundup<br>Ready Flex® cotton | Herbicide tolerance (glyphosate)<br>Insect resistance (cry1Ac +<br>cry 2Ab)<br>Selectable marker (antibiotic)<br>Reporter gene expression | MON-88913-8;<br>MON-15985-7;<br>MON-88913-8 x<br>MON-15985-7;<br>MON-Ø1445-2;<br>MON-Ø1445-2 x<br>MON-15985-7   | <a href="#">Licence DIR<br/>066/2006</a>       |
| <b>Cotton</b><br><i>Gossypium hirsutum</i> L.<br><br>Liberty Link® Cotton<br>Liberty Link® x Bollgard<br>II®   | Herbicide tolerance (glufosinate<br>ammonium)<br>Insect resistance (cry1Ac +<br>cry 2Ab)  | ACS-GH001-3;<br>ACS-GH001-3 x<br>MON-15985-7  | <a href="#">Licence DIR<br/>062/2005</a>       |
| <b>Canola</b><br><i>Brassica napus</i> L.<br><br>InVigor® x Roundup<br>Ready® canola   | Herbicide tolerance (glufosinate<br>ammonium + glyphosate)<br>Hybrid breeding system  | ACS-BNØØ7-1;<br>ACS-BNØØ8-2;<br>ACS-BNØØ1-4;<br>ACS-BNØØ2-5;<br>ACS-BNØØ3-6;<br>ACS-BNØØ4-7;<br>ACS-BNØØ5-8;<br>(and hybrids of<br>these) x MON-<br>ØØØ73-7 | <a href="#">Licence DIR 108</a>                |
| <b>Canola</b><br><i>Brassica napus</i> L.  | Herbicide tolerance (glufosinate<br>ammonium)   | ACS-BNØØ7-1;<br>ACS-BNØØ8-2;  | <a href="#">Licence DIR<br/>021/2002</a>       |

<sup>3</sup> LMOs are only entered on the GMO Register after a period of licensing and after the Regulator is satisfied that any risks are minimal and that it is no longer necessary for the LMO to be licensed directly

<sup>4</sup> DIR = dealings involving intentional release to the environment

|  |                                  |  |                                      |
|--|----------------------------------|--|--------------------------------------|
| InVigor® canola  | Hybrid breeding system           | ACS-BNØØ1-4;<br>ACS-BNØØ2-5;<br>ACS-BNØØ3-6;<br>ACS-BNØØ4-7;<br>ACS-BNØØ5-8;<br>ACS-BNØØ5-8 x<br>ACS-BNØØ3-6 |                                      |
| <b>Canola</b><br><i>Brassica napus</i> L.<br>Roundup Ready® canola | Herbicide tolerance (glyphosate) | MON-ØØØ73-7  | <a href="#">Licence DIR 020/2002</a> |
| <b>IMOJEV™ vaccine</b><br>Yellow fever virus 17D                   | Japanese Encephalitis vaccine    |  | <a href="#">Licence DIR 098</a>      |

### ***Criteria for identifying LMOs not likely to have adverse effects***

The Regulator must not issue a licence for environmental release of an LMO unless satisfied that any risks to the health and safety of people and the environment can be managed. The Regulator must prepare a risk assessment and risk management plan in respect of each licence application and must consult with a range of experts and agencies.

The Regulator's approach to undertaking risk assessments for LMOs is detailed in the Risk Analysis Framework 2009<sup>5</sup>. This includes consideration of the LMO and introduced trait, the biology of the parent organism, and the receiving environment<sup>6</sup>. Criteria used to identify and assess the likelihood of adverse effects are provided by the Australian *Gene Technology Regulations 2001*<sup>7</sup> and include consideration of:

- the properties of the organism to which dealings proposed to be authorised by a licence relate before it became, or will become, a GMO
- the effect, or the expected effect, of the genetic modification that has occurred, or will occur, on the properties of the organism
- provisions for limiting the dissemination or persistence of the GMO or its genetic material in the environment
- the potential for spread or persistence of the GMO or its genetic material in the environment
- the extent or scale of the proposed dealings
- any likely impacts of the proposed dealings on the health and safety of people
- any previous assessment by a regulatory authority, in Australia or overseas allowing or approving dealings with the GMO
- the potential of the GMO concerned to:
  - be harmful to other organisms
  - adversely affect any ecosystems
  - transfer genetic material to another organism
  - spread, or persist, in the environment
  - have, in comparison to related organisms, an advantage in the environment
  - be toxic, allergenic or pathogenic to other organisms
- the short term and the long term

Based on these criteria the LMOs listed in Table 1 were assessed as not likely to have an adverse affect on the health and safety of people or the environment.

<sup>5</sup> <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/riskassessments-1>

<sup>6</sup> OECD, Safety Considerations for Biotechnology: Scale-up for Crop Plants (1996) [www.oecd.org/dataoecd/26/26/1958527.pdf](http://www.oecd.org/dataoecd/26/26/1958527.pdf)

<sup>7</sup> regulations 9A and 10, <http://www.comlaw.gov.au/Details/F2011C00732>

### *Post release experience of adverse effects*

Licence holders are required to inform the Regulator if they become aware of any additional information indicating a risk to the health and safety of people or the environment, or of any unintended effects associated with the dealings authorised by the licence. After a licence has been issued, the Gene Technology Regulator continues to monitor the scientific and other literature for any new information in relation to LMOs, and assess this information for its potential to impact on any existing regulatory approvals.

Beginning with the field trial release of LMO virus resistant potatoes in 1992, no credible reports of adverse effects on the health and safety of people or the environment have been linked to the intentional environmental release of any LMO in Australia. A number of the LMOs authorised for unrestricted commercial release in Australia have also been released in other jurisdictions. Australia's 2009 submission to the CBD (Notification SCBD/BS/MPDM/JH/67587, regarding LMOs that might have adverse effects on the conservation and sustainable use of biodiversity) stated that "no credible information has arisen, either domestically or internationally, to support a link between GM crops approved by the Regulator for commercial release in Australia and adverse impacts on human health or the environment" and no new information has arisen to change this conclusion.

## Appendix A: Total DIR Licences issued to 1 May 2012

| LMO                           | Number of Releases |   |   |
|-------------------------------|--------------------|---|---|
|                               | Total              | General   | Limited & controlled  |
| Cotton                        | 39                 | 7 (insect resistance, herbicide tolerance)      | 32 (insect resistance, herbicide tolerance, modified fatty acid in oil, fungal resistance, water use efficiency, waterlogging)  |
| Canola                        | 8                  | 3 (herbicide tolerance, hybrid breeding system) | 5 (herbicide tolerance, hybrid breeding system, male sterility, fertility restorer, enhanced yield, delayed leaf senescence)  |
| Sugarcane                     | 6                  | 0   | 6 (altered sugar, reporter gene, water use efficiency, nitrogen efficiency, shoot architecture, expression of sucrose isomerase, herbicide resistance)                  |
| Wheat                         | 6                  | 0   | 6 (herbicide tolerance, salt tolerance, altered grain starch, drought tolerance, altered grain composition, enhanced carbon assimilation, grain weight, heat tolerance) |
| Wheat/barley                  | 7                  | 0   | 7 (drought tolerance, altered grain starch, nutrient use, abiotic stress tolerance)   |
| Banana                        | 4                  | 0   | 4 (enhanced disease resistance, enhanced nutrition)   |
| Canola/Indian Mustard         | 2                  | 0   | 2 (hybrid breeding system, herbicide tolerance)   |
| Oilseed Poppy                 | 2                  | 0   | 2 (altered alkaloid production)   |
| Pineapple                     | 2                  | 0   | 2 (blackheart reduction, delayed flowering)   |
| Rose                          | 2                  | 1 (modified flower colour)                      | 1 (modified flower colour)  |
| Torenia (flower)              | 2                  | 0   | 2 (modified flower colour, phosphate phenotype)   |
| White Clover                  | 2                  | 0   | 2 (virus resistance)  |
| Carnation                     | 1                  | 1 (modified flower colour)                      | 0   |
| Grapevine                     | 1                  | 0   | 1 (modified fruit colour and sugar composition, fruit development)  |
| Indian Mustard                | 1                  | 0   | 1 (herbicide tolerance, hybrid breeding system)   |
| Maize                         | 1                  | 0   | 1 ((functional characterisation of maize genome)  |
| Papaya                        | 1                  | 0   | 1 (delayed ripening)  |
| Rice                          | 1                  | 0   | 1 (herbicide tolerance)   |
| Ryegrass & Tall Fescue        | 1                  | 0   | 1 (altered sugar levels, altered structural components of plant cell walls)   |
| Cholera (vaccine)             | 1                  | 1 (attenuation)                                 | 0   |
| Japanese Encephalitis Vaccine | 1                  | 1 (altered antigenic profile)                   | 0   |
| Fowl Adenovirus (vaccine)     | 1                  | 0   | 1 (attenuation and enhanced immuno-modulation)  |
| Bovine Herpesvirus (vaccine)  | 1                  | 0   | 1 (attenuation and enhanced immunogenicity)   |
| Bovine parainfluenza virus    | 1                  | 0   | 1 (attenuation, foreign antigen expression)   |