

Genetic Manipulation Advisory Committee

**GMAC Advice to
Proceed in Respect of a
Dealing Involving an Intentional
Release of a GMO
into the Environment**

Part 1: Advice to proceed

This instrument, including its attachments, is an advice to proceed for the purposes of section 190 of the *Gene Technology Act 2000* ('the Act').

When Division 5 of Part 12 of the Act commences, this advice to proceed will become a GMO licence for the purposes of the Act. This means that from 21 June 2001, the holder of this advice to proceed will be a licence holder under the Act and the holder of this advice to proceed and any persons covered by this advice to proceed must comply with this advice to proceed and the provisions of the Act as if this advice to proceed is a licence under that Act.

The holder of this advice to proceed may only transfer this advice to proceed with the prior agreement of the Regulator in accordance with section 70 of the Act.

Holder of advice to proceed

The holder of this advice to proceed is the organisation identified at "Organisation Name" at Attachment A.

Project supervisor

The project supervisor in respect of this advice to proceed is the person identified at 'Project Supervisor' at Attachment A.

Persons covered by this advice to proceed

The persons covered by this advice to proceed are anyone dealing with the GMO, subject to the conditions of this advice to proceed.

Description of GMO covered

The GMOs covered by this advice to proceed are identified at Attachment B. Collectively, these GMOs are referred to as 'the GMOs' in this advice to proceed.

Guidance note: The holder of this advice to proceed may make an application to the Regulator to vary this advice to proceed to include additional cultivars.

Dealings authorised by this advice to proceed

This advice to proceed authorises the persons covered by this advice to deal with the GMOs during the period covered by this advice to proceed and in accordance with this advice to proceed.

'Deal with' has the same meaning as section 10 of the Act.

Guidance note: 'Deal with' has a technical meaning. Section 10 of the Act provides that 'deal with', in relation to a GMO, means the following:

- (a) conduct experiments with the GMO;*
- (b) make, develop, produce or manufacture the GMO;*
- (c) breed the GMO;*
- (d) propagate the GMO;*
- (e) use the GMO in the course of manufacture of a thing that is not the GMO;*
- (f) grow, raise or culture the GMO;*
- (g) import the GMO;*

and includes the possession, supply, use, transport or disposal of the GMO for the purposes of, a dealing mentioned in any of paragraphs (a) to (g).

Period covered by this advice to proceed

This advice to proceed covers the period 21 June 2001 to 20 June 2003.

Guidance note: A written notice from the Regulator can affect these dates. For example, the Regulator can cancel this advice to proceed or vary these dates (see sections 68 and 71 of the Act). The maximum period for this advice to proceed is 2 years from 21 June 2001, or the specified dates on this advice to proceed, whichever is earlier.

Part 2: Interpretation and definitions used in this advice to proceed

Words and phrases used in this advice to proceed have either the same meaning as they do in the *Gene Technology Act 2000* ('the Act') and the Gene Technology Regulations ('the Regulations'), or the meanings set out below in this Part 2. Where a word or phrase is defined in this advice to proceed and the definition is the same as the definition in the Act or the Regulations, this is indicated.

In this advice to proceed:

GM means genetically modified;

GMO has the same meaning that it does in the Act,

GM crop means the GMOs described at Attachment B as planted in a crop;

GM plant material means the plants, seed, stubble, pollen or any other genetically modified material derived from the GMOs described at Attachment B;

GM product means a thing (other than a GMO) derived or produced from the GMO. This is the same definition as used in the Act;

GMAC means the Genetic Manipulation Advisory Committee;

Regulator means the Gene Technology Regulator. This is the same definition as used in the Act;

the Act means the *Gene Technology Act 2000*.

Part 3: Conditions of this advice to proceed

The holder of this advice to proceed and any persons covered by it must comply with the conditions attaching to this advice to proceed.

Guidance note: Sections 34 and 35 of the Act provide that failure to comply with the conditions of a licence is an offence

The conditions attaching to this advice to proceed follow.

Section 1 – General conditions

1. The holder of this advice to proceed and any persons covered by it must, at all times, comply with the conditions in sections 63, 64 and 65 of Act.

Guidance note: Sections 63 to 65 of the Act provide as follows:

Condition about informing people of obligations (section 63)

(1) It is a condition of a licence that the licence holder inform any person covered by the licence, to whom a particular condition of the licence applies, of the following:

- (a) The particular condition, including any variations of it;
- (b) The cancellation or suspension of the licence;
- (c) The surrender of the licence.

(2) Requirements in relation to the manner in which information is provided under subsection (1) may be:

- (a) Prescribed by the Regulations; or
- (b) Specified by the Regulator.

(3) Such requirements may include, but are not limited to, measures relating to labelling, packaging, conducting training and providing information.

(4) If such requirements are prescribed or specified, it is a condition of a licence that the licence holder complies with the requirements.

Condition about monitoring and audits (section 64)

(1) It is a condition of a licence that if:

- (a) a person is authorised by the licence to deal with a GMO; and
- (b) a particular condition of the licence applies to the dealing by the person;

the person must allow the Regulator, or a person authorised by the Regulator, to enter premises where the dealing is being undertaken, for the purposes of auditing or monitoring the dealing.

(2) *Subsection (1) does not limit the conditions that may be imposed by the Regulator or prescribed by the Regulations.*

Condition about additional information to be given to the Regulator (section 65)

(1) *It is a condition of a licence that the licence holder inform the Regulator if he or she:*

(a) *becomes aware of additional information as to any risks to the health and safety of people, or to the environment, associated with the dealings authorised by the licence; or*

(b) *becomes aware of any contraventions of the licence by a person covered by the licence; or*

(c) *becomes aware of any unintended effects of the dealings authorised by the licence.*

(2) *For the purposes of subsection (1):*

(a) *the licence holder is taken to have become aware of additional information of a kind mentioned in subsection (1) if he or she was reckless as to whether such information existed; and*

the licence holder is taken to have become aware of contraventions, or unintended effects, of a kind mentioned in subsection (1) if he or she was reckless as to whether such contraventions had occurred, or such unintended effects existed.

2. The holder of this advice to proceed and any persons covered by it must, at all times, comply with any conditions prescribed by the Gene Technology Regulations ('the Regulations'), as varied from time to time.

Guidance note: As at 21 June 2001 there are no such conditions prescribed by the Regulations.

3. The holder of this advice to proceed and any persons covered by it must, at all times, comply with any written notice issued under section 71 of the Act, varying this advice to proceed.

Guidance note: Section 71 of the Act provides that the Regulator may, at any time, by notice in writing given to the licence holder, vary a licence. Section 62 of the Act describes the kinds of things that the Regulator can include in licence conditions.

4. The holder of this advice to proceed and any persons covered by it must, at all times, only deal with the GMOs in accordance with, and comply with, the requirements, conditions and obligations in the following instruments, as they exist from time to time:
- (a) the Act;
 - (b) the Regulations;
 - (c) corresponding State law.

Guidance note: 'Corresponding State law' has the same meaning as it does in the Act. You must also continue to comply with any other relevant Australian laws.

Training of persons covered by the advice to proceed

5. The holder of this advice to proceed and any persons covered by it must be sufficiently trained to enable them to carry out the dealings with the GMOs in accordance with the conditions of this advice to proceed.

Informing the Regulator of any material changes of circumstance

6. The holder of this advice to proceed must immediately, by notice in writing, inform the Regulator of any material change in circumstance of the holder of this advice to proceed, of any of the following matters:
 - (a) any relevant conviction of the holder of the advice to proceed;
 - (b) any revocation or suspension of a licence or permit under any law relating to the health and safety of people or the environment;
 - (c) the capacity of the holder of this advice to proceed to meet the conditions in it.

Guidance note: These matters are described in subsections 58(1) and 58(2) of the Act and are matters that the Regulator may take into account in obtaining satisfaction about the suitability of a person to hold a licence. 'Relevant conviction' has the same meaning as in section 58 of the Act. In general terms, it means a conviction in respect of a law relating to the health and safety of people or the environment.

Written directions from the Regulator

7. The holder of this advice to proceed and any persons covered by it must comply with any written direction issued to the holder of this advice to proceed, under section 146 of the Act.

Guidance note: Section 146 enables directions to be issued to the holder of this advice to proceed, or a person covered by it, if there are reasonable grounds for the belief that a direction is necessary to protect the health and safety of people or to protect the environment. Failure to comply with a direction is an offence.

Compliance with technical and procedural guidelines

8. The holder of this advice to proceed and any persons covered by it, must only deal with the GMOs in accordance with any applicable technical and/or procedural guidelines issued by the Regulator under section 27 of the Act.

Remaining an Accredited Organisation

9. The holder of this advice to proceed must, at all times, remain an accredited organisation in accordance with Guidelines for Accreditation of Organisations issued by the Regulator under section 98 and comply with any conditions attaching to the holder's accreditation, as varied from time to time.

Guidance note: Sections 94 to 96 of the Act enable the Regulator to attach conditions to an accreditation at the time of accreditation, as well as vary and add to the conditions attaching to an accreditation or cancel or suspend an accreditation at any time. Section 92 of the Act and the Regulations provide for the accreditation of an organisation.

Changes to details

10. The holder of this advice to proceed must immediately notify the Regulator in writing if any of the contact details of the project supervisor change.

Guidance note: Changes to the contact details (phone, fax, e-mail, postal address) for the project supervisor must be made by notice in writing to the Regulator. All other changes in relation to this advice to proceed and the conditions in it, for example changes to the identity of the project supervisor, or the details of the GMO, are variations requiring the approval of the Regulator and you must not act otherwise than in accordance with this advice to proceed without first obtaining that approval.

Section 2 – Specific conditions

Conditions relating to where the GMOs are dealt with, including growing and transportation of the GMOs

1. The GMOs may be grown only in the cotton-growing regions of NSW and Queensland south of latitude 22°S. Viable GMOs or GM products may be transported or used as stockfeed only south of latitude 22°S. Transport or use of viable GMOs or GM products as stockfeed north of latitude 22°S may only be undertaken subject to the conditions outlined in Attachment C, or with written agreement of the Regulator. This agreement may be subject to specific conditions additional to those contained in this advice to proceed.

Contingency Planning

2. If dissemination of the GMOs occurs to a location outside the cotton-growing regions of NSW and Queensland south of latitude 22°S (without the prior written agreement of the Regulator), the holder of this advice to proceed must take all reasonable steps to minimise the impact of the dissemination of the GMOs, including taking any applicable actions detailed in contingency plans provided to GMAC.

Annual Reporting

3. The holder of this advice to proceed shall provide the Regulator with a written annual report, by November each year, in accordance with any guidelines issued by the Regulator in relation to annual reporting. The annual report must contain details of the locations of GM crop sites and their dates of sowing and details of activities undertaken in relation to the environmental monitoring plan.

Audit

4. The holder of this advice to proceed shall retain detailed records of its release of the GMOs into the environment for a period of ten years from the record being created. This shall include:
- a) details of the location of each of the GM crops, and the dates of sowing;
 - b) any other information reasonably requested by the Regulator in relation to the GMOs.

Guidance note: *This condition is to facilitate proper auditing of compliance by the holder of this advice to proceed with its obligations under this advice to proceed.*

Attachment A to the draft Advice to Proceed in respect of a dealing involving an intentional release of a GMO into the environment

GMAC Proposal No: GR-3

IBC Reference No:

***Full Title:** GR-3: Application for commercialisation of insect-resistant (INGARD®) cotton

Organisation Details

***Organisation:** Monsanto Australia Ltd

Postal address: PO Box 6051
ST KILDA ROAD CENTRAL VIC 8008

Phone No:

Fax No:

Email Address:

Project Supervisor Details

Surname: Boyce

First Name: Roger

Title: Mr

Phone No: (03) 9522 7178

Fax: (03) 9525 2253

Email Address: roger.d.boyce@monsanto.com

Position: Cotton Business Manager

Organisation: Monsanto Australia Ltd

Postal Address: PO Box 6051
ST KILDA ROAD CENTRAL VIC 8008

IBC Details

IBC Name: Monsanto Australia Ltd

IBC No: 334

Attachment B to the draft Advice to Proceed in respect of a dealing involving an intentional release of a GMO into the environment

GMO Description

***Parent Organism(s) Common Name:** Cotton, cultivars

***Parent Organism(s) Scientific Name:** *Gossypium hirsutum*

***Cultivars of the GMO:**

The following cultivars produced by backcrossing INGARD cotton with Australian cotton cultivars will be released: NuCOTN37, NuCOTN38, NuPEARL, NuOPAL, NuTOPAZ, DP 20B, Sicot 289i, Sicot 51i, Sicot 42i, Siokra V-16i, Siokra 201i, Siokra S-101i, Sicala V-3i, NuEMERALD, NuSAPPHIRE, D 50B, Sicala 40i, Siokra V-17i.

Modified Trait(s):

***Category:** insect resistance

***Description:**

The genetically modified plants have been modified to produce a highly specific insecticidal protein (Cry1Ac, also known as Bt) that is toxic to the major caterpillar pests of cotton.

In addition, the genetically modified cotton plants contain a protein, neomycin phosphotransferase, that confers resistance to the antibiotics kanamycin and neomycin.

***Gene(s) Responsible for Conferring the Modified Trait(s):**

Insect resistance is conferred by a delta-endotoxin gene derived from the bacterium *Bacillus thuringiensis* that codes for the CryIA(c) insecticidal protein.

Resistance to the antibiotics kanamycin and neomycin is conferred by the *nptII* bacterial marker gene.

Resistance to spectinomycin and streptomycin is conferred by the *aad* bacterial gene. This gene is not expressed in the genetically modified plants.

Purpose of the Dealing with the GMO:

Commercial planting of Ingard cotton in the cotton growing regions of New South Wales and Queensland, south of latitude 22°S.

*** Information that shall be included in the Record of GM Products and GMO Dealings.**

Attachment C to the draft Advice to Proceed in respect of a dealing involving an intentional release of a GMO into the environment

Conditions relating to transportation of the GMOs or use as stockfeed north of latitude 22° S

1. Transport, or use of the GMOs or viable GM products as animal feed, north of latitude 22°S may only be undertaken subject to the following conditions, or with written agreement of the Regulator.
 - a) the GMOs or viable GM products shall be transported in accordance with transport guidelines issued by the Gene Technology Regulator, or other conditions agreed by the Gene Technology Regulator;
 - b) the following areas shall be monitored for volunteer cotton plants:
 - i) roadsides along routes by which the GMOs or viable GM products are transported;
 - ii) areas in which animals fed with the GMOs or viable GM products are grazed or housed;
 - iii) roadsides along routes by which the animals are transported within 14 days of consuming the GMOs or viable GM products;
 - c) Any volunteer GM cotton plant(s) found during monitoring shall be removed and/or destroyed prior to flowering by:
 - i) herbicide treatment; or
 - ii) hand weeding;
 - d) details of the site location, transport routes and conditions, and monitoring protocols shall be provided to the Gene Technology Regulator.